The impact of including caregivers in self-management interventions in long-term cardiorespiratory illnesses

Submitted by Miriam Catherine Noonan to the University of Exeter as a thesis for the degree of Doctor of Philosophy in Medical Studies, July 2020.

I certify that all material in this thesis, which is not my own work, has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

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Abstract

Background: An estimated 6.5 million people are providing unpaid care in the UK. Cardiorespiratory illnesses, including heart failure, chronic obstructive pulmonary disease and coronary artery disease are amongst the leading causes of mortality and hospitalisations globally. People living with these conditions are required to adapt their lifestyle and behavioural to manage their illness. Caregivers are increasingly relied upon to provide support in these lifestyle and behavioural changes. However, understanding the impact of including caregivers on the health outcomes of patients living with long-term cardiorespiratory illness is inconsistent. Additionally, understanding the impact of including caregivers in self-management interventions on caregivers' quality of life lacks clarity.

Aim: This first aim of this research was to understand the impact of including caregivers in self-management interventions for patients and caregivers living with long-term cardiorespiratory illnesses. The second aim of this research was to understand how inclusion in a self-management intervention informed caregivers in their role and the subsequent caregiver actions which influenced patient health related quality of life.

Methods: Four linked research studies were completed. First, a mixed-methods systematic review was undertaken to understand the lived experience of being a caregiver for patients living with long-term cardiorespiratory illness (chapter 3). Second, a meta-analysis was conducted to synthesise the current body of evidence of randomised controlled trials (RCTs), which included caregivers in intervention delivery for long-term cardiorespiratory illnesses (chapter 4). Third, quantitative and qualitative secondary analyses of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) trials were undertaken. REACH-HF is a home-based self-management intervention for heart failure patients and their caregivers that formally included caregivers in its design and delivery. Quantitative analyses were completed at 4 and 6 months follow-up. These analyses examined three aspects of caregiver involvement in REACH-HF. The impact on patient health-related quality of life when formally involving caregivers in the REACH-HF intervention. The impact on caregiver quality of life following participation in the REACH-HF intervention and, lastly, whether there were factors that predicted caregiver health outcomes in response to the REACH-HF intervention (chapter 5). A qualitative secondary analysis utilised a cross-case analysis approach. The purpose of this analysis was to explain the quantitative findings and examine the nature of caregiving and how this contributed to patient self-care (chapter 6).

Results: The mixed-methods systematic review synthesised 54 studies (26,453 caregivers) (chapter 3). The concepts identified in this review emphasised the complexity of caregiving for adults with long-term cardiorespiratory illnesses and demonstrated the impact of caregiving on: (1) mental health, (2) caregiver role, (3) lifestyle change, (4) support for caregivers (5) knowledge, and (6) relationships. Four concepts were explicitly identified in the qualitative literature: (7) expert by experience, (8) vigilance, (9) time, and (10) shared-care. The quantitative meta-analysis of 13 RCTs (1,701 patient-caregiver dyads) (chapter 4) demonstrated that the pooled effect of patient health-related quality of life in RCTs that included caregivers in intervention delivery compared with studies that did not include caregivers were not significantly different ($p = 0.84$). Quantitative analysis of the pooled REACH-HF randomised controlled trials included 266 heart failure patients and 118 caregivers. The univariate analysis demonstrated improved health-related quality of life outcomes for patients when a caregiver was included in the intervention. Mean increase in overall Minnesota Living with Heart Failure Questionnaire score of 10.6 (CI 95% 2.7 to 18.4, $p = 0.008$) at 4 months follow-up. The direction of effect towards caregiver presence remained at 6 months follow-up (9.6, CI 95% 1.1 to 18.2, $p =0.026$). Multivariate analysis demonstrated that an interaction effect on patient HRQoL in favour of patients with a caregiver remained at 4 months follow-up (9.9, 1.9 to 18.0, $p = 0.015$). However, this was not sustained at 6 months follow-up (2.2, -0.5 to 4.9, $p = 0.113$). Increased patient illness severity was the most consistent predictor of caregiver outcomes, however this was not observed across all caregiver outcomes measures. REACH-HF did not consistently demonstrate improvements across all caregiver outcomes; however, it did demonstrate potential to improve caregiver anxiety as well as social and lifestyle burden. The qualitative secondary analysis demonstrated that as a result of REACH-HF, caregivers were enabled to engage in overt and discrete caregiving tasks. Overt caregiving tasks included use of the REACH-HF progress tracker to communicate effectively about HF self-management. Discrete caregiving tasks included utilising the knowledge obtained from the patient manual and caregiver resource to make decisions about how much assistance to provide to the patient dependent on what the caregiver observed (e.g. face colour, tone of voice). Sustained change was difficult to achieve for some patient-caregiver dyads, some caregivers had difficulties motivating the patient to maintain engagement with self-management strategies. A combination of factors was identified by patient-caregiver dyads who reported difficulty maintaining change. These included, the duration of diagnosis, the severity of illness, the demands on the caregivers' time, and the concept of the meaningfulness of the task for the patient.

Conclusions: Caregivers do have a key role in the self-management of patients with long-term cardiorespiratory illnesses, such as HF and COPD. Understanding the caregiver role and the nature of the patient-caregiver relationship can significantly influence how we can better engage patients in the self-management of their illness. REACH-HF facilitated patients and caregivers to communicate effectively about HF self-management, increased their HF knowledge and skills and enabled caregivers to feel supported with the inclusion of the wider family. That disease severity was the most consistent predictor of poor caregiver outcomes, and the challenges of sustaining behaviour change indicates the need for ongoing healthcare support for both patients and caregivers as disease progresses. The value of engaging in self-management tasks that are meaningful to the patient and caregiver was an important finding and is an approach that may facilitate sustained behaviour change. This thesis discusses the methodological and practical implications of these findings on the involvement of caregivers in healthcare interventions for long-term cardiorespiratory illnesses and future research.

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Table of contents

List of Tables

List of Figures

List of Appendices

Author's Declaration

I declare that all the research reported in this thesis is my work, and each of the chapters and the empirical research presented in chapters 3-6 was planned, conducted and written by me.

This thesis contains four empirical research studies. At the time of submission of this thesis, chapters 3 and 4 have been published in peer-reviewed journals. These manuscripts are co-authored, but all are primarily my own work as the result of this PhD thesis. All the manuscripts are written by me. Throughout the PhD, supervisory guidance was provided by the co-supervisors, Professor Rod Taylor (RT), Dr Julia Frost (JF), and Professor Nicky Britten (NB). Additional guidance was provided by Dr Jenny Wingham (JW) and Dr Hasnain Dalal (HD).

Detailed below is my substantial contribution to each of the co-authored manuscripts

Chapter 3: The experiences of caregivers of patients living with heart failure, chronic obstructive pulmonary disease, and coronary artery disease: a mixed-methods systematic review. This manuscript was submitted to BMJ Open and published in July 2018. I developed the protocol for the systematic review and meta-analysis, conducted the searches, screening, data extraction, quality appraisal, data analysis, and manuscript writing. Information specialists from the College of Medicine and Health provided advice on the search strategy. RT and JW commented on the protocol, conducted double full paper screening, quality appraisal and data extraction of the full-text articles, and provided advice at all stages of the review. All authors commented on the manuscript and signed off on the final version.

Chapter 4: The impact of involving caregivers in the delivery of self-management interventions for patients with heart failure and COPD: systematic review and meta-analysis. This systematic review and meta-analysis was submitted to the Journal of Advanced Nursing and published in August 2019. I developed the protocol for the systematic review and meta-analysis, conducted the searches, screening, data extraction, quality appraisal, data analysis, and manuscript writing. Information specialists from the College of Medicine and Health provided advice on the search strategy. RT commented on the protocol, conducted double full paper screening, quality appraisal, data extraction of the full-text articles, statistical guidance, and provided advice at all stages of the review. RT, JW, and HD commented on the manuscript and signed off on the final version.

Detailed below are my substantial contributions to the rest of the chapters in this thesis.

Chapters 1 (Background), 2 (Introduction), and 7 (Discussion) were written by myself and reviewed by my supervisors (RT/JF/NB).

Chapter 5: Involvement of caregivers in a home-based rehabilitation intervention for patients with heart failure (REACH-HF): quantitative analysis of the impact on patient and caregivers' outcomes. For this study, I developed the statistical analysis plan, merged the two trial data sets, conducted the statistical analyses, interpreted the results, and drafted the chapter. RT was involved in the study conception, provided advice with the statistical analysis plan, and conducting the analysis. All other authors reviewed the chapter.

Chapter 6: The impact of REACH-HF on the nature of caregiving and how it contributes to improved patient health-related quality of life. A qualitative study of caregiver contributions to HF self-care management following participation in REACH-HF. For this study, I developed the analysis plan, conducted the analysis, interpreted the results, and drafted the chapter. JF and NB were involved in the study conception and provided advice on the analysis and interpretation of results. All authors reviewed the chapter.

Publications related to this thesis

At the time of submission, this thesis has produced two papers for publication. Chapters presenting these published manuscripts (chapters 3 and 4) are presented in this thesis based on their published format. However, efforts have been made to reduce repetition and highlight the narrative of this thesis.

Chapter 3 has been published as:

Noonan MC, Wingham J, Taylor RS.' Who Cares?' The experiences of caregivers of adults living with heart failure, chronic obstructive pulmonary disease, and coronary artery disease: a mixed-methods systematic review. BMJ Open. 2018 Jul 1;8(7):e020927.

Chapter 4 has been published as:

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Abbreviations

CAD	Coronary Artery Disease
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
HF	Heart Failure
HFpEF	Heart Failure preserved ejection fraction
HFrEF	Heart Failure reduced ejection fraction
HRQoL	Health-Related Quality of Life
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
IACO	International Alliance of Carer Organisations
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
QoL	Quality of Life
RAISE	Recognize Assist Include Support and Engage
RCT	Randomised Controlled Trial
REACH-HF	Rehabilitation Enablement in Chronic Heart Failure
REACH II	Resources for Enhancing Alzheimer's Caregivers Health II (REACH II)
SMD	Standardised Mean Difference
TIDieR	Template for Intervention Description and Replication

CHAPTER 1. Introduction

1.1 Brief problem statement

Life expectancy is increasing and people are living longer, often with long-term illness (1), thus resulting in increasing pressure on healthcare delivery (2). In the United Kingdom (UK), it is expected that there will be 18 million people living with a long-term illness by 2025 (3). In England alone 30% of the population live with a long-term illness (4). Healthcare delivery for patients with long-term illness is oriented towards self-management interventions. Thus, there is increasing expectations and reliance upon patients to engage in self-management of their illness (5-7). Self-management interventions aim to enable patients such as those living with cardiorespiratory illnesses to live with and manage the signs and symptoms of their illness (8-12). Cardiorespiratory illnesses are those conditions which affect the heart and lungs and can significantly impede an individual’s functioning in their activities of daily living. Poor cardiorespiratory health has been associated with increased mortality (13). Patients living with cardiorespiratory conditions such as heart failure (HF), chronic obstructive pulmonary disease (COPD) or coronary artery disease (CAD) rely on family and friends to help in their self-management. Consequently, the demand for unpaid caregivers (carers) is growing exponentially. In the UK the number of caregivers is growing faster than overall population growth, with approximately 6,000 people becoming caregivers daily (14, 15). The term caregiver will be used throughout this thesis to reference individuals who are carers.

A caregiver is defined as someone who provides unpaid care for a family member or a friend who requires support due to their physical or mental health needs, which leads to an interruption of their day-to-day functioning (16). For this thesis, a patient is an adult living with a long-term illness who is in receipt of healthcare services from healthcare professionals and requires support from a family member or a friend on a day-to-day basis to manage their illness (17). The types of care provided to patients by a caregiver include practical support in the form of medication administration, symptom monitoring, personal care and transport to appointments. Caregiving also involves emotional support, such as motivating the patient, advocating on their behalf with healthcare professionals and observing any mental health changes in the patient (16). Undertaking a caregiving role can have a physical and psychological impact on caregivers' health, as well as a financial and social impact on their lifestyle

(18-21). Research examining caregiving has increased in prevalence (22), however, understanding the experiences of caregivers and their inclusion in interventions for long-term cardiorespiratory illnesses is not as established as caregiving research in other long-term conditions (23-25). Much caregiver research is oriented towards the direct influence of caregivers on patients, and primarily only examines patient outcomes (22). Caregiver research is often presented as a linear association with little attention to the processes and context in which caregiving occurs (22). There is a need to examine and understand the interpersonal factors as well as the psychosocial and physical aspects of caregiving in long-term cardiorespiratory illnesses to identify how these impact patient outcomes (10, 26).

Understanding the complexity of caregiving and the context and impact of caregiver contributions on patients and caregivers is vital for a number of reasons (25, 27). Firstly, due to the increasing reliance on caregivers as a resource in the management of long-term cardiorespiratory illness. Secondly, for caregivers to manage and maintain their health and wellbeing. Thirdly, to inform the design and delivery of interventions that address both patient and caregiver needs.

1.2 The aims and scope of the research

The overarching aim of this research was to understand the impact of including caregivers in self-management interventions for patients living with common long-term cardiorespiratory illnesses, including HF, COPD and CAD. This PhD was originally conceived to ultimately focus on the qualitative and quantitative data available from the two linked studies conducted on a home-based self-management intervention specifically designed and conducted in people with HF and their caregivers. Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention. REACH-HF was an evidence-informed self-management intervention, for patients and caregivers living with HF (28). The inclusion of patients with COPD and their caregivers (chapter 3 and 4) and patients with CAD and their caregivers (chapter 3) in the earlier parts of this research enabled an understanding of the role of caregivers in the wider context of cardiorespiratory illness.

Two specific questions underpinned the overall research:

1. What is the impact on patients' health related quality of life (HRQoL) when caregivers are included in the delivery of self-management interventions?
2. What is the impact on caregivers' quality of life (QoL) outcomes when they are included in the delivery of self-management interventions?

Utilising a multi-methods approach, the specific aims were:

1. To understand the lived experience of being a caregiver for patients with common long-term cardiorespiratory illnesses (HF, COPD and CAD).
2. Identify and synthesise randomised controlled trials (RCTs), which have included caregivers in the delivery of self-management interventions in HF and COPD.
3. Evaluate the impact of involving caregivers in REACH-HF on patient HRQoL and caregiver QoL outcomes.
4. Explain the quantitative research findings by conducting a secondary analysis of qualitative data to identify how caregiver contributions to HF self-management within the context of participating in REACH-HF influenced patient HRQoL outcomes.

These aims were achieved via the completion of two systematic reviews, a meta-analysis, and a multi-method sequential secondary analysis of data gathered for the REACH-HF trial (29, 30).

The findings of this research will contribute to the evidence base in this field by providing an understanding of:

1. Caregivers' experience of caring for patients living with long-term cardiorespiratory illnesses.
2. The impact of involving caregivers in intervention delivery in long-term cardiorespiratory illnesses.
3. The context and processes of caregiver contributions to HF self-management and the influence of this on patient's HRQoL.

1.3 Overview of this thesis

Chapter 2 provides a background to the current caregiver evidence base. Specifically, the perspectives of caregiving for patients with HF and COPD are outlined. Current policy and legislation related to caregiving are discussed. A literature review examining the impact of caregiving on patient outcomes and caregiver outcomes in healthcare delivery is presented. Finally, methodological issues in past caregiver literature and the theoretical frameworks underpinning caregiver research are outlined. This chapter presents the rationale for the rest of the thesis.

Chapters 3 to 6 present the four linked individual empirical research studies.

Chapter 3 presents a systematic review that addresses the following question: What are the experiences of caregivers on a day-to-day basis when caring for patients with HF, COPD, and CAD? This systematic review aimed to understand the lived experience of caregivers when providing care for patients living with the aforementioned cardiorespiratory illnesses. This review sought to understand the implications of being a caregiver and in turn inform healthcare professionals' interactions with caregivers when delivering self-management interventions.

Chapter 4 presents a systematic review and meta-analysis which asked the following question: Are patient outcomes for HF and COPD better when caregivers are involved in the delivery of self-management interventions? The aims of this systematic review and meta-analysis were to identify the impact of including caregivers in intervention delivery on both patient and caregiver outcomes. Randomised controlled trials (RCTs) were included for meta-analysis. Eligible RCTs were pooled to obtain a standardised mean difference (SMD) to compare the impact of involving caregivers in intervention delivery with usual care.

Chapter 5 is a quantitative analysis of secondary data collected from the pooled REACH-HF randomised controlled trials (RCTs) (29, 30). This analysis aimed to ascertain the impact of caregivers' involvement in REACH-HF on patient and caregiver outcomes, and to identify the predictors of caregiver outcomes following participation in REACH-HF. This chapter addressed the following questions:

1. Do patients with HF participating in the REACH-HF intervention, achieve a better HRQoL outcome, when they have a caregiver who is involved in the intervention delivery?

2. What are the predictors of baseline HRQoL, for caregivers of HF patients, receiving the REACH-HF intervention?
3. What is the impact of the REACH-HF intervention on caregiver outcomes?

The findings of this chapter informed the qualitative analysis completed in chapter 6.

Chapter 6 is a secondary analysis of qualitative data which asked the following question: What is the impact of REACH-HF on the nature of caregiving, which contributed to improved patient outcomes on the Minnesota Living with HF Questionnaire (MLHFQ)? This chapter presents an analysis of how caregiver actions as a result of participating in REACH-HF influenced patient HRQoL.

Chapter 7 summarises and interprets the findings presented in this thesis. This chapter outlines an overall discussion of the strengths, limitations, and the implications for future research and healthcare delivery.

CHAPTER 2. Background

2.1 Overview of caregivers and caregiving

Due to advances in healthcare and the orientation of health services towards home-based care and self-management interventions, the need for unpaid caregivers is growing exponentially (31-33). Self-management, in relation to long-term illness is the concept of engaging in medical and behavioural strategies to enhance or maintain ones day-to-day life while living with a long-term illness (34). Caregivers play a key role in supporting an individual living with a long-term illness. On a global scale, there are an estimated 43.5 million caregivers in the United States, 2.86 million caregivers in Australia and 6.5 million caregivers in the UK. The value of care provided by caregivers to the UK's economy is an estimated £132 billion per year (32, 33, 35, 36). To put this value into context, the entire NHS spend for 2019 was £140 billion (37). The International Alliance of Carer Organisations (IACO) collated data from 519 caregivers from Australia, USA, Canada, and the UK and provided an overview of caregivers' demographics (38). This four-nation study reported: caregivers are predominantly female, providing care for approximately 22 hours per week with 80% experiencing comorbidities including musculoskeletal disorders, diabetes, and mental health needs (38).

Caregivers provide practical and emotional support (16). This can include tasks such as managing medication, monitoring for signs and symptoms of ill health, responding to exacerbations of illness, organising and coordinating healthcare or other support services and liaising with healthcare professionals (39). In times of the patient's ill health, caregivers are frequently relied upon to make complex medical decisions by proxy (40). Thus, caregivers often become "lay professionals". For many caregivers they perceive that healthcare professionals consider them to be healthcare managers (41, 42), meaning, they are responsible for coordinating the patient's healthcare and illness management. This can result in significant change to the life of someone who finds himself or herself in a caregiving role. Becoming a caregiver can have positive and negative impacts on a person's life (20, 33, 43).

Figures regarding caregivers are understood in relative terms. This is due to the prevalence of what is termed "hidden caregivers" (44). These are caregivers who do not identify or classify themselves as caregivers (44). Maintaining their identity and a sense of self has been reported as being of high importance for caregivers (45). In

Canada, of those providing care, approximately 1 in 30 people identify themselves as caregivers, in the UK, this figure is 1 in 5 and in Germany, it is 1 in 3 (46, 47). A survey of family caregivers identified caregivers' report a preference to be defined in terms of their relationship to the person for whom they are providing care (48).

Consequently, caregivers classify themselves as a parent or spouse as opposed to being defined or identified as a caregiver (48). This presents a challenge for healthcare professionals when trying to recognise whether a patient has a caregiver involved in their self-management and how they can meaningfully engage caregivers in healthcare interventions. Caregivers have reported that having direct access to healthcare professionals is necessary when providing care (39). Thus, there is an onus on healthcare providers to engage with caregivers. Healthcare professionals should be aware of who the caregiver for their patient is, what the caregiver's needs are, and how to communicate with caregivers to encourage them to identify and engage support to address their needs. Caregivers are completing complex healthcare activities and routines (43). Therefore, they can be considered an integral part of the healthcare team (49).

One of the key recommendations from the global study conducted by IACO was the necessity for healthcare services to pay attention to caregivers to facilitate them in the maintenance of their role and the management of their health and well-being (38). When caregivers are compared to the non-caregiving population, one of the consistent messages is the significant impact on caregivers' health and well-being. Thus is it important to consider caregiver needs as a priority in public health research and policy development (50, 51). On a global scale, government organisations are now recognising the invaluable role of caregivers. In 2007, The European Parliament established a special interest group on caregivers (52). This forum aims to ensure caregivers have a voice and are involved in European Union policy development (52). In the United States, in 2018, the Recognize, Assist, Include, Support and Engage (RAISE) family caregivers act was passed by Congress (53). This bill aims to develop an advisory council to support family caregivers in the workplace with access to respite and management of financial issues (53). In the UK, the Department of Health carers' action plan 2018-2020, outlines that the government recognises caregivers as expert caregiving partners. The carers' action plan places emphasis on ensuring caregivers are supported, and their needs addressed, to maintain their health and well-being in their caregiving role (54). This aim was superseded by the establishment of the 2014 Care Act, which stipulates that caregivers now have a legal right to a needs assessment (55). However, uptake for this is limited; only 27% of almost 6,000 caregivers living in England reported that they were offered and completed a needs assessment in 2019 (3). The small numbers completing a carer's needs assessment highlight a gap between recommended best practice guidelines and the reality of the limited way caregivers are engaged and their needs addressed by healthcare professionals.

The experience of caregiving is equated to that of a roller coaster of emotions, particularly when there is a sudden change in the patient's health status, or the patient requires aggressive interventions (56). Caregivers report experiencing shock, anxiety, and uncertainty in response to managing the patients' illness (57). Caregivers of patients living with dementia report experiencing higher anxiety, depression, and hopelessness (58). Stressors secondary to the direct caregiving experience also impact on caregivers (57, 59). Secondary stressors include relationships with other family members, engagement in employment, financial implications due to caring and limitations in the caregiver's social life (57, 59). These stressors are particularly prevalent when caregivers are trying to manage the role alongside other responsibilities such as family and paid employment (3). Currently, there are 1.3 million people who are defined as "sandwich carers," 72% of these caregivers have reported ill health (60).

Caregivers who perceive they are engaged in complex care tasks over many hours in the day (20+ hours per week) for patients with higher care needs, reported more symptoms of mental ill-health (60, 61). This perception is significant, particularly as the four-nation study conducted by IACO identified that caregivers were providing care on an average of 22 hours per week (38). A secondary analysis of the UK Household Longitudinal Study (UKHLS) examined the longitudinal relationship between psychological distress and caregiving (50). This analysis reported a plateau effect of the negative impact of caregiving over time (50). This finding from the UKHLS is of interest as much caregiver literature is cross-sectional, therefore this survey provides important insights into the longitudinal implications of caregiving. Additionally, it identifies a plateau effect over time which contradicts what has previously been reported in caregiver research in cardiorespiratory illnesses (10, 62).

Caregiving can lead to feelings of isolation and a loss of meaningful activity. Caregivers who provide care over a more extended period have reported significant negative impacts on their health (18, 20, 57, 63, 64). Research examining family caregivers of patients living with dementia has identified caregivers' dissatisfaction with life, and significantly reported that caregivers have contemplated suicide and homicide as a result of the caregiving role (65, 66). A review of caregiving literature identified that over time females caring for greater than 20 hours per week in conjunction with employment experienced a decline in mental health (20). Female caregivers experienced increased distress when compared with non-carers (20). In this review by Hill and Broady (20), they report no effect was identified with regards to male caregivers' mental health. However, drawing assumptions from these findings should be considered with care as Hill and Broady (20) present the international literature on caregiving but do not discuss the characteristics or context of these caregivers. Chapter 1 of this thesis identified that it is important to consider the implications of caregiving within the context in which that caregiving is taking place.

The research by Hill and Broady has been synthesised based on surveys from carer organisations within Australia (20). Thus, this type of research brings its own limitations particularly with regard to subjective bias. The findings of these surveys identified that prolonged caregiving has negative implications for the caregiver's health (20), this contradicts the findings of the UKHLS (50). Other characteristics identified which are increasing caregivers' risk of poorer health include, living with their own illness, receiving financial assistance, belonging to a minority ethnic group, identifying as female and being under the age of 25 (20). A synthesis of 15 studies conducted by Bom et al. (67), examined the impact of caregiving for older adults. Unlike Hill and Broady's rapid review (20), Bom et al. (67) reported that the impact of long-term caregiving was inconclusive. They recommend examining the impact of long-term caregiving from the perspective of specific subgroups of caregiving (67). This could include examining illness specific populations such as HF, COPD or CAD. Bom et al. (67) only examined quantitative research, this may demonstrate that capturing the nuanced impact caregiving has on an individual's health over time and may not be easily demonstrated utilising quantitative outcome measures only.

Research examining the impact of caregiving on caregiver physical health in comparison to caregiver psychological health has been less extensive (68, 69). Caregivers have reported poorer physical health when compared to the non-caregiving population (18, 21, 68). A meta-analysis of the physical health of caregivers of dementia patients compared to non-caregivers demonstrated that caregiver physical health is influenced by living with the patient and the relationship between the caregiver and patient (21). This meta-analysis is limited due to the statistically significant demographic differences between the included caregivers and non-caregivers. Whilst, this meta-analysis is almost 20 years old it does highlight the importance of considering caregivers physical health needs (21). Pinquart and Sörensen (68) further contributed to this body of research by examining the correlates of caregivers' physical health. They concluded that the predictors of caregiver physical health are different from those of caregiver psychological health (68). Caregiver physical health was associated with being an older caregiver, living with the patient, lower income, lower educational attainment and the duration of the caregiving role (68). However, the effect sizes for these associations were small in magnitude (<0.20). Interestingly, while Pinquart and Sörensen (68) report that predictors of caregiver psychological and physical health differ, Hill and Broady (20) identified that these predictors are similar. These include: the duration of caregiving and being in receipt of financial assistance (20). This demonstrates the variability across the caregiver literature when trying to determine predictors of caregiver health outcomes.

More recently, Lambert et al. (69) synthesised 14 experimental studies examining physical activity interventions on caregiver outcomes. Whilst this review did not include RCT’s this comprehensive synthesis spanned 3 decades. Significant impact on caregiver physical health outcomes were not consistent, however, they did note improvements in psychological health outcomes (69). The authors concluded that physical activity should be utilised as a target intervention with caregivers, yet, the current research base is lacking in methodological rigour (69). Findings were unable to be synthesised for a meta-analysis and presented in descriptive format (69). This may have been an opportunity to include vote counting as an additional way of presenting the findings (70). While vote counting does have methodological limitations, presenting it alongside the narrative synthesis of physical health outcomes may have contributed to a discussion about the trends observed in the literature. The majority of studies in this review included caregivers of patients living with dementia or Alzheimer's disease followed by, cancer, mental health and older age (69). Recommending physical activity to caregivers as part of their role is an emerging area of research according and one that is worth consideration in the design and delivery of interventions targeted towards caregiver outcomes due to the well-known espoused benefits of engaging in physical activity (69). A UK based longitudinal study of caregivers indicated that poorer physical health has been reported by female caregivers in (50). Research examining the gender experiences of caregivers in mental health suggests that gender should be examined in the context of relationship to the patient, sociodemographic variables, culture, and ethnicity as well as patient factors (59, 71). Overall, research into caregiver physical health has been mixed and limited in quantity and quality, particularly when compared to research on caregiver mental health (68).

Caregiving is not always a negative experience (72). Caregivers have reported experiencing a sense of fulfilment, joy and closeness to the person they are caring for, as well as satisfaction in the caregiving role (20, 73). The concept of positive aspects of caregiving was initially reported in the 1990s (74). Kramer (74) identified that in order to enhance theory development, validate caregiver experience and understand caregiving from a holistic perspective, positive aspects of caregiving should be examined. More recently, in the field of stroke caregiving, a synthesis of qualitative and quantitative research identified the components of positive aspects of caregiving for (75). The authors of this this review acknowledge that examining positive aspects of caregiving is sparse in the caregiver literature, with little written about it since Kramer's 1997 publication (74). They included nine studies for synthesis, primarily exploratory and cross-sectional, which demonstrates the methodological limitations of the research examining positive elements of caregiving (75). The findings of this review demonstrated that caregivers could identify positive aspects to their role (75). These include, when the patients' makes progress (i.e. stability of illness, management of signs and symptoms), a good relationship between patient and caregiver, when caregivers experience increased self-esteem and when they felt appreciated (75). This review presents useful insights into positive aspects of caregiving (75). These are important elements to target consider when including caregivers in intervention delivery.

A narrative synthesis of 53 studies examining the positive aspects of dementia caregiving suggested that caregivers who identified positive elements to the role were more likely to have a greater sense of wellbeing (76). Specifically, positive aspects of caregiving in dementia were significantly associated with the following caregiver factors: less depressive symptoms, better mental health and higher QoL including life satisfaction (76). There was no significant association identified between role strain, stress and burden (76). This narrative synthesis was comprehensive as it spanned a large time frame, 1989 - 2017, however quantitative studies only were included (76). The exclusion of qualitative data and a different illness population make it difficult to make direct comparisons with the review by MacKenzie and Greenwood (75). However, it is worth noting that Quin and Toms (76) reported the association between positive aspects of caregiving and self-efficacy was not significant whilst MacKenzie and Greenwood (75) identified that caregiver self-esteem was a key theme in caregivers' positive perceptions of caregiving. Changes in caregiver perspective of positivity towards the role do change over time, caregivers who were newer to the role identified more positive experiences than those who were caregiving over a longer period of time (75). Interestingly, both reviews note that there is a lack of conceptual agreement on defining positive aspects of caregiving and conclude that longitudinal research is required to examine whether caregivers continue to identify positive aspects of caregiving in the long-term (75, 76).

A robust longitudinal study examining the factors related to the psychosocial wellbeing of family caregivers in HF yielded interesting insights with regard to positive and negative emotions experienced by family caregivers (77). Grigorovich et al. (77) demonstrated that caregiver related factors influenced caregiver emotional wellbeing whilst there was no association between patient-related factors and caregiver emotional wellbeing. Caregiver positivity was associated with caregivers receiving social support and having the ability and opportunity to engage in meaningful social activity with the patient (77). The elements of this research which enhanced the methodological rigour was the collection of data at several time points and application of individual growth curve modelling to identify changes over time (77). Individual growth curve models allows for analysis within and across variables, it has demonstrated higher statistical power compared to traditional models of longitudinal analysis (78). However, this was a single-centre study, with over half of the caregivers identified as at risk of depression at baseline, reporting of patient NYHA status was not categorised and illness duration was not reported. Each of these variables may have implications with regard to the finding that patient-related factors do not influence caregiver emotional wellbeing (77). An important outcome from Grigorovich at al.'s (2017) study is the psychological influence of support and social activity on caregiver emotional wellbeing. Buck and colleagues have suggested that caregiving in HF is a spectrum of experiences (12). Caregiving for patients with HF is neither wholly positive or negative but a series of transitions for which the patient and caregiver must adapt (79). This perspective of caregiving aligns with the concepts of the stress process model.

2.2 The Stress Process Model

The stress process model (80-82) is one of the predominant middle range theories cited in caregiver literature. Middle range theories include measureable and observable concepts which facilitates their application in a clinical context (83). The stress process model is an example of a middle range theory. Stress is the discord between the persons' capabilities and the conditions the are living with (84). The stress process model is based on the premise that transitions are embedded throughout the life course (80). People respond to this by adapting and evolving into differing roles over their life course (80). Some transitions in life are normative, for example, retirement. However, some such as the onset of illness, interrupt the life course (80). Multiple changes together may create stress, even if they are individually benign (80). Pearlin classifies caregiving as an "unexpected career"; caregiving for a patient is not a role that someone expects to undertake (80). Frequently, caregiving requires an interruption to the expected life course.

The stress process comprises a background or context to stress, the stress itself (this may be a primary or secondary stressor), mediators of stress and finally outcomes or manifestations of stress (81, 82). The background and context of stress include caregiver characteristics, personal and social resources, caregiving history, relationship between the patient and caregiver, the extent of illness, duration of caregiving and the composition of the family in which caregiving is taking place (82). Primary and secondary stressors include objective and subjective stress (82). For example, caregiving and being engaged in employment may be primary stressors, however, the strain of balancing these roles can lead to secondary stress such as burden, financial stress relationship breakdown or time stress (82).

Mediators of stress include a person’s ability to cope and their available social support (82). Subsequently outcomes or manifestations of stress may include physical and mental health impacts and diminished ability to engage in the caregiving role (82). It is suggested by Pearlin (80, 82) that supportive social settings and systems (e.g. communities, healthcare services, policies) can enhance caregivers’ feelings of inclusion. Thus these can be protective factors for caregivers and facilitate them to use coping mechanisms in their role (80). Therefore, it is essential to understand caregivers' lived experience and what contributes to effective self-management when designing interventions (80). This model proposes that having "agency," i.e. being able to choose, make decisions and live according to one’s goals and values can contribute to mastery and self-esteem in the role, thus are protective factors for caregivers (80).

The stress process model has been utilised to inform much caregiver research. Application of the stress process model has been examined in caregiving of dementia patients, caregivers of AIDS patients and caregivers of those awaiting liver transplant. Whitlatch et al. (85) conducted a cross-sectional study informed by the stress process model to determine the predictors of caregiver depression in relation to caregivers of patients with dementia in nursing homes. Utilising a regression analysis the researchers identified that the relationship between patient and caregivers, and interactions with nursing home staff influenced how well the patient and caregiver adjusted to the nursing home surroundings (85). The ease of this transition was a predictor of caregiver depression (secondary role strain) (85). This study demonstrated the utility of the stress process model, in particular identifying that caregiver characteristics and the support perceived by the caregiver from nursing home staff mediated caregiver depression (85). However, it is important to note in this piece of research that this was a secondary analysis and the stress process model did not guide the original research question, therefore the outcome measures selected may not have been representative of capturing all elements of the applicability of the stress process model. This study does highlight how caregiver appraisal of a situation is an important factor when considering the stress process (85).

The stress process model underpinned research into the caregiver characteristics that may predict risk of anxiety and depression when caring for someone awaiting a liver transplant (83). Patients living with liver disease were mainly younger men, it was hypothesised that this might result in a secondary stressor for their wives due to the potential impact on the marital relationship (relational deprivation) (83). A second hypothesis was that the impact on finances may be a secondary stressor (83). Caregivers at 6 to 12 months post-transplant were included for analysis, it is worth noting that while QoL post-transplant initially is limited, over time this will improve (83). The authors concluded that sex is an indicator of subjective stress, identifying that females perceived more burden and distress (83). However, this conclusion needs to be considered with respect to the methodological limitations of the sample. The sample was predominantly comprised of female caregivers with the hypothesis considering heterosexual couples only. There was little discussion in the findings about the original hypothesis of relational deprivation and finance as a stressor. Additionally, as this study was specific to post-transplant patients the expectation is that their health will improve, thus caregivers may perceive the future differently and may have a significant reduction in their caregiving role, unlike in other long-term conditions. The authors of this research do emphasise the importance of nurses understanding the components of the stress process model and in turn utilising this to inform their approach with caregivers (83). This study presented a description of the model and how the findings correlated with aspects of the model, they did not take a critical approach in their application of the stress process model. However, research into the experiences of caregiving in mental health has identified the need to conduct a critical review of the stress process model to determine whether it remains applicable in the modern day mental health context (84).

Since 2010 there are over 25, 000 articles citing the stress process model, thus demonstrating the prolific use of this model (84). Au (84) recognises that stress exists on this continuum; this is similar to how Jones (79) and Buck (12) describe providing care to someone living with HF. A critique presented in the review of the stress process model, suggests that it is based on a nuclear family but in present day that family does not necessarily exist in the originally conceived structures as considered at the conception of this model (84). However, the model considers an individual’s roles on a micro level (individual roles and status) and a macro level (within their community and society) thus still remains applicable today. This review did not present any discussion on how it identified studies to include in this review, only stating it did not include studies that discussed the application of the stress process model (84). Understanding the rationale for including and excluding studies would have provided a greater insight into the critical approach presented by the author. Au (84) does recognise that many core concepts of the stress process model do remain relevant today. The loss and gain of roles and the need to adapt to new roles may be softened by having the opportunity to prepare people for the role, for example caregiving post diagnosis of COPD compared to caregiving following myocardial infarction (84). Stress proliferation may be an issue if one spouse is experiencing stress and as a result, there is a spill over effect of this on the other spouse, likewise if adult-child caregivers are managing multiple roles, or experiencing role conflict with the parent for whom they are caring (84). This is important to consider in terms of self-management in cardiorespiratory illness. For example, whether the patient avoids HF self-management or pro-actively engages in it may increase or minimise caregiver stress. Likewise, adult-child caregivers may experience intrapersonal conflict due to role restructuring thus increasing stress. The stress process model is one of the conceptual frameworks informing the empirical research in this thesis (chapters 3-6).

2.3 Bandura's theory of self-efficacy

Mastery is the ability to handle stress (84) thus, Bandura’s theory of self-efficacy also informed the empirical research in this thesis. Bandura suggested that one's belief in oneself, impacts on confidence and beliefs about one's ability (86). Through engagement with tasks, attaining a sense of accomplishment, and comparing oneself to others, one begins to develop self-efficacy (86). Success and positive experiences via achievements and accomplishments increase self-efficacy (86). Personal mastery impacts coping and engagement in tasks and occupations (86). Thus, caregivers who experience a sense of accomplishment and achieve a sense of mastery in the caregiving role via perceived success and positive experiences of the role are likely to be confident in their ability to provide care. Bandura argues that people choose activities and settings in which they will be self-efficacious (86), however, as noted previously, caregivers of people with long-term ill health often do not choose to become caregivers. It is a role that evolves, often as an interruption to ones expected life course. Therefore, intervening with caregivers requires an element of understanding whether they feel confident and efficient in their role and if not, identifying methods of enhancing caregivers' self-efficacy in the role. Bandura's theory provides a framework for understanding personal and environmental factors for caregivers and the impact of caregiving in the management of illness.

A cross-sectional study of Australian caregivers of patients living with multiple sclerosis demonstrated that caregivers who scored higher on caregiver strain scores correlated with a lower QoL but not with their self-efficacy (87). This is an interesting insight as the authors hypothesised that caregiver strain would be influenced by self-efficacy (87). Both patients and caregivers reported they were in good health and just under half of the respondents were receiving paid personal or domestic care at home (87), this has implications for interpreting these results. Caregiver's may have perceived strain however, identifying good baseline health and having access to paid support may have enabled caregivers' to engage in other meaningful roles which may have maintained their self-efficacy. Additionally, over half of the respondents reported low caregiver strain scores (87), this potentially limits the identification of self-efficacy influencing caregiver strain. A review of research examining self-efficacy of caregivers of cancer patients demonstrated that caregiver self-efficacy is a predictor for caregiver psychological health outcomes (88). This review included 71 studies for synthesis, however these were primarily cross-sectional in design (88), furthermore this review included studies with dyads and caregivers only, with little discussion differentiating between the two. Given that self-efficacy is suggested to be influenced by the context (86), addressing whether there are differences in self-efficacy outcomes in caregiver only or dyadic studies is important to acknowledge. The authors suggest that self-efficacy is an important concept to focus on in the design and delivery of interventions for caregivers of cancer patients (88).

2.4 Dyadic interventions in caregiving

A dyadic process refers to the interaction between the patient and caregiver and how this interaction informs their management of illness (89) (The term dyad will be applied throughout this thesis to reference patient-caregiver dyads). Dyadic interventions aim to facilitate a collaboration between the patient and their caregiver in order to facilitate a collaborative approach to engage in health behaviours and disease management for example in HF self-care (90). The following section presents a review of the literature, examining both patient outcomes and caregiver outcomes when caregivers are included in healthcare delivery.

2.4.1 Patient outcomes with caregiver involvement in healthcare delivery

A systematic review of qualitative studies regarding rheumatic disease, cancer and chronic kidney disease synthesised 37 studies and identified that support is a crucial component for patients to be successful in self-management of long-term illness (91). The types of support required by patients are instrumental (e.g. medical management of the illness), psychosocial (e.g. providing emotional support and facilitating the development of coping strategies) and relational (e.g. the partnership and the quality of the partnership) when engaging in self-management (91). Importantly the authors note, the extent to which a patient engages in these types of support is dependent on the illness (stage and duration of illness) and the individual themselves (age, ethnicity, cognitive capacity and ability to engage in complex self-management regimes)(91). This review is important as it demonstrates that while support is essential for self-management, the pragmatic aspects of that support is dependent upon the person and their context (91). Unfortunately, there is very limited discussion on the role of family caregivers in providing this support.

Lopez-Hartmann et al. (92) identified that caregivers are an essential resource in supporting patients in their self-care. Self-care is categorised as a naturalistic decision making process whereby people engage in to self-care maintenance, monitoring and management activities to sustain their health (93). Dependent upon the individual and the condition that someone is living with, caregivers may have a key role in these self-care processes. Such is the importance of understanding the processes of self-care, a theoretical construct outlining the components of self-care in long-term illness has been developed (94). The middle-range theory of self-care in chronic illness is concerned with providing a holistic understanding of the processes individuals engage with which result in health-promoting behaviours, to achieve optimum QoL whilst living with a long-term illness (94). Individuals who participate in all three interacting components (monitoring, maintenance and management) are most proficient at self-care (95). Primarily patients develop proficiency in self-care maintenance first, with mastery of the other elements forming over time (95). However, as with the nature and trajectory of long-term illness such as HF or COPD, learning to engage in self-care is not a linear process (95). A recent refinement of this theory suggests the concept of self-care monitoring requires further exploration as to whether patients who are adept at self-care monitoring are more attuned to responding to symptom changes (95). Furthermore, it is suggested symptom recognition and interpretation vary for each individual and should be identified as a core element of self-care both as a precursor and as an outcome to self-care (95).

Technology has an ever increasing role in healthcare delivery and is cited as a key indicator for healthcare delivery in the NHS long term plan (96). An examination of the role of technology interventions for patients and caregivers living with long-term conditions was conducted by Irani et al (97). Nineteen studies were included for analysis, with a focus on patient or dyadic outcomes (97). There was little discussion on how caregivers were involved in technological interventions. Telehealth was also excluded with little discussion as to why as potentially it could be argued this is a technological intervention, particularly as studies utilising text messages were included (97). There were no limitations on the duration of people living with long-term conditions, (97), this may be an important implication in terms of outcomes achieved due to the potential efficacy in illness management achieved over time, or due to the progression of the illness. Included in the synthesis were patients and caregivers living with, cancer (n = 7), cardiovascular disease (n = 6) with a focus on HF (this is a unique aspect of this review as many reviews do not identify the subgroups of cardiovascular illness), depression (n = 3), diabetes (n =3), and obesity (n = 1) (97). Interestingly there were no studies included which examined dementia which is a prominent area of dyadic research, or COPD, which receives very little attention in the dyadic literature. The two studies in this review which did observe any improvements were targeted at the dyad (97).The narrative summary approach presented in this review demonstrated that patients reported improvements in self-management behaviour and QoL but there was very limited improvement in psychological outcomes (97). Outcomes regarding caregiver burden were inconsistent (97). As embedding digital technology into healthcare is an emerging area of practice this review only included feasibility and acceptability studies, patients and caregivers reported high satisfaction with the interventions and reported they facilitated meaningful communication (97). What was evident from this review was the lack of mapping theory to intervention components (97). In order to comprehensively understand how to design interventions which include both patients and caregivers it is important to be informed by a robust theoretical base.

A meta-analysis of 72 published RCTs examining the benefits of family member involvement in psychosocial interventions for a range of long-term illnesses (dementia, heart disease, frailty, cancer, chronic pain, stroke, rheumatoid arthritis and brain injury) demonstrated positive outcomes for patients when their spouses were involved in the intervention for depression and mortality (98). Family involvement did not have an impact on patient anxiety or physical ability (98). A strength of this review was the comprehensive search strategy undertaken, the inclusion of RCTs only and the stratified approach to meta-analysis, however this may have been limited due to the inclusion of only peer reviewed published studies, indicating potential publication bias. Whilst this review sought to examine the impact of family involvement across a range of long-term illnesses, the majority (44%) of included studies were in the field of dementia caregiving, followed by heart disease 21% (with 2 of these studies examining HF) (98). This review does not present discussion on the specific context or components of the intervention delivery; additionally the mode of caregiver involvement is not clear. Understanding these aspects will provide greater insights into how outcomes may or may not have been achieved. This review conducted by Martire et al. (98) was one of the first reviews to synthesise the evidence base on caregiver involvement in intervention delivery. However, the aggregate effect of outcomes on patient depression and mortality was small in magnitude, thus while it provides some insights it does not present a comprehensive picture of whether family involvement can significantly and consistently positively influence patient QoL (98).

A later meta-analysis published in 2010 compared usual care with family based interventions for patients living with chronic illness (99). A strength of this meta-analysis was the broad classification of the term family. A family member was classified as any (unpaid) individual involved with the patient’s management of their chronic illness, therefore, not necessarily a relative (99). Family based interventions included education (i.e. informing families about the condition and strategies for self-management) and relationship focused (i.e. communication skills with regard to behaviour change and managing stress in the relationship) (99). The pooled effect of the meta-analysis demonstrated statistically significant outcomes in favour of patient physical and mental health outcomes as a result of family based treatment compared to usual care (99). Interestingly, patients demonstrated statistically significantly improved physical health outcomes when they had spousal caregivers participating in the intervention compared to other caregivers (99). Furthermore, subgroup analysis demonstrated the effect was higher for relationship focused interventions as opposed to educational interventions and the involvement spousal caregivers over other relationship typologies, however relationship focused interventions were limited in cardiovascular disease (99). This indicates the importance of the strength of the relationship between the patient and caregiver, demonstrating the importance of comprehensively understanding the influences of the interpersonal dynamics between patient and caregiver and the value of developing intervention strategies which can support this relationship when living with long-term illness.

The value of relationship dynamics in promoting health behaviours was evidenced in a systematic review and meta-analysis conducted by Carr et al. (100). They identified that dyads who had shared goals or were friends achieved the most statistically significant improvements in physical activity (101). However, this significance was only for individual goals, as opposed to dyadic oriented goals (100). This is an interesting outcome in terms of how dyadic interventions are approached for those living with long-term illness. It could be suggested that goal setting should consider patient goals, caregiver goals and subsequently any dyad related goals. Sixty-nine studies were include for synthesis in the review, sixteen of these included participants with the following health conditions: a significant cardiac event, osteoarthritic knee pain, breast cancer, stroke or any type of cancer except squamous or basal cell skin cancers (100). Over half of the included studies conducted with healthy participants (100), thus the pooled effect of individuals living with and without various health conditions does need to be interpreted with this limitation in mind. Furthermore, this review included formal (paid) caregivers, therefore the dynamic of this type of relationship may significantly influence whether one engages with physical activity.

Similar to previous published reviews examining a partner’s involvement, the level of partner involvement in interventions was not clear. Larger effect sizes were demonstrated for individuals living with health conditions (100). The implications of this finding indicate the role of intrinsic and extrinsic drivers in behaviour change. The diagnoses included the meta-analysis conducted by Hartmann et al. were cardiovascular disease, arthritis, stroke, cancer, diabetes, aids, lupus erythematosus (99). Cardiovascular disease and stroke was combined to conduct subgroup analysis, the authors reported this subgroup could be the only one interpreted with confidence with regard to patient outcomes. However, considering the differing disease specific characteristics of stroke, myocardial infarction and HF amongst other illnesses which can be considered as cardiovascular diseases, this categorisation may be problematic in interpreting the results of this subgroup analysis. Overall, whilst the trend is in favour of involving a caregiver in chronic illness interventions, the aggregate effect of outcomes was small which was similar to the findings of Martire et al. (98, 99). The heterogeneity of studies including, poor reporting of what constitutes usual care, vast differences in intervention intensity and duration, lack of reporting on how the interventions were facilitated and the attempt to produce a pooled effect size for a variety of illnesses limit the findings of this meta-analysis.

A synthesis of meta-analyses published over five years up to 2009 identifies that published dyadic research is primarily in the field of dementia, followed by heart disease (102). The type of heart disease is not specified, furthermore Chesla (102) reports there is very little research published examining caregiver involvement in respiratory illness for example, COPD. Synthesising interventions across the lifespan demonstrated that involving family members in self-management interventions had positive outcomes on patient physical health and depressive symptoms when compared to usual care (102). Similar to earlier meta-analyses, the effect sizes in this meta-analysis were small in magnitude (102). Multimodal intervention delivery (education, exercise, diet, communication skills) for long-term illness which require significant lifestyle change have demonstrated most efficacy (102). However, what constitutes significant lifestyle change in long-term illness is not discussed in detail. Arguably any diagnosis which requires maintenance over one’s life time can be considered requiring significant lifestyle change. The processes of how to include caregivers in interventions for individuals with long-term illness lacks clarity. Examining patients and caregivers living with specific illnesses may provide further clarity with regard to the optimum components of caregiver inclusion to enhance self-care in long-term illness. Methodologically rigorous mixed method research is required, explicitly examining defined patient-caregiver dyads (e.g. HF patient-caregiver dyads), to identify and design interventions to address the specific needs of this defined group of patient-caregiver dyads (98, 99, 102).

Meta-analysis of 23 RCTs of dyadic interventions in cancer care examined QoL and improvements in psychosocial elements (103). There were no significant differences identified between family involved interventions and patient only interventions on patient outcomes. (104). However an important limitation is that caregiver outcomes were not reported. The methodology of how caregivers were engaged in dyadic interventions was not reported. This review provided little discussion on the mode, duration and type of intervention making it difficult to discern how dyadic interventions were delivered. Furthermore key discussion points were lacking depth of explanation. Examples of this include a lack of discussion on the potential that the primary included interventions did not achieve anticipated outcomes, and a lack of reporting on whether studies were targeting patient only outcomes or dyadic outcomes. Compared with usual care, dyadic intervention at 3 months follow-up was associated with statistically and clinically significant improvements in patient total QOL including, emotional, social and mental aspects, depression, anxiety and marital functioning (104). At 6 months follow-up, dyadic intervention compared with usual care was associated with significant improvements in patient social aspect and depression. No effect was seen for patient physical and functional aspects of QoL, hopelessness, pain, fatigue or survival (104). Meta-analyses did not stratify by illness type or provide consideration of illness duration, which, considering the illness population may have provided greater depth of insight to the sustainability of outcomes.

2.4.2 Caregiver outcomes when involved in formal healthcare delivery

In the meta-analysis conducted by Martire et al., discussed earlier in this chapter (98), caregivers experienced positive outcomes for reducing burden, anxiety and depression when self-management interventions included them in the delivery (98), however, once again, long-term follow up was limited (98). A mixed-methods study conducted in 2015 examined the perception of rehabilitation, one-year post-stroke for patients and their caregivers. Caregivers reported less burden when the patient's rehabilitation needs were met (105). The authors of this mixed-methods trial propose that caregivers can increase researchers and healthcare practitioners understanding of the processes involved in patient self-care and enable comprehension of the more comprehensive complex external factors and influencers on the patient's rehabilitation (105).

Limited reporting on theoretical foundations of studies was identified in a narrative synthesis of 48 RCT's evaluating interventions of people with dementia over the past 20 years, specifically focusing on managing behavioural and psychological symptoms in the community (106, 107). Included studies synthesised interventions targeted towards patients with dementia (n=7), caregivers of patients with dementia (n = 23) and interventions targeted towards patient-caregiver dyad (n = 18) (107). A strength of this work, not often reported in systematic reviews is the robust engagement of key stakeholders', including healthcare professionals, patients and caregivers. Interventions varied greatly with regard to duration, intensity and dose (107) which has been evidence in other illness populations where there has been an attempt to synthesise the literature. The authors identified that interventions delivered over the longer term demonstrated more positive outcomes for the patient and their caregiver (107). This indicates a need for ongoing input from healthcare interventions with long-term illness whereby the trajectory of the illness is functional deterioration over time. There was no discussion in this review about whether the included RCT's had conducted a process evaluation or whether they included a qualitative component to their trials (107). This may have yielded a holistic insight into patient, caregiver and dyadic outcomes. One dyadic study in this review demonstrated a reduction in distressing behaviour (107). However this study had a high attrition rate, thus limiting the efficacy of making robust conclusions about the outcomes. Family education and training helped caregivers in short term and was of short term benefit to patients but not sustained at 12 months. (107). Caregivers who were described as "activated" (actively engaging in using intervention strategies) reported a reduction in distressing behaviours engaged in by the patient compared to caregivers engaging/utilising intervention strategies less (107). However, this was not a predictor for caregiver burden or wellbeing (107). Family caregivers improved psychological health with support from case managers, predominantly Occupational Therapists (107). This indicates the value of caregivers having access to a healthcare professional via regular home visits and telephone calls.

Building on the systematic review conducted by Trivedi at al. (107), a multi-site, multi-component intervention was developed and delivered for caregivers of patients living with Alzheimer's. The Resources for Enhancing Alzheimer's Caregivers Health (REACH) trial was a 6 year trial testing the feasibility and outcomes of multiple different intervention approaches, targeted enhancing caregiver outcomes (108). The purpose for trailing a multitude of interventions was to identify a variety of approaches which could be utilised to address caregiver needs (108). Interventions included:

1) Individual information and support strategies (caregiver only information/support)
2) Group support and family systems therapy
3) Psychoeducational skill-based training (education and skills for managing patient behaviours)
4) Home-based environmental intervention
5) Enhanced technology support systems

The outcomes of this significant research demonstrated that active involvement of caregivers in any intervention format reduced caregiver burden and depression (108). It is important to note that these were feasibility trials and therefore may not have been sufficiently powered. Additionally, the primary outcome was to determine the acceptability and ability to deliver these interventions.

One of the trials from this multi-site study was a structured parallel intervention (109). There were two interventions delivered and these were compared against each other, this in itself may be a limitation with regard to identifying the true efficacy of either intervention. It could be posited that any input may have improved patient and caregiver outcomes if usual care consisted of no input. These parallel interventions included managing patient behaviours compared with managing patient behaviours and an information leaflet on improving caregiver wellbeing (109). This site recruited 167 dyads, with data collection every 6 months, 76 dyads were retained at 24 months for longitudinal analysis, this is a high attrition rate but given the illness population examined this may be expected (109). The longitudinal follow-up is a strength of the REACH trial as this type of data collection is limited in caregiver research. The intervention duration and dose consisted of 30 minute (patient behaviour) or 60 minutes (patient behaviour and caregiver support) interventions every three months for two years. Caregivers who completed the intervention were caring for a shorter duration of time than non-completers (109), this is interesting because the caregiver research generally identifies that caregiving over a period of time can have significant impacts on an individual's health (110). Therefore there is potential that the outcomes are skewed by caregivers who were in a better health state due to the shorter time frame they were providing care, thus able to cope better with the demands of caregiving throughout the duration of this intervention.

Overall, the outcomes of this arm of the REACH trial demonstrated that caregivers in the enhanced care group experienced a reduction in depression but this was not significant, additionally caregivers in the patient behaviour intervention group did not experience any reduction in depression (110), this may be due to the progression of the patients illness throughout the 24 months duration of the trial. There is similarities with HF and COPD patients, they can experience periods of stability and periods of deterioration (111, 112), therefore stabilising caregiver mood rather than making any significant improvements may be all that can be managed in the longer term. There were no significant differences identified with regard to caregiver perception of patient challenging behaviours (110). Therefore it could be suggested that while patient behaviour did not change, caregivers' ability to cope with challenging behaviours improved. This indicates the importance of education and support for caregivers' in establishing coping strategies in their role.

Following on from the knowledge obtained in REACH, an RCT, REACH II was established. All six sites implemented the same intervention and collected the same data (113). The significant conclusion from this RCT is that caregiving presents multiple challenges that are not easily addressed. As a result, there is no single, easily implemented, and consistently effective method for achieving clinically significant effects among caregivers or care recipients (108). Understanding the complex nature of caregiving, for example the person (caregiver), their environment (social, financial, cultural) and their engagement with caregiving tasks does not easily lend itself to a clearly targeted standardised intervention. Flexibility is required to meet the nuanced caregiver needs and abilities in the design and delivery of interventions for the caregiver population. RCTs targeting caregivers of patients living with cancer were synthesised to determine the efficacy of including caregivers in cancer care interventions (114). Interventions delivered to caregivers were psychoeducational (education about cancer treatment and social and emotional needs of patients and caregivers), skills training (communication, problem-solving, managing dressings, wound care) and therapeutic counselling (relationship dynamics) (114). As has been seen with other synthesis of caregiver research the intensity (1.7 – 18 hours contact time), duration (a few days to 18 months) and dose

(2 – 12 sessions) of interventions delivered varied (114). Out of the 29 RCTs included for synthesis 9 of these were caregiver only intervention. Similar to previous trials which have included caregivers, the primary outcomes were concerned with developing caregiver skills to enhance patient outcomes, skills for maintaining or enhancing the quality of the relationship between the patient and caregiver and finally caregiver self-care was commonly a secondary outcome of the research (114). Of significance this meta-analysis demonstrated that caregivers reported reduced burden, increased perceived caregiving benefit, reduced information needs, improved QoL in both physical and mental health needs and improved relationship quality (114). The longitudinal outcomes which were sustained included coping skills (problem-solving), self-efficacy and less distress (114). However, as has been consistent with caregiver research, the effect size is small to medium with regard the significance of these findings (114). These findings are interesting as firstly, they are not consistently demonstrated longitudinally in the literature, they demonstrate the value of ensuring caregivers’ knowledge and skill base is accurate as, thirdly, potentially with the treatment trajectory with cancer care either patient health improving, less dependency and demand on caregiver health or declining health may have had an influence on distress and anxiety. Caregivers included were primarily female, Caucasian, variability of illness populations (breast cancer, colorectal cancer, advanced cancer) may limits the applicability of this synthesis. It would have been useful to stratify the results by stages of illness, for example, early or advanced cancer and provide an indicator of the demands on the caregiver at the time thus provide insight into caregiver outcomes achieved. There were no effects on caregiver depression or social functioning, however these were low at baseline and not deemed areas of problem (114).

A systematic review of 10 quasi-experimental RCTs, examining caregiver inclusion in intervention delivery for patients with traumatic brain injury (TBI) identified that caregiver targeted interventions achieved better outcomes than dyad targeted or patient only interventions (115). However, this synthesis lacked clarity on the specifics of dyadic interventions and subsequent outcomes. Discussion regarding the methodology of caregiver inclusion in dyadic intervention delivery was also not clear. This systematic review stated the initial aims were to examine TBI, however during the search for papers acquired brain injury was included without providing a rationale or justification for this. The authors recommended that dyadic interventions delivery should be between 5 to 9 intervention sessions and be tailored to the dyads needs (115). However, these conclusions are limited by the lack of transparency in this review and the lack of methodologically robust included studies. The authors concluded that dyadic research with this illness population is an important area of research, however included studies were of poor methodological quality. (115). Given the limited research in this area and the poor methodological quality, a scoping review may have been more appropriate to identify the available research that has been conducted in this illness population.

Family caregiver involvement in interventions requires health professionals and researchers to understand the associative link between family caregivers and patient health to determine how to deliver healthcare interventions (104). Creative solutions tailored to address the needs of patients and caregivers at their particular stage of illness merit further exploration. According to Oyebode and as demonstrated thus far in this thesis, understanding the impact of caregiving on caregiver outcomes is complex (116). Henwood et al. (117) mapped the national and international caregiver research by conducting a scoping review. The purpose was to scope the breadth and depth of caregiver research conducted since 2000. The team identified 62 themes categorised into four headings: support and carers, type of care, impact of care and carer variables (117). These categories were generated from 3,434 references included in this review, the most common research conditions identified in this review were dementia, older people, end of life, cancer care and mental health (117). There is no specific mention of HF or COPD indicating the limited research examining these conditions (117).

2.5 Heart Failure (HF)

Heart Failure (HF) is a syndrome typified by the presentation of shortness of breath on exertion or at rest, retention of fluid, as well as functional or structural abnormality of the heart observed via objective assessments (118). In essence, the heart is not pumping blood effectively around the body. HF is defined clinically as a syndrome in which patients have typical symptoms (e.g. breathlessness, ankle swelling, and fatigue) and signs (e.g. elevated jugular venous pressure, pulmonary crackles and displaced apex beat) resulting from an abnormality of cardiac structure or function. (118). It is differentiated by reduced ejection fraction (< 35%) or preserved ejection fraction (>35%) and is one of the most common diagnoses for hospital re-admissions

(119). HF has a significant impact on the patient, their caregivers and the healthcare system (120).

Electrocardiography (ECD) is undertaken which can identify abnormal left ventricular systolic dysfunction as well as a chest radiography (121). Blood tests are undertaken which examine urea and electrolytes (HF patients experience abnormal electrolyte and renal function), blood count (due to commonality of anaemia), ferritin levels, liver function, thyroid function, urate levels, cardiac magnetic resonance and B-type natriuretic peptide (BNP) and N-terminal (NT)-pro hormone BNP (NT-ProBNP) (121). BNP and NT-ProBNP are natriuretic peptides, a hormone released by the heart ventricles in response to stretching of the walls of the heart, caused by increased ventricular blood flow (122, 123). When the heart cannot pump efficiently BNP and NT-ProBNP levels increase (122). Therefore natriuretic peptides are an indicator of the presence and severity of HF. Research is inconsistent with regard to the cut off values of natriuretic peptides which indicate the onset of HF, this is due to increasing BNP and NT-ProBNP as a result of age, gender and other renal or pulmonary issues (122-124). BNP of ≤100pg/mL is considered within the normal range for BNP levels (125). However smaller observational studies have indicated that patients with HFpEF can present with BNP levels lower than 100pg/mL (126, 127). Therefore natriuretic peptide levels alone should not be used to determine the presence of HF (123, 128).

HF can be divided into Heart Failure Reduced Ejection Fraction (HFrEF) and Heart Failure Preserved Ejection Fraction (HFpEF) (129). HFrEF consists of an ejection fraction of <35% and HFpEF consists of an ejection fraction of >35% (129). There are a multitude of factors which can contribute to the development of HF such as, coronary artery disease, intrinsic myocardial disease, valvular heart disease, congenital heart disease, hypertension, arrhythmias and cardiac conduction disturbances, high output cardiac failure and pericardial disease (130). The factors resulting in HFpEF appear to be slightly different and include atrial fibrillation (129). Patients' diagnosed with HFpEF are more often older at diagnosis and are more likely to be female (131). The evidence base for HFrEF (reduced ejection fraction) is much better established than for HFpEF (preserved ejection fraction). HFrEF affects the contraction of the heart muscle, whilst in HFpEF contraction remains, however the impairment is due to inability of the ventricle to fill during diastole (129).

HF affects approximately 1% of individuals in their 50s and this increases to 80% for individuals in their 80s, with higher prevalence of HFrEF in males (132). There are over 900,000 people in the UK living with heart failure (133). The prevalence of HF is increasing, this is attributable to the increasingly ageing population and improved survival rates for other cardiac diseases (121, 132). HF comprises 4-5% of all acute hospital admissions (130). HF prognosis is variable and is dependent upon NYHA classification, aetiology, ejection fraction, age and co-morbidities (118). HF cannot be cured but it can be managed with medication, cardiac devices and lifestyle alterations (118). The most commonly used classification of HF is the New York Heart Association (NYHA) Classification of functioning. It falls under four categories (118):

1) NYHA Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea.
2) NYHA Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation or dyspnea.
3) NYHA Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
4) NYHA Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

The goal of HF treatment is to manage the disease and symptoms of HF.
ACE inhibitors are first line defence in treatment of HF, hydralazine with nitrate is an alternative first line defence if an individual cannot tolerate ACE inhibitors (118). ACE inhibitors achieve a relative risk reduction in morbidity and mortality of 20-25% (121). Second line treatment consists of β-Blockers, Mineralocorticoid receptor antagonists, Ivabradine, angiotensin II receptor antagonists, and hydralazine and nitrates (118). Diuretics are also routinely used for all types of HF to reduce fluid retention (121). Device therapy for patients with HF is progressing. Device therapy includes, Implantable cardioverter defibrillators (ICD's), cardiac resynchronization therapy (CRT), mechanical circulatory support (MCS) and cardiac transplantation (121). There are a number of lifestyle factors which can be modified in the treatment of HF. Patients should be encouraged to cease smoking, abstain from alcohol, and engage in exercise (120). Weight loss may be recommended in some situations, a low in salt and restriction of fluids to 1.5 – 2 litres per day is recommended (120). HF patients

are recommended to attend cardiac rehabilitation, however historically uptake is low in the UK (134).

The HF patient’s clinical team consists of their Cardiologist, GP, specialist nurse and allied health professionals such as physiotherapist, social worker or occupational therapist. Additionally, in many circumstances and the focus of this research, unpaid caregivers are key individuals involved in supporting HF patients in managing their HF. In summary HF can be a life-limiting condition which has a significant impact on daily functioning and on health care services. Caregivers may have a significant role in supporting patients in the management of their HF.

2.6 Chronic Obstructive Pulmonary Disease (COPD)

Chronic Obstructive Pulmonary Disease (COPD) is a disease associated with an obstructed airflow which is long lasting and non-reversible (135). Dyspnea, coughing and sputum are frequent symptoms (135). Airflow obstruction is defined as a reduced FEV1/FVC ratio (where FEV1 is forced expired volume in 1 second and FVC is forced vital capacity), such that FEV1/FVC is less than 0.7 (133, 136). Tobacco smoking and environmental factors such as air pollution are risk factors for COPD, as well as genetic abnormalities such as abnormal lung development are also risk factors (136). Early diagnosis is key with COPD in order to implement a medication regime (133). It is estimated that by 2030 COPD will be the third largest cause of death globally, current prevalence is estimated to be between 4 and 10% in Europe (137). COPD is the second most common lung disease in the United Kingdom with an estimated 1.2 million people diagnosed with the condition, individuals are commonly over 50 years of age by the time they are diagnosed (133).

Patients present with chronic and progressive dyspnea, coughing, wheezing, chest tightness and sputum are all presenting symptoms (133). A detailed medical history is taken, examining family history of COPD and identifying whether there is a history of recurrent lower respiratory tract infections (136). Risk factors such as smoking and environmental factors are also considered (136). The stage of severity COPD dictates an individual’s prognosis and outcomes. COPD is categorised into four stages with each stage increasing in severity and reducing functional ability (136). The most commonly used classification is the global initiative for chronic obstructive lung disease (GOLD) strategy (138):

1) Stage 1 (mild): FEV1 ≥ 80% predicted
2) Stage 2 (moderate): FEV1 50-90% predicted
3) Stage 3 (severe): FEV1 30-49% predicted
4) Stage 4 (very severe): FEV1 < 30% predicted

A combination of FEV1, dyspnea, exercise capacity and body mass index are all predictors of mortality in COPD (139). Respiratory failure is the primary cause of death (140). COPD can be managed and maintained by engaging with pharmacological treatment and adapting lifestyle behaviours such as stopping smoking or participating in physical activity (133). This can reduce the risk of exacerbations, slow disease progression and reduce morality (138). First stage treatment of COPD is pharmacological and once the condition has stabilised patients are advised on non-pharmacological treatments (133). Initial stage of treatment for COPD is a short acting β2 agonist (SABA) or SAMA for mild stage, patients with moderate to severe/ more symptomatic COPD are treated with long acting LABA OR LAMA (136, 138). If the individual is a smoker, smoking cessation is a key primary intervention (133). Pulmonary rehabilitation is a patient tailored intervention aimed at self-management of COPD via health behaviour changes through exercise training and education (133). Pulmonary rehabilitation has demonstrated reduced readmission and mortality in patients, however, it is not recommended for patients to begin pulmonary rehabilitation prior to hospital discharge (133).

Patients diagnosed with COPD are generally managed by their GP initially, by the time an individual with COPD is referred to a pulmonologist they are far more symptomatic (138). COPD is characterised by periods of stability and exacerbation and requires management of a complex medication regime in addition to engaging in healthy lifestyle behaviours to live well with the condition (133). Therefore, caregivers have an important role in supporting the patient to manage the complexities associated with COPD.

2.7 Caregiving for patients with HF or COPD

A diagnosis of HF or COPD can be a life-changing event (141, 142). Both are long-term, life-limiting illnesses, characterised by a significant impact in functional ability (143-145). HF and COPD display some similar symptoms such as functional deterioration over time, breathlessness, fatigue, chest tightness, and reduced ability to exercise (144, 146, 147). Consequently, immediate family or close friends are the primary sources a person has access to for support in self-care (12, 144, 148-150). Due to the complexity of these tasks and the implications of living with an illness such as HF or COPD, caregivers are often relied on to support self-care. This reliance on caregivers signifies why caregiving in cardiorespiratory illnesses is described as a dyadic process (151, 152).

Best practice guidelines for intervening with these illnesses acknowledge the important role of caregivers. Clinical guidelines published by the National Institute for Health and Care Excellence (NICE): "Chronic heart failure in adults: management" (NG106) and, "Chronic obstructive pulmonary disease in over 16s: diagnosis and management" (NG115), emphasise the inclusion of family members or caregivers in discussions about self-management of these illnesses (120, 133). However, discussion regarding caregiver inclusion in the intervention delivery is prominently discussed in HF guidelines, whilst the COPD guidelines make a minimal reference to the caregiver or family member. Additionally, there exists no clear processes on how caregivers should be included or pragmatically what constitutes caregiver inclusion in self-management interventions in HF or COPD. Another rationale for the selection of HF and COPD as the conditions of interest for this PhD research is with regards to the evolution of rehabilitation programmes for both of these conditions. Rehabilitation is an all-encompassing concept for the strategies utilised to overcome or return to optimum function following an illness or injury (153). There is burgeoning research with regard to considering the potential benefits of including both HF and COPD patients in rehabilitation programmes due to the prevalence and co-occurrence of these conditions (154, 155).The design and delivery of rehabilitation is dependent upon, the setting, the illness, as well as the design and delivery of the service (153). Developing skills in self-management, maintenance and monitoring can be considered as components of rehabilitation.

Patient and caregiver interdependences have been identified in the broader caregiver literature, in relation to health and QoL (156). This interdependency has similarly been identified in caregiving for patients with HF or COPD (25, 157). Quality of life (QoL) is a dynamic multidimensional concept, incorporating personal, social and emotional influences on a person’s satisfaction and lifestyle (158, 159). Due to its subjective and dynamic nature, there is no singular definition of quality of life.

Broadly speaking it encompasses the ability to engage in a meaningful way, and derive satisfaction from the roles and routines which are important to the individual (159, 160). Health-related quality of life (HRQoL) is concerned with the influence of an individual’s health status on their ability to participate and derive satisfaction from their life roles (161). Individuals with long-term illness do report diminished QoL due to limitations in accessing social and environmental opportunities (162). For the purposes of this PhD research, QoL encompasses patient and caregiver’s personal (physical and psychological) and environmental (physical, financial, social and cultural) factors which can facilitate or inhibit their lifestyle and participation in activities which are satisfying and meaningful (158).

Research into caregiving for patients living with HF or COPD indicates that patient and caregiver characteristics have been associated with an impact on patient-caregiver dyads quality of life (163, 164). Patient illness severity was associated with caregiver strain for caregivers of patients’ living with HF. (163). A strength of this research was the mixed methods approach utilised to capture a comprehensive understanding of caregiver characteristics (163). However, the outcome measures completed in this research were not aligned with caregiver outcomes, a geriatric questionnaire was used to gather data on caregiver depression, however 30% of caregivers were under the age of 60 (163). Furthermore, the quantitative data presented in this review was baseline data only limiting the applicability of determining whether caregiver or patient characteristics change over time with regard to their association with caregiver strain or QoL. A cross-sectional study of caregivers of patients living with COPD reported burden was influenced by the relationship with the patient, the majority of patients in this sample were classified as experiencing severe COPD (FEV1 30-49% predicted, forced air expired in 1 second) (164). The concept of burden relates to the strain experienced by caregivers as a result of their role, this can include patient or caregiver factors such as the mental, physical, social or financial impact of providing care (165, 166). The systematic review in chapter 3 presents a synthesis of the mental health implications of burden experienced by caregivers. Interestingly, patients living with COPD had more positive perceptions of the patient-caregiver relationship than caregivers (164). Although this was a cross sectional study with a small sample of caregivers (n = 42) (164), it demonstrates the importance of considering caregiver needs and the influence of the patient-caregiver relationship in long-term illness, particularly as the illness progresses.

Strachan et al. (167) conducted a meta-synthesis of 45 qualitative studies which examined the processes and context of HF caregiving. This review established that caregiver presence was consistent in positively influencing patient self-care (167). HF self-care was defined in this meta-synthesis as the decisions and behavioural tasks engaged in by patients maintain QoL (167). The health status of patients and the duration of living with HF was unclear from this review, which has implications with regard to the intensity of caregiving provided and how this influences patient self-care. Patient self-care was also influenced by financial status, availability of external supports, geographic location and vocational status (167). Thus demonstrating that understanding the context in which HF self-care takes place is imperative in comprehending how patients and caregivers manage the illness. A small-scale focus group study conducted in Canada of patients living with COPD identified similarities with regard to the influence of patients' current context on whether they engaged in self-care activities (168). The patients in this study reported the need to adjust emotionally with support prior to being able to adjust physically to living with COPD, they needed to find purpose and meaning to life before being able to implement self-care strategies (168). The authors of this study conclude that family members have an important role in self-care (168), however there is little commentary with regard to caregivers or family in the findings of the study that indicates this assertion. Additionally, due to the lack of inclusion of a topic guide for the focus groups it is unclear whether specific family or caregiver questions were asked. However, it is interesting to note that 75% of the participants were living with family (168). Therefore, exploration of the role of family in self-care would have been pertinent. Research examining caregiver involvement for patients' living with COPD has not significantly progressed since Cicutto et al.'s research conducted in 2004 (168). A review of intervention research in COPD identified significant gaps in the evidence base, acknowledging a distinct lack of research targeted towards caregiver outcomes (169). This is important to note considering the identification of significant needs to carers of patients with COPD (27).

A systematic review conducted in 2015 by Buck et al. identified that the evidence base examining the contributions of caregivers in heart failure self-care requires further exploration (12). In particular understanding the longitudinal impact of caregiver involvement in heart failure self-care. This was one of the first comprehensive systematic reviews examining caregivers in this context, the review included qualitative and quantitative research and examined a depth of literature from 1948 to 2012 (12). More recently, a meta-ethnography published in 2020 examining the past 10 years of caregiver literature in HF self-care identified that caregivers experience burden, are required to re-frame their lifestyle and face a challenge in juggling caregiving with other demands (170). Kim et al. (170) introduce their review by discussing the difference between HFrEF and HFpEF, however having identified the different presentations and implications of these conditions the findings of this synthesis do not reflect these differences and both are classified under the HF umbrella. This may have been an opportunity to present a comprehensive synthesis of caregiver experiences of living with these HF sub-types. Although, it could be considered that discussions in the HF literature are not stratified by HF type and thus the authors would have been unable to present a synthesis of caregiver experiences of living with HFpEF or HFrEF. This synthesis of the literature emphasises the need to establish a family approach to intervention, additionally, they place an emphasis on supporting caregivers to identify their own physical and psychological needs (170). One suggestion to support healthcare professionals in facilitating caregivers to identify their needs is through the use of comprehensive assessment with validated outcome measures (171). Additionally, completing a carer's needs assessment is another comprehensive method of capturing and identifying support mechanisms for caregivers (55).

2.8 Dyadic interventions in HF and COPD caregiving

Research examining dyadic self-care in HF has suggested there are four typologies in HF self-care, this is an indicator of the complexities of dyadic research (172). These typologies encompass patient-caregiver dyads that are patient-led, or caregiver-led, collaborative, complementary or incongruent (172). Incongruence refers to the presence, or lack of agreement, harmony and compatibility in the patient-caregiver dyad (173). Incongruent patient-caregiver dyads may limit the caregiver from stepping in to take charge when required or necessary, thus potentially putting patient care and health at risk (173). Patient reactions to their diagnosis of HF can inform the extent of how much caregivers become involved in

HF self-care and how patient-caregiver dyads are formulated (174). A qualitative synthesis of patients' beliefs and responses to a diagnosis of HF was completed by Wingham et al., (174) four categories of patient reactions to their HF diagnosis were constructed The robust approach to this systematic review was enhanced by the inclusion of a patient and public advisory group as well as members of the REACH-HF expert group to comment on the concepts identified from the synthesis. Patient responses include the "strategic avoider", they are unable to cope with the implications and consequences of such a diagnosis. Thus control and management of HF self-care is in the hands of a caregiver. The "selective denier", patients recognise the implications of HF. However, they do not personalise it, and because their HF is managed, they perceive it as a temporary condition. Thus caregivers may have to be pro-active in monitoring for any changes in HF and advocate engagement in HF self-care. The "well-intentioned manager", HF self-care is actively managed by the patient, but knowledge and understanding are incomplete. Thus differences in opinion of how to manage HF may exist between patients and caregivers (174).

As with HF self-care, patients living with COPD face similar challenges with regard to the complex regimes required in order to manage the condition. Russell et al. (175) synthesised the knowledge base of patient barriers and facilitators to engaging in self-management of their COPD. The parameters of this review were not clearly stated, for example inclusion and exclusion criteria, objectives of the review and the approach to the synthesis of findings. Nevertheless, important insights to living with COPD were outlined. Patients' beliefs and knowledge about the condition informed their response, for example, if patients were smokers and could rationalise their behaviour they continued to engage in this occupation (175). This aligns with the construct of the "selective denier" identified by Wingham et al. (174). Russell et al. (175) identified that family members took on the role of clarifying information and implementation of self-management strategies, similar to the "well-intentioned manager" as identified by Wingham et al. (174).

An important outcome from the study conducted by Russell et al. was the recognition that for those living with COPD, self-management skills develop over time (175). This suggests responses to a diagnosis such as HF or COPD require a period of adjustment, this may need to come before patients' can consider engagement in self-management and subsequently become efficacious in their self-care. Reliance on caregivers during this period of adjustment and thereafter can lead to disagreement about self-management approaches and a lack of understanding and knowledge from the patient about the management of the condition, leading to frustration and ambivalence in the patient-caregiver dyad (175). Patients who engaged in effective self-management post-diagnosis were those adults who were able to understand the implications of HF and apply this new knowledge to adapt their lifestyles (174). This group were classified as "advanced managers", they realised how their decisions impacted on caregivers and had little reliance on them except for in times of crises (174). Therefore, it can be suggested that these patient-caregiver dyads experienced congruence in their management of HF. The reactions to their diagnosis and self-management approach by patients consequently impacted the role required of caregivers. This may lead to incongruence in patient-caregiver dyads. Patient-caregiver dyads living with COPD were more likely to experience congruence following the passage of time as patients became more adept at managing their COPD (175). Additionally, those patients who addressed their mental health needs with the same emphasis as their physical health were more effective in managing their COPD (175). Thus the patient-caregiver dyad may develop congruency as a result. It is important to note that much of the literature regarding self-management in long-term conditions uses the phrase interchangeably with self-care (176). However, conceptually, these are distinct terms. Self-management, in addition to monitoring and maintenance is a component of self-care (94).

Further dyadic research is required to understand and mediate the impacts and effects of distress and psychosocial issues on the patient and caregiver (105). Interventions for patients and caregivers require the promotion of concordance between the patient-caregiver dyad (177). Incongruence within dyads results in more stress, distress and tension for both the patient and caregiver, thus impacting on the relationship between the patient and caregiver (178). Incongruence leads to differing views in the management of illness, the timing of accessing healthcare services, and communication (178). Self-management interventions may require a change of behaviour by both members of the dyad. This behaviour change may seem impossible for some dyads; therefore, they may be unsuccessful in self-management (151). Understanding whether incongruence exists and its influence on the management of cardiorespiratory illnesses can inform the development of evidence-based self-management interventions.

High priority demands perceived by caregivers as impacting on their quality of life include: performing multifaceted activities that revolve around HF, their ability to adapt to, and understand the emotional changes in the patient, negotiating engagement in treatment plans, patients not disclosing their true feelings and caregivers not being consulted by health professionals about HF issues (179). The concerns identified by caregivers of patients with COPD include the constant fear of breathlessness or an acute exacerbation of the condition (180). The ever-changing nature of COPD or HF coupled with the responsibility of managing exacerbations, rehospitalisation and promoting self-care engagement, results in caregivers continually adapting to meet the current needs of patients (116, 156). Greater awareness of caregivers' lived experience of being part of the dyad, as well as a formal systematic assessment of their needs is required to appropriately design and deliver optimal interventions to enhance self-care (27, 181). Overall, the context of caregiving is an essential factor to understand when exploring the dynamics of the patient-caregiver dyadic relationship (116). The next section outlines a literature review focused on patients and caregivers HF and COPD. This was conducted to determine firstly, whether caregivers have an impact on outcomes of patients in healthcare delivery and secondly, to identify and describe what the outcomes caregivers experienced when they are involved in healthcare delivery.

2.8.1 Outcomes for HF or COPD patients with caregiver involvement in healthcare delivery

A synthesis of RCT’s which were targeted at patient and caregivers living with HF or caregivers of HF patients only, concluded that that HF knowledge improved as a result of caregiver inclusion (182). However for patients, knowledge was only reported in one study, thus significantly limiting the conclusions of the authors. Improvements in secondary outcomes were not sustained, these included, patient self-care behaviour, quality of life for patients and caregivers, perceived control, re-hospitalisation and caregiver depression, anxiety and burden (182). Only 6 studies met the inclusion criteria for this review demonstrating the lack of RCTs explicitly examining family involvement in HF self-management interventions (182). Methodological weaknesses of the included studies were a lack of reporting on intervention effect sizes, missing outcome data, unclear risk of bias concerning blinding of participants and personnel delivering the intervention, and limited collection of caregiver outcome measures (182). The components of the interventions included education delivery through multiple sources, for example education booklets, CDs, DVDs and PowerPoint presentations (182). This review may have been limited due to their focus on education. Considering the complexity of HF self-care, a more comprehensive review of the literature may have been to synthesise research that has included caregivers in intervention delivery addressing multiple components such as skill building, education, exercise engagement and caregiver self-care. Furthermore, this synthesis did not consider the potential negative impacts caregivers could have on patients. Each of these elements of intervention delivery was considered by Buck et al. in a realist synthesis of self-care dyadic interventions in HF (90). In contrast to the review by Srisuk et al. (182), this realist review only included dyadic interventions.

In accordance with the process for realist reviews studies included trials that were completed and trials that were in progress (i.e. protocols with assumptions about outcomes were included for analysis) (90). This broad scope of inclusion, which was a strength of this review due to the limited research conducted in dyadic HF self-care enabled a robust discussion with regard to the components context of intervention delivery in HF self-care. Included interventions were delivered at home or in hospital and were categorised as education, support and guidance, as noted in the wider caregiver literature, duration, dose and intensity of intervention delivery varied widely (90). Findings were mixed with regard to patient outcomes, positive outcomes were identified with regard to condition, behaviour, affect and a reduction in use of healthcare service, however none of these outcomes were sustained (90). Due to the variability of the included studies, comprehensive conclusions could not be made with regard to the impact of dyadic interventions (90).

Whilst the context in terms of whether interventions were delivered by telephone or face to face was noted in the review by Buck et al. (90), nuanced elements of intervention delivery was not noted, for example who was present (dyad together or individuals separately). Information such as this can provide insights into the quality and dynamics of the relationship within the dyad which may be important aspects of dyadic intervention. Another element not considered in the synthesis of these studies was whether dyads were included in the design of these interventions. Given that this study was conducted in 2016, the current procedures of patient and public involvement in intervention development may not have been as rigorous or robust. Involving dyads in intervention design may be a key to unlocking what they identify their needs as, thus informing intervention design and delivery to influence sustained health behaviour changes. A 12-week RCT of HF self-management targeted 155 patient-caregiver dyads with the purpose of improving their perceived control over HF management (63). Intervention delivery took place over three sessions and were either in the home or in a clinic (183). In addition to education, relational aspects were addressed, such as, caregivers' being overprotective and how this may impact on patients' self-management, this was a strength of this research (183). Follow up of the intervention occurred at 3 and 12 months to evaluate the long-term effects on both patients and caregivers (63). This duration of follow up was a strength of this research, as longitudinal trials and repeated measures are limited in the caregiver literature. There was an initial improvement in managing HF and perceived control amongst patients, however physical and mental health effects were limited and similar to what has been identified in the previously mentioned systematic reviews, results were not sustained (63). The HF status of patients included in this trial was primarily categorised as NYHA III, which indicates marked limitation of physical activity, there is potential that over time that these dyads established a comfort and confidence in their routine, thus perceived control stabilised. Following the three intervention sessions there was no intervention follow-up with patients or caregivers. This suggests a possible need for follow-up intervention with dyads in order to re-assess their knowledge, functioning and coping strategies.

A theoretically informed qualitative study which examined caregiver impact on patient outcomes conducted in India identified that patients who engaged in self-management reported better support from children, grandchildren and neighbours in prompting them to participate in self-care (184). Interviews were conducted with patients and caregivers separately to determine their understanding of what supported patients to maintain adherence to complex medication regimes (184). The sample in this study was small and specific to India. However, this study does provide insight into the importance of caregivers in regions, such as India, where there is little HF research but a high prevalence of HF (184). Whilst specific to India, qualitative research such as this is important in capturing patients and caregiver perceptions of the perceived influence of including caregivers in HF self-care. A review of medication adherence which included caregivers of HF patients established that patients demonstrated greater adherence to medication management which was sustained at 3 month follow-up with caregiver support (185). A strength of this intervention was the development of the intervention, which was theoretically informed, however, there was a lack of discussion about the engagement of patients and the public in the intervention design. Additionally, researchers completed a mixed methods approach thus ensuring a robust method of data collection and analysis. Although, this study did demonstrate a larger effect and positive outcomes from dyads, in comparison to other adherence studies, it was a single centre trial and had limited description of how caregivers were involved (185). This study is unique as it demonstrates that caregivers do have positive impacts on specific patient outcomes, for example in this example, medication adherence. There was also an emphasis in this study on literacy of the patient and caregiver, it could be suggested by ensuring resources were robust in terms of their language accessibility dyads understood and retained the information and were subsequently able to implement sustained change. Larger multi-centre RCTs are required to ensure this efficacy is sustainable and generalisable to a broader population of HF caregivers (185).

Bryant et al. (169) conducted a systematic review of the literature regarding COPD intervention studies which included caregivers. They examined whether caregivers were included in intervention delivery and the effectiveness of this caregiver inclusion (169). The inclusion criteria for caregiver involvement in COPD interventions was vague and the authors included any research which made reference to caregivers in COPD interventions. This has implications in terms of understanding the role of the caregiver in these trials, additionally it lacks clarity as to whether interventions were designed specifically to include caregivers or whether this was an accepted variation in the trial. Nine studies were included for narrative synthesis, intervention delivery was either at home or in a clinic setting and interventions were targeted at both patients and caregivers together (169). The methods reported for including caregivers consist of inviting caregivers’ to attend education sessions or providing reassurance to caregivers about COPD (169). This indicates the lack of clarity regarding the inclusion of caregivers in these trials is lacking and is a limitation of this synthesis. Similar to HF research, inclusion of caregivers resulted in mixed outcomes, trials reported that caregiver involvement reduced rehospitalisation, treatment adherence and quality of life. However, due to the poor recording of caregiver inclusion and the lack of parameters on what constituted caregiver inclusion as well as the poor methodological quality of included studies interpretation of results with caution is warranted. Interventions were predominantly target at patients' who were admitted to hospital for an acute exacerbation (169), hence going through an acute phase of illness may indicate a greater likelihood of observing change in parameters such as treatment adherences and QoL. This review did highlight the lack of research which involves caregivers in interventions for patients living with COPD.

A systematic review of research output in COPD was conducted to determine the impact of interventions and the inclusion of caregivers for patients with COPD (149). This review highlighted a lack of robust research of caregiver included studies in COPD. This review included 27 studies examining caregiving and burden in COPD, 14 of these studies were descriptive, one was a feasibility study which reported on an intervention to alleviate the burden for patients with COPD and their caregiver, and 25 of the included studies were cross-sectional (149). Furthermore, there was a limited examination of patient and caregiver factors which may influence caregiver burden (149). This emphasises the need for more rigorous research with regard to caregiving and COPD. The impact of involving caregivers in the delivery of self-management interventions on patient outcomes in cardiorespiratory illnesses such as HF or COPD is not well understood. The research conducted thus far lacks clarity and methodological rigour, and findings are inconsistent with regards to how caregivers are included (90, 169, 186). Researchers are encouraged to examine patients and caregivers using a mixed-methods approach to understand how patient and caregiver health-related quality of life are influenced by caregiver or family member involvement in self-management interventions (102). Additionally, longitudinal studies are required to determine predictors of caregiver contributions and whether they influence patient outcomes (187).

2.8.2 Outcomes of caregivers of patient's with HF or COPD when involved in formal healthcare delivery

Evaluating caregiver outcomes when included in the delivery of self-management interventions for patients living with HF or COPD is limited. There is more reporting of patient outcomes with little attention to caregiver outcomes (64, 169, 188, 189). The RCT completed by Ågren et al. (63)discussed earlier in this chapter is unique as it presents an intervention which is targeted at the patient-caregiver dyad and evaluates caregiver outcomes. Interestingly, this trial did not demonstrate any improvement in caregiver outcomes (63). A later intervention study of post-operative HF patients and their caregivers completed by Ågren and colleagues (190) indicated an improvement in the emotional and mental health of caregivers. However, these outcomes were not sustained in the long-term. This trial consisted of an interdisciplinary psychoeducational support and education intervention. Intervention sessions focused on discussions and there was no reference to the provision of written materials for patients and caregivers (190). These outcomes indicate the potential for ongoing, long-term healthcare input for caregivers and an examination of larger sample sizes (63, 190).

A review of interventions delivered to caregivers only of HF patients' synthesised eight studies (186), of these four demonstrated improved caregiver outcomes for burden, depression, confidence, preparedness and mastery in the caregiving role (186). Due to lack of consistency and clarity in the description of intervention design, components of intervention delivery and lack of methodological rigour, a robust analysis of the impact of the interventions targeted at caregivers was difficult, this limits the quality of these findings. Therefore, these outcomes need to be interpreted with caution. The authors of this review emphasise the need for further rigorous testing of interventions, which include caregivers, to contribute to the caregiver evidence base (186). This point was reiterated in 2017 and 2020 in a review of the scientific evidence base of caregiving in HF (25, 64). Exploration of caregivers' needs in palliative care interventions in HF, demonstrated that patients and caregivers identified needs of caregivers as similar to those in the broader caregiver literature. They require more support, ongoing education about the illness, and understanding of symptom relief; there was also an emphasis on the need for greater inclusion in the intervention process (12, 151).

A qualitative study of caregivers in Italy identified that caregivers learned from their lived experiences of caregiving and by talking to family and friends (191). They passed their knowledge onto the patient and empowered the patient to engage in self-management and self-maintenance strategies (191). This study identified that the caregiving role requires communication skills, specifically, negotiation tactics on behalf of the caregiver to enhance the patient's skills in self-care (191). These communication skills dictate the level of caregiving required, for example, whether the caregiver needs to be active (dictate self-care strategies required) or passive (observe patients self-care engagement) in supporting self-care tasks (191). A risk of this caregiving approach is that caregivers may be providing incorrect guidance due to their knowledge being incomplete or inaccurate (191). If caregivers are unsure or uncertain, this may impact their confidence which may limit how they contribute to patient self-care. Convenience sampling and limiting this study to exploration of the Italian population hinder the applicability of this research. Caregiving in the Italian context is viewed as central occupation in the family, caregiving is an expected family duty, this has been recognised and written about in the context of caregivers of patients with Alzheimer's disease but the same could be suggested for Italian caregivers of patients with HF (192). The value of this study was the use of a theoretical framework to inform the research, the situation-specific theory of HF self-care (191). This theoretical framework is discussed in greater detail in section 2.10 of this chapter. This study does provide insight into the need to understand how caregivers obtain knowledge, the accuracy of this knowledge and in turn how this impacts patients' self-care in HF (193).

Exploration into the caregiving role in HF has indicated that caregivers feel hindered in their activities of daily living as a result of providing care (189). This mixed-methods study identified that over half of the caregivers were identified as being distressed, which they linked to caregiver depression (189). The authors reported this was an indicator of caregiver burden (189). This study was concerned with HF patients who were at the end of life. Therefore patients who were classified as NYHA I and II severity were excluded (189). This exclusion of patients with NYHA severity I and II is relevant to note as the caregivers in this study were preparing for the end of life of their loved one, which may have had an impact on their mental health. The experience of caregivers of patients with NYHA III and IV may be very different from what a caregiver of a patient who is living with NYHA I and II might experience.

The extent of caregiver burden is suggested to be linked with the amount of symptomatic behaviour of the patient (194). There is a higher likelihood that interventions targeted at caregivers may not be effective due to their limited ability to engage in the intervention or retain the content of intervention sessions if they are feeling burdened or depressed (189). Thus, caregivers' underlying mental health needs need to be addressed (189). Bryant et al. (169) conducted a systematic review which identified a small sample of studies (n = 9), where caregivers of COPD patients were included in interventions. The variability with regard to the inclusion of caregivers demonstrated that caregiver involvement was not robust. This is perhaps reflected in the lack of caregiver outcomes identified. The core component of the intervention was the education of caregivers, particularly regarding COPD signs, symptoms and progression (169). The three studies which targeted patient-caregiver dyads to address the needs of the dyad provided minimal description of how they achieved this (169). Involving caregivers in self-management interventions, such as pulmonary rehabilitation programmes, is a recommended first step to identifying caregiver needs and the impact of this on caregiver specific outcome measures, which can assist in the design of interventions to address the needs of caregivers (157).

A review of family counselling interventions targeted at caregivers of patients living with COPD identified that caregiver experiences with self-management interventions were not well received (195). Caregivers highlighted a lack of support or acknowledgement from healthcare professionals, identified their needs were not addressed in intervention sessions, they had a lack of information about COPD and they perceived they were provided with limited information about coping skills (195). What constitutes family counselling was poorly recorded and lacked clarity in the inclusion criteria for this review. Nonetheless, this review demonstrates the challenges faced by caregivers of patients living with COPD, even when it is perceived that they are included as part of intervention sessions. This indicates the importance of ensuring caregiver inclusion is meaningful and not a token acknowledgement of their presence. Caregiver outcomes are influenced by a multitude of factors, as demonstrated earlier in this chapter. However, these factors do not present consistently across HF or COPD literature. Therefore, this indicates the complexity faced by researchers when designing interventions to address patient and caregiver needs, and for healthcare professionals when trying to engage patients and caregivers in a clinically meaningful manner.

2.9 Methodological issues in past caregiver literature

The focus of caregiver literature is predominantly on long-term illnesses, such as dementia and cancer (104, 186, 196). While the evidence base for HF and COPD is growing, there are some methodological limitations which are prevalent in the literature regarding the experience of caregivers of patients with HF or COPD and caregivers' inclusion in intervention delivery for patients with HF or COPD (39, 64, 98, 169). These limitations include a lack of longitudinal research, limited reporting on caregiver outcomes, small sample sizes and participants who are homogenous (72, 149, 151, 182, 197). Much of the caregiver literature over the past 20 years in either HF or COPD has focused predominantly on spousal or adult child caregiver and provides insight from the perspective of Western cultures. There is less written and examined regarding the familial or cultural aspects of caregiving. Thus, further understanding of the role caregivers' in HF self-care, as well as the context in which this is occurring, the implications of this on caregivers' QoL and patient HRQoL is imperative. The literature reviews presented earlier in this chapter demonstrate there is inconsistent evidence as to whether involving caregivers in the intervention process has positive outcomes either on patient or caregiver health-related quality of life. The unique contribution to knowledge of this PhD research is:

- It provides an understanding of the impact of caregiver contributions on patient self-management in HF.
- It portrays the nature of caregiver contributions in HF self-management.
- It presents caregiver outcomes following participation in HF self-management interventions.

While the unique methodological contribution is that this research examines data collected over several time points, with access to both quantitative and qualitative data, this thesis utilised a multi-methods approach, analysing both qualitative and quantitative data rigorously, in a sequential manner. An initial reading of the qualitative data informed the quantitative analysis completed. Subsequent qualitative analysis expanded upon the findings from the quantitative study (198). This research has enabled this researcher to make a substantive contribution to understanding the needs of caregivers and the impact of involving caregivers in HF self-management interventions on both patient and caregiver health outcomes.

2.10 The situation-specific theory of caregiver contributions to HF self-care

Due to the methodological limitations of the identified research and inconsistent caregiver influences and outcomes, conceptual underpinnings of intervention development must be at the forefront of caregiver research in HF and COPD. Conceptual underpinnings have recently been addressed in a systematic review of family-focused interventions for patients with HF (199). This systematic review concluded that conceptual and theoretical foundations are not explicit in HF and caregiver intervention development (199). Similar has been concluded about COPD caregivers and their inclusion in intervention design and delivery (188). A greater understanding of the theoretical foundations of the implications of caregiving is required (90, 102). In addition to the theoretical models discussed earlier in this chapter: The stress process model (80-82), Bandura’s theory of self-efficacy (86) and the middle range theory of self-care of chronic illness (94). The situation specific theory of caregiver contributions to HF self-care (200) contributed to the formulation of the empirical research in chapters 5 and 6 which was focused specifically on HF (Figure 2.2).

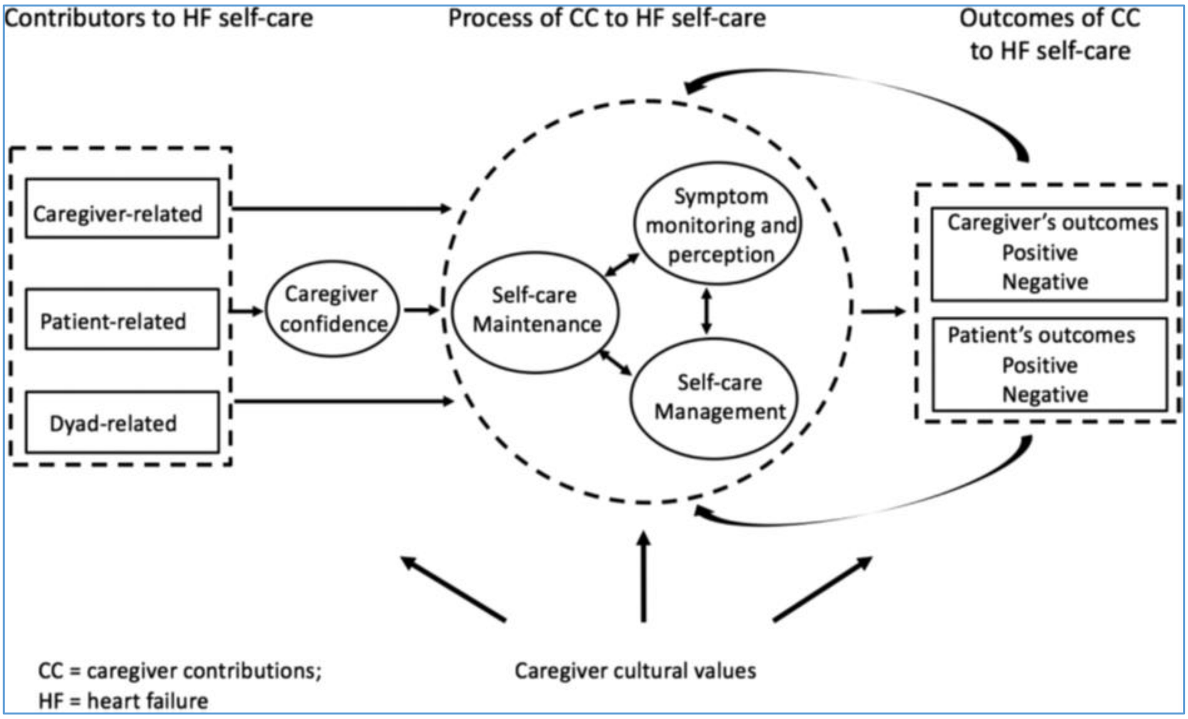
The aim of this theory is to support healthcare professionals to understand the phenomenon of lay caregiving in heart failure (200). This theory was formally introduced in 2019 and presents an overview to the process of how caregivers contribute to HF self-care, the factors that influence their contributions and the outcomes of these contributions (200). Caregiver, patient and dyad related factors are all identified as having a key influence on HF self-care, these factors are all underpinned by the cultural context in which HF self-care is taking place (200). This theory evolved from the middle range theory of self-care of chronic illness and the situation specific theory of HF self-care (200). The situation specific theory of caregiver contributions to HF self-care is underpinned by some key assumptions (200).

(1) Caregivers love their patients with HF and they want the best for them
(2) Patients with HF want to receive care from their caregivers
(3) The quality of the relationship between the patient and their caregiver influences the willingness of the caregiver to contribute to the patient’s care
(4) The type of relationship between the patient and caregiver (spouse, child, or friend) influences the willingness of the caregiver to contribute to the patient’s care and the willingness of the patient to accept care
(5) Patients with HF and their caregivers influence each other (200).

The situation-specific theory of caregiver contributions to HF self-care indicates that caregivers are enhancing patients' self-care behaviours by encouraging self-care maintenance, including, reminders to weigh, dietary prompts and supporting engagement in exercise (201) and participating in self-care management, for example, symptom monitoring and symptom perception. Caregiver confidence is a key element of these contributions (201). Caregiver and patient outcomes will further influence how the processes of caregiver's contributions occur (201). Each of these elements is underpinned by the caregiver's cultural perspective, values and beliefs, encompassing the social, cultural, political and financial context (201). It is worth considering whether concept of culture should be considered from a dyadic perspective of cultural values rather than caregiver cultural values. This theory suggests the quality of the relationship is a key component in understanding caregiver contributions to HF self-care, therefore considering dyadic cultural values is important. For example, if an adult-child is the caregiver for their parent, if they have differing belief systems with regard to norms, value, feelings and beliefs this could impede the caregiver contributions. However, if the dyad shares cultural values may enhance the caregiving process and outcomes. The contributors to HF self-care are the patient, caregiver or dyadic factors that influence directly or indirectly the processes by which caregivers contribute, these are mediated by caregiver confidence (200). This theory posits that maintenance begins the process, then monitoring, perception and management follow, outcomes in HF self-care experience by patients or caregivers either positive or negative feedback into the processes of HF self-care to inform ongoing HF self-care (200).

Caregivers' contributions to self-care requires more research to clarify further the processes occurring and the influencers of caregiver contributions of HF self-care (201). Additionally, more research is needed regarding the impact of caregivers on patient and caregiver outcomes in HF self-management (201). Literature examining caregiver contributions has identified that the relationship between the patient and caregiver and caregiver confidence are vital elements in caregiver contributions to HF self-care (201). Chen et al. (202) report caregiver confidence is mediated by knowledge, perceived control and support. However, the HF literature is not clear on how this process occurs. There is some research identifying that the mutuality of the relationship (i.e. the positive interactions) between patient and caregiver is indicative of caregiver contributions, as well as the patient's abilities dictating how much caregivers can contribute to patient self-care (90, 187, 203).

Figure 2.1 A situation-specific theory of caregiver contributions to HF self-care (Reprinted from Vellone et al., 2019, p. 168).



According to the literature caregiver contextual factors and characteristics influence their ability to engage in HF self-care (187), this includes anxiety, confidence, support from others, knowledge, skills and perception of control (201). Vellone et al. examined the role of social support in self-care interventions (187). They found that all self-care indices tended to increase with social support. Instrumental and emotional support were independently associated with higher levels of self-care confidence, and emotional support was associated with higher self-care management scores (187). Assistance with self-care was positively associated with maintenance of health behaviours, while those with low perceived instrumental support increased in self-care confidence over time (187). Thus social support is another element which should be assessed when examining patient-caregiver dyads in HF. Congruent patient-caregiver dyads are working towards a shared goal with the same underpinning beliefs and values of how to achieve this; thus it is posited that these dyads will be more confident and efficient in self-care behaviours (151, 201).

Prior research conducted by Vellone et al. (204) examining caregiver contributions to HF self-care demonstrated that caregiver involvement in self-care maintenance was a factor in reducing patient mortality. However, caregiver contributions to self-care management demonstrated an opposite effect (204). This may be as a result of poor patient health and the need for increased caregiver involvement in management activities when patients are unable to complete these tasks themselves. One of the caregiver factors which may influence caregiver contributions to HF self-care is caregiver preparedness. Caregiver preparedness is the readiness of caregivers to take care of the physical and emotional needs of the patient (205). This trial was a secondary analysis of a multi-centre RCT and only included patients with NYHA status II – IV (205). Validated caregiver specific outcome measures were used in this study which is a strength of the analysis. A limitation of this research was the cross sectional nature of the study and the characteristic differences between caregivers (n = 323) who were included in this analysis compared to those who were excluded from analysis, excluded caregivers were older and primarily female (205). Caregivers were mainly female, spousal or adult-child caregivers who were unemployed, had a high school education and were providing care for more than 9 hours per day (205). Higher perceived caregiver preparedness was associated with higher caregiver confidence scores, as well as self-care maintenance and self-care management scores (205).. This aligns with the concepts in the situation specific theory of caregiver contributions to heart failure self-care theoretical framework. As this is a new theoretical model in the field of HF and caregiver research more research is required to determine the accuracy of the assumptions of the model.

2.11 Conclusions

Given the life changing implications of a HF or a COPD diagnosis, this PhD research is specifically examining caregiving in relation to HF and COPD. The trajectory of these illnesses such as, increased mortality and re-hospitalisations, the significant impact on functioning and the long-term reliance on a family member or friend to provide care suggests it is imperative to understand the impact on both caregivers and patients when caregivers are involved in HF or COPD self-care. Individuals living with long-term illness evaluate their quality of life in relation to their current life situation and re-evaluate to adapt to illness or the ageing process, this indicates there may be difficulty in measuring and identifying post intervention quality of life changes (159, 206). This may suggest why there are inconsistencies in HF research concerning patient-caregiver interdependencies in relation to quality of life, in particular with regards to caregiver outcomes (25).

Caregivers experience an impact on their physical and mental health when they engage in a caregiving role. The experience of caregiving is diverse, and the contributions of caregivers to patient outcomes are complex (72, 207). The research into caregiving for patients with HF or COPD is developing. The context within which caregiving is taking place requires greater understanding to identify how to design and deliver appropriate interventions for patients with HF or COPD and their caregivers. National and international policies do recognise the value of supporting caregivers and their importance in contributing to patient care. However, what is identified in policy is often not reported in caregiver experience, particularly regarding the caregivers needs assessment. This demonstrates a gap between best practice recommendations and implementation.

It appears uncertain as to whether caregiving contributes sustained benefits to patient health and whether caregivers can derive benefit from being involved in interventions. Patient and caregiver characteristics influence patient outcomes. However, this appears inconsistent as to what specific factors influence outcomes. Furthermore, reporting on caregiver outcomes is greatly lacking. The interactions between patient and caregivers, as well as the interpersonal relationship, needs to be examined. A longitudinal approach incorporating quantitative and qualitative methods is necessary. Firstly to understand the experience of being a caregiver for patients with cardiorespiratory illnesses. Secondly, to identify the impact of caregivers on patient outcomes and the impact of caregiver inclusion in self-management interventions on caregiver outcomes. Thirdly, to understand, the context within which caregiving is taking place and the contextual factors which influence the patient-caregiver dyad in self-care.

CHAPTER 3. The experiences of caregivers of adults living with heart failure, chronic obstructive pulmonary disease and coronary artery disease: a mixed-methods systematic review

This chapter is an amended version of the full published paper: Noonan MC, Wingham J, Taylor RS. “Who Cares?” The experiences of caregivers of adults living with heart failure, chronic obstructive pulmonary disease and coronary artery disease: a mixed methods systematic review. BMJ open. 2018; 8(7):e020927.

3.1 Introduction

Caregivers are an important resource to patients with cardiorespiratory illnesses. The literature review conducted in chapter 2 demonstrated that caregivers frequently facilitate self-care, either directly or indirectly, that has also been described as visible or invisible caregiving (208). However, little attention has been paid to the experience of caregivers when providing care to patients with cardiorespiratory illnesses. Greater awareness of caregivers’ lived experience is required to inform the design and delivery of self-management interventions for caregivers of patient living with cardiorespiratory conditions (181). In particular knowledge development is needed with regards to the relational, physical, social and emotional factors in which caregiving takes place (10, 181, 186). Finally, caregiver needs should be assessed in a systematic and formalised manner (27). Thus, there is a need to explore the perspective of the lived experience of caregivers.

3.2 Objectives of this study

Using a mixed-methods systematic review methodology, including both qualitative and quantitative literature this study aimed to understand the experiences of adult caregivers when supporting patients with HF, COPD or CAD and in turn to inform future research.

The overarching question asked in this systematic review was:
What are the experiences of informal caregivers on a day to day basis when caring for individuals with HF, COPD or CAD?

3.3 Methods

This systematic review was conducted and written in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (209).

3.3.1 Patient and Public Involvement

These results were presented to patients and caregivers living with HF and a local organisation providing support to caregivers. They provided input to the formulation of the questions for the secondary analysis of the REACH-HF trial (chapter 5 and 6).

3.3.2 Study Design

This study employed a mixed-methods systematic review assessing both qualitative and quantitative studies (210). The rationale for using a mixed-method review approach was multifaceted. Firstly, to gain a qualitative assessment of the type and extent of caregivers experiences. Secondly, to assess the quantitative predictors of caregivers experiences. Thirdly, to develop a holistic perspective of what caregivers experience. Finally, to determine the degree of convergence between qualitative and quantitative experiences.

3.3.3 Search Strategy

The search strategy was designed in conjunction with Information Specialists. The following PECOS informed the search strategy:

- Population – Adult caregivers.
- Environment/Exposure – Caregivers exposed to patients with the following long-term illnesses: HF, COPD, or CAD (inclusive of myocardial infarction, ischaemic heart disease, coronary revascularisation, and atherosclerosis).
- Comparator – Not applicable in this review.
- Outcomes – Caregiver experiences including psychological and physical outcomes reported, occupational engagement and routine.
- Setting – Any setting except residential care.

Search terms included condition-specific terms, i.e. “heart failure”, “COPD” and “coronary artery disease”, caregiver specific, plus experience related terms, “experience”, “quality of life” “activities of daily living”, “occupational engagement”, “time use”, “self-efficacy”, “coping strategies”, “leisure activity”, “information exchange” and “caregiver expectation”. Appendix 1 includes the full list of search terms. A systematic search was conducted of the following databases: Medline Ebsco, PsycInfo, CINAHL Plus with Full Text, Embase, Web of Science, Ethos: The British Library and ProQuest. Grey literature was identified using Global Dissertations and Theses and Applied Sciences Index and hand searches and citation checking of included references. To ensure the contemporary nature of the evidence identified the search time frame was January 1990 to August 2017. The lead researcher (MN) initially screened titles and abstracts. Selection of full papers was performed by two researchers (MN and either JW or RT) and cross-checked with the eligibility criteria.

3.3.4 Study Selection

Studies were included if they addressed ‘caregiver experience’ which was defined as encompassing the daily activities of caregivers and the impact of these activities on their lives. These were English language studies involving unpaid adult caregivers (>18 years), providing care for patients with HF, COPD or CAD living in the community and not living in residential settings with paid care staff. Qualitative, quantitative and grey literature studies were all included in the search strategy. Conference papers were excluded. Outcomes of interest included psychological and physical outcomes reported, occupational engagement and routine. As this researcher sought to inform the practice of the UK and other high-income countries, studies undertaken in low- and middle-income countries were excluded. The definition of “The World Bank Data” http://data.worldbank.org/country (211) was used to inform this. Caregivers of children, systematic reviews, and studies published in a language other than English were excluded.

3.3.5 Data Extraction

Data extracted from retained studies included: study design, sample and recruitment, study description, method, findings, discussion and authors conclusions and limitations. Caregiver quotes were extracted from qualitative studies. For quantitative studies, data extraction also included details of attrition and data analysis.

3.3.6 Study quality assessment

Qualitative studies were appraised utilising the Critical Appraisal (CASP) tool (212). In the absence of an existing quality tool that could be used to appraise quantitative studies addressing the specific question of this study, a quality assessment tool was developed by the research team. This tool was based on what were deemed to be the appropriate core biases:

1. Was the study design longitudinal (score of 1) or cross-sectional (score of 0),
2. How was the sample recruited? Purposive (score of 1) or convenience (score of 0),
3. Was the level of attrition/response rate acceptable? Attrition of 20% or lower or response rate of 80% or above (score of 1) or attrition of more than 20% or response rate less than 80% (score of 0),
4. Was a validated quantitative outcome(s) used? Validated (score of 1), non-validated (score of 0),
5. Were the methods of data analysis appropriate? Multivariate (score of 1) or univariate (score of 0).

Based on their quality assessment, scores were totalled, and studies were ranked: 1 or 2 “low quality”, 3 “medium quality” and 4 or 5 “high quality”. Data extraction and quality appraisal was first conducted by the lead researcher (MN) and checked by one of two experienced researchers (JW or RT).

3.3.7 Data analysis and Synthesis

The methodology of mixed methods data synthesis is an emerging approach, and no single approach has yet been universally accepted (213). In this study a results-based convergent design was chosen (214, 215). This approach requires the transformation of one method into another. Due to the heterogeneity of the quantitative methods, a meta-analysis was not appropriate. Instead, applying a narrative profile formation, quantitative data was converted into qualitative data (216). Extracted data from quantitative and qualitative studies were imported into separate spreadsheets. A meta-ethnographic approach was utilised to synthesise qualitative studies (217). A narrative formation approach (218) was utilised to synthesise the quantitative data into a qualitative data set. The narrative formation approach is a verbal description via the use of profiles of each of the studies (218). The five profiles are modal, average, holistic, comparative and normative (218). Table 3.1 provides an example of this approach. Appendix 2 contains the narrative formation of each quantitative study. This approach of analysis to the quantitative and qualitative studies resulted in two qualitative data sets for synthesis (219). Concepts were identified from these two data sets. A mapping table was completed to provide an audit trail of how overall concepts across all papers were derived (Appendix 3). The initial synthesis was conducted by the lead researcher (MN) and corroborated by two experienced researchers in quantitative (RT) and qualitative (JW) research.

Table 3.1 Narrative Formation (Example: Chung, 2016 (220)).

Profile	Explanation of Profile	Modal narrative extracted from study	Emerging from study	Concept
Modal	This is a narrative description of the group being studied	102 dyads, predominantly spousal caregivers. Group is caregivers of patients with HF. Comparing depressed and non-depressed HF pts. and their caregivers	This study considers whether caregiver experiences are different for caregivers when caring for depressed or non-depressed patients Spouse as a caregiver. Impact of depression on the caregiver.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied	Caregiver Mean age 56.7, 78% female, white (94%). 41% of pts. NYHA III-IV “42% caregivers reported severe burden	Caregiving resulted in burden experienced by caregivers in this study	Mental Health (burden)

		(the Zarit Burden Interview (ZBI)≥17)”[28]		
Comparative	This is a description comparing studies and comparing individuals being studied.	Caregivers who provided care for depressed patients reported higher burden than those caring for non-depressed patients. Caregivers related their burden to social life limitations, poor perceived control, stress of family obligations, and patients’ dependency “Caregivers of patients with depressive symptoms had a higher level of burden (25±13 vs 13.5±12 on the ZBI; p<0.001), spent more time caregiving (37±12 vs 30±11 on the Oberst Caregiving Burden Scale; p = 0.004), and reported worse mental quality of life (46±10 vs 51±10 on the SF-12v2; p	Patient illness severity impacts on caregiver Life changes negatively impacted on caregivers Depressive symptoms of patients are associated with poor outcomes of caregivers Caregiver’s subjective and objective response to the patient’s illness severity	Lifestyle adjustment Mental health

		= 0.026) than those of patients without depressive symptoms.”[28]		
Normative	A comparison of the study individuals with the general population	27% of patients in this study scored 14 or higher on Becks Depression Index (a score of 14 or higher is clinically significant for depression) Family members caring for HF patients with depressive symptoms had significantly higher levels of caregiving burden and worse quality of life compared to those caring for patients without depressive symptoms. “Most difficult task for both sets of caregivers – providing emotional support (M=3.3, SD=1.2)”[28]	Greater impact on caregivers lives when patients were depressed	Mental health Role of caregivers
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Female, white caregivers, experienced greater levels of burden, loss	

			of roles and greater distress when patients were depressed. This could be due to the increased need for practical and emotional support, feeling they need to be constantly present	

3.4 Results

3.4.1 Study Selection

The study selection process is summarised in a PRISMA Flow diagram shown in Figure 3.1. Following the removal of duplicates, the search strategy generated a total of 8,026 title and abstracts. Of these 242 full papers were reviewed, of which 57 papers (54 studies) were included for synthesis. A detailed summary of the included studies is provided in Table 3.2. A comprehensive outline of the study results and concepts generated by each study is included in Appendix 4.

Figure 3.1 PRISMA Flow Diagram

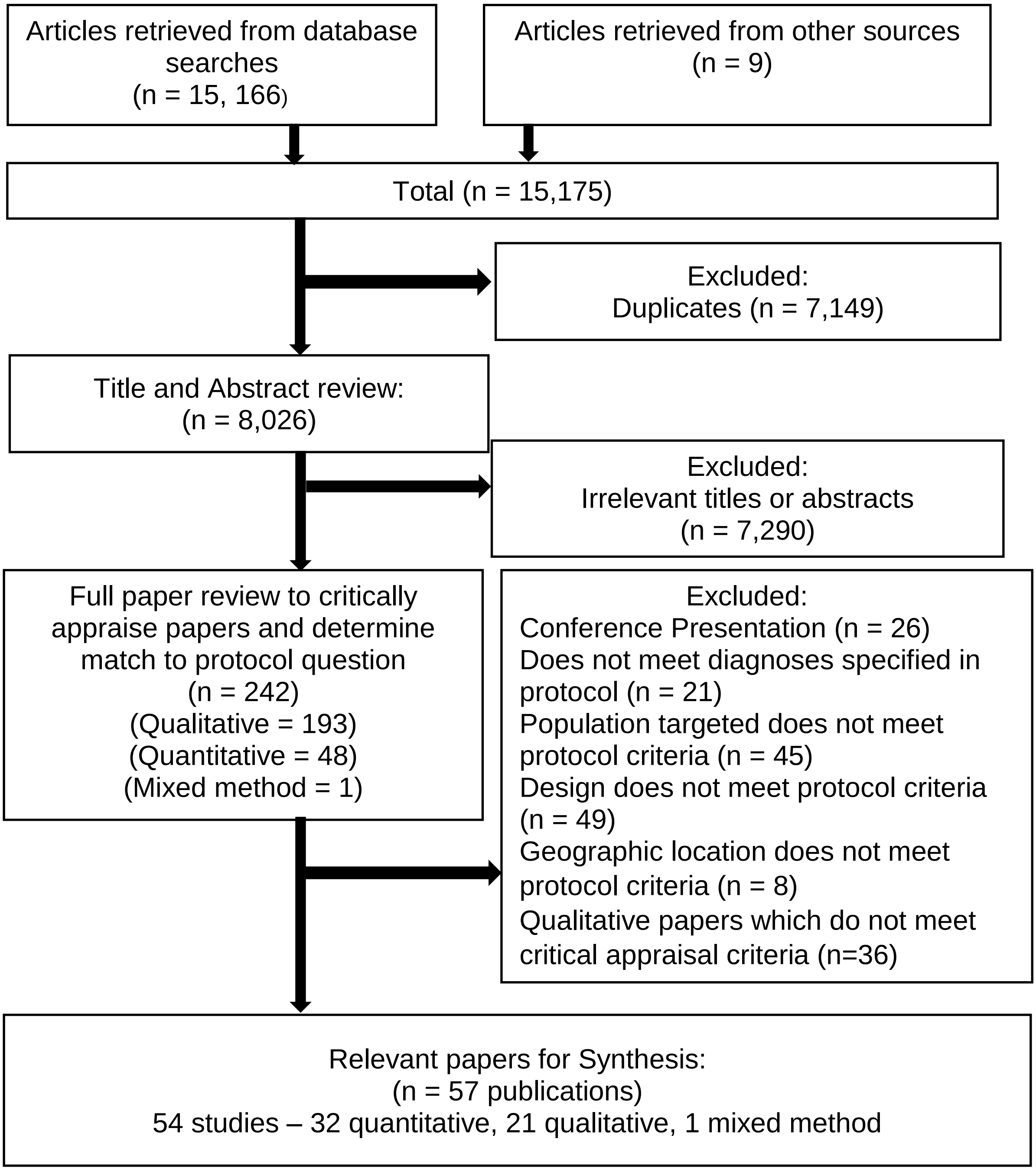


Table 3.2 Summary of included studies

First Author (Year)	Diagnosis	Aims	Methods	Country	Data Collection Sampling	Caregiver (Time caregiving)	Mean Age (caregiver/recipient
Ågren (2010)	HF (NYHA II-IV)	Describe the levels and identify independent predictors of cg. burden in partners of pts. with HF	QUANT (Correlational)	SWEDEN	Cross Sectional Purposive	135 101F, 34M (N/S)	69/71
Al-Rawashdeh (2017)	HF (NYHA I – I)	To examine whether individuals' sleep disturbance predicted their own and their partners' QoL in HF	QUANT	USA	Cross Sectional Purposive	78 Dyads 58F, 20M (N/S)	62.2./59.5
Andersen (2015)	HF	Obtain knowledge on experiences, views and the desire for knowledge of family cg. of HF pt. Identify their competence and support required	QUAL	NORWAY	Interviews Convenience	19 17F, 2M (N/S)	63/N/S

Badr (2017)	COPD	Individual-level predictors of pt. and cg. depression in COPD as well as how dyad members effect each other's depression	QUANT	USA	Cohort Study Purposive	89 68F, 21M (N/S)	54.8/67 (N/S)
Bakas (2006)	HF (NYHA II-IV)	Examine relationships among age, perceived control, perceived difficulty, and perceived mental and general health among cg. of persons with HF	QUANT (Descriptive/correlational)	USA	Cross Sectional Convenience	21 20F, 1M (N/S)	59.6/62.7
Baker (2010)	HF (LVAD in situ)	To describe experiences of cgs. of pts. who received LVAD therapy as a bridge to transplantation	QUAL (Descriptive/ Phenomenological)	USA	Interviews Convenience	6 5F, 1M (26-372 days)	51/N/S
Bove (2016)	COPD	Explore how spouses	QUAL	DENMARK	Focus Groups Purposive	22 13F, 9M	69.4/N/S

	(GOLD C and D)	of pts. with severe COPD experience their role				(N/S)	
Burke (2014)	HF (NYHA II-IV)	Understand what roles cgs. perceive and desire for themselves, and to compare and contrast these roles with those they perceive to be desired by the health care system	QUAL (Inductive)	USA	Interviews Purposive	20 18F, 1M, 1N/S (<1 - > 8 hours per week)	59/64
Chung (2016)	HF (NYHA II-IV)	Examine differences in cg. outcomes between cgs. who care for HF pts. with and without depressive symptoms	QUANT	USA	Cross Sectional Convenience	102dyads 79F, 23M (N/S)	56.7/61.4
Clark (2008)	HF (NYHA II – IV)	To examine the complexity of caregiving for pts. with HF	QUAL	SCOTLAND	Interviews Convenience	30 23F, 7M (N/S)	68F,67M/N/S
Cossette (1993)	COPD (GOLD III-V)	Examine relationship between	QUANT	CANADA	Cross Sectional Convenience	89F (Mean = 13yrs)	65/68.6

		caring tasks and impact on mental health of cgs.					
Evangelista (2002)	HF (NYHA I – IV)	Describe emotional wellbeing of HF pts. and cgs. Identify factors associated with emotional wellbeing of pts. Determine gender differences in the emotional wellbeing of pts. and cgs.	QUANT (Descriptive)	USA	Cross Sectional Convenience	103Dyads 73F, 30M (N/S)	59.4/57.6
Figueiredo (2013)	COPD (GOLD I-IV)	Examine coping strategies of family cgs. of pts. with early and advanced COPD and how those relate to their subjective health	QUANT (Correlational)	PORTUGAL	Cross Sectional Convenience	158 120F,38M (> 4 years)	58.4(early COPD) 60.8 (Adv. COPD) /69.4
Figueiredo (2014)	COPD (GOLD I-IV)	To analyse subjective burden of	QUANT (Correlational)	PORTUGAL	Cross Sectional Convenience	167 125F, 42M (> 4 years)	58.3(early COPD) 60.5 (Adv. COPD) /69.3

		family cgs. of early and advanced COPD pts. and its predictor variables					
Figueiredo (2015)	COPD (Moderate to Severe)	Obtain knowledge on experience of husbands and sons providing care to a family member	QUAL	PORTUGAL	Interviews Purposive	12M (> 4 years)	70.9(Husbands) 43.4(Sons)/72.1
Grigorovich (2017)	HF (NYHA II-IV)	To examine changes in cgs. wellbeing over time. Identify pt. and cg. factors associated with positive and negative outcomes	QUANT (Repeated measures)	CANADA	Longitudinal Convenience	50 31F, 19M (Mean = 18 months)	58/61.6
*Halm et al. (2006) *Halm et al. (2007)	CAD	To determine cg. burden after CABG surgery	QUANT	USA	Cross Sectional Convenience	166 136F, 30M (≤12 months)	64.7/66.8
*Halm (2016) *Halm (2017)	CAD	To describe the concern's needs, strategies and advice of CABG cgs. during the first	QUAL	USA	Interviews Purposive	32 16F,16M (N/S)	60.6 (M<70)/60.1 61.5 (F<70)/62.5 75.9(M>70) /74.4 73.6(F>70) /77.6

		3 months post- surgery To explore cg. burden by age and gender					
Hess (2009)	HF	To examine the association between cg. literacy and medication administration	QUANT (Correlational)	USA	Cross Sectional Convenience	5 (F) (N/S)	65/72.8
Hooley (2005)	HF (NYHA III or IV)	To explore if greater cg. burden is associated with increasing disease burden and depressive symptoms in pts. and cg.	QUANT	CANADA	Cohort Study Convenience	50 40F, 10M (N/S)	61/72
Hwang (2011)	HF (NYHA I – IV)	To identify factor associated with the impact of caregiving	QUANT	USA	Cross Sectional Convenience	76 Dyads 54F, 22M (Mean = 53.4 months)	53.4/53.8
Hynes (2012)	COPD	To explore the experiences of cgs.	QUAL (Phenomenological)	IRELAND	Interviews Convenience	11 9F, 2M (1 – 15 years)	N/S

Imes (2011)	HF (NYHA III-IV)	To describe cgs. experience of living with HF	QUAL (Descriptive)	USA	Interviews Convenience	14 11F, 3M (N/S)	64.8/68
Karmilovich (1994)	HF (NYHA III - IV)	To examine cg. demands and components of caring. Assess stress and correlation with cg. burden.	QUANT (Correlational)	USA	Descriptive survey Purposive	41 30F, 11M (N/S)	56.7/N/S
Kitko (2010)	HF	To gain a deeper understanding the type of work in spousal caregiving	QUAL	USA	Interviews Convenience	20 14F, 6M (2 months – 9 years)	67/70
Kneeshaw (1999)	CAD	To examine cg. mutuality and preparedness for caring post CABG surgery.	QUANT	USA	Longitudinal Convenience	49 32F, 17M (N/S)	50.1/72.6
Liljeroos (2014)	HF	To understand perceived caring needs in dyads and understand areas of support for cgs.	QUAL	SWEDEN	Focus Groups Convenience	19Dyads 7F, 12M (N/S)	70/72

Lindqvist (2013)	COPD (Mild to severe)	To describe conceptions of daily life for women caring for men with COPD	QUAL (Phenomenological)	SWEDEN	Interviews Purposive	21F (N/S)	72/N/S
Loftus (2004)	HF (NYHA II-IV)	Investigate outcomes of caregiving in late stage HF	QUANT (Correlational)	UK	Longitudinal Convenience	53 41F, 12M (6.66 hours per day)	66.7/76.3
Lum (2014)	HF (NYHA II-IV)	Measure of relationship quality and cg. benefit burden and depression	QUANT (Correlational)	USA	Cross Sectional Purposive	19 7F, 12M(<1 - >8 hours per week)	59/69
Luttik (2007)	HF	Experience and needs of cgs. wellbeing factors	QUAL	NETHERLANDS	Interviews Convenience	13 10F, 3M (N/S)	66/88.6
Luttik (2009)	HF (NYHA II-IV)	Investigate QOL in cgs. Of HF pts. versus QOL in people with healthy partners	QUANT	NETHERLANDS	Cross Sectional Purposive	303 (N/S)	67/6
Marcuccilli (2011)	HF – LVAD in situ	Explore life adjustments of cgs. caring for long-term LVAD pts.	QUAL (Phenomenological)	USA	Interviews Convenience	5F (N/S)	56.6/N/S
Marcuccilli (2014)	HF - LVAD as DT	Explore experience of caring for	QUAL (Phenomenological)	USA	Interviews Purposive	7 6F, 1	65/N/S

		family member with HF				(18 – 24 hours per day)	
Miravitlles (2015)	COPD	Analyse burden of cgs.	QUANT	SPAIN	Survey Representative	22,795 (Mean = 12.7 hours daily, severe COPD)	56.5/72
Nakken (2017)	COPD	Investigate differences in male and female cgs. and their perception of pts. symptoms	QUANT (Correlational)	NETHERLANDS	Cross Sectional Convenience	188 Dyads 103F, 85M (N/S)	65.4/63.3F 65.1/68.7M
Näsström (2017)	HF	Cgs. Participation and perspective of home care services	MIXED METHOD	SWEDEN	Interviews Purposive	15 11F, 4M (N/S)	77/N/S
Park (2013)	CAD	Difficulty and demands of cg. tasks for older cgs. of CABG pts.	QUANT	USA	Cross Sectional Convenience	35 29F, 6M (Mean = 19days)	60/N/S
Pattenden (2007)	HF	Explore how pts and cgs. cope with daily life with HF	QUAL	UK	Interviews Purposive	20 18F, 2M (N/S)	67.8/N/S
Yeh PM (2012)	HF	Explore burden on family cgs. of older HF pts.	QUANT (Correlational)	USA	Cross Sectional Purposive	50 35F, 15M (< 6 months - > 1 year)	60.3/77.6

Pressler (2013)	HF (NYHA I-IV)	Examine changes in cg. burden and HRQO. Determine different perceptions between cgs. of low HF pts. and cgs. of high HF pts. Estimate time spent on cg. tasks	QUANT	USA	Longitudinal Convenience	65 48F, 17M (Mean = 9.3 years)	59.7/69
Riegner (1996)	COPD	To understand QOL and its association with role strain, humour and support in cgs. and pts.	QUANT (Correlational)	USA	Cross Sectional Convenience	83 Dyads 50F, 33M (N/S)	63.2/65.6
Rolley (2010)	CAD	Describe experience of cgs. of pts. undergoing percutaneous coronary intervention	QUAL	AUSTRALIA	Focus Groups Convenience	18F (N/S)	N/S
*Saunders (2009) *Saunders (2008)	HF (NYHA I-IV)	To determine indicators of cg. HRQOL	QUANT (Correlational)	USA	Cross Sectional Purposive	50 42 F, 8M (Mean = 5.9 years)	58.1/77.6
Saunders (2010)	HF	Compare employed and unemployed	QUANT	USA	Cross Sectional Convenience	41 37F, 4M	59 (Unemployed cgs)/78

		cgs. on depression and wellbeing				(2.9 – 6 years)	52(Employed cgs)/77
Schwarz (2003)	HF	Evaluate support on stress outcomes for cgs.	QUANT	USA	Cross Sectional Convenience	75 55F, 20M (Mean = 6 years)	63/N/S
Scott (2000)	HF	HRQOL of cgs. and pts. receiving community-based inotropic infusions	QUANT	USA	Cross Sectional Purposive	18 16F, 2M	63/69.3
Spence (2008)	COPD - Advanced	Needs and experiences of family cgs.	QUAL (Descriptive)	NORTHERN IRELAND	Interviews Purposive	7 6F, 1M (1 – 4 years)	N/S
Strøm (2015)	HF	Next of kin's experience and responsibilities	QUAL	NORWAY	Interviews Convenience	19 17F, 2M (N/S)	Median 63/NS
Takata (2008)	COPD (Long term O2 Therapy)	Explore cg. burden	QUANT	JAPAN	Cross Sectional Convenience	45 Dyads 37F, 8M (N/S)	68/75.2
Vellone (2015)	HF (NYHA I-IV)	Examine cg. self-efficacy and contribution to pt. self-care	QUANT (Correlation)	ITALY	Cross Sectional Convenience	515 Dyads 270F, 245M	56.6/75.6
Wallin (2013)	CAD	To describe cgs. need for support and	QUAL (Descriptive)	SWEDEN	Interviews Purposive	20 14F, 6M (N/S)	55/N/S

		information and impact after a cardiac event					
Woolfe (2007)	COPD	Identify needs of cgs. and how this impacts cg. wellbeing	QUANT (Descriptive)	AUSTRALIA	Cross Sectional Convenience	63 39F, 24M (N/S)	N/S
Wingham (2015)	HF	Identify needs of cgs. to inform development of a caregiver resource for use in a home- based self-management intervention	QUAL	UK	Interviews (I) Focus Groups (FG) Purposive	22 16F, 6M (6 months – 8 years)	(I) 67/N/S (FG) 62 /N/S

HF = Heart Failure, QUANT = Quantitative, QUAL = Qualitative, COPD = Chronic Obstructive Pulmonary Disease, LVAD = Left Ventricular Assist Device, LVAD DT = Left Ventricular Assist Device Destination Therapy, CAD = Coronary Artery Disease, Cg./cg./cgs. = Caregiver/s, Pt/Pts./pts. = patient/s, M = Male, F = Female, N/S = Not stated, CABG = Coronary Artery Bypass Graft, QOL = Quality of Life, HRQOL = Health related quality of life, ADL = Activities of daily living, O2 - Oxygen *= Same study

3.4.2 Study Characteristics

Of the 54 studies, 21 were qualitative, 32 quantitative and one mixed methods. Thirty-four focused on HF, 14 COPD and 6 CAD. The total number of caregiver participants was 26,453. Caregivers were primarily female (63%), with a median age of 62 years. Patient median age was 69. A summary of study characteristics is provided in Table 3.3.

Table 3.3 Summary of study characteristics

Summary of Study Characteristics	n = 54 Studies	
Aetiology of patients		
CAD n (%)	6 (11)	
HF n (%)	34 (63)	
COPD n (%)	14 (26)	
Caregiver Participants*		**Patients ***
Median age (range)	62 (43-77)	69 (36-93)
Median % of female (range)	63% (5–270)	38% (1-229)
Relationship between patient and caregiver (n = 26,008 caregivers)		
Spousal/Partner n (%)	2,321 (9)	
Son/Daughter n (%)	610 (2)	
Sibling n (%)	22 (<1)	
Parent n (%)	10 (<1)	
Friend/Relative n (%)	228 (<1)	
Not stated	22,961 (88)	
Type of study		
Qualitative n (%)	21 (39)	
Quantitative n (%)	32 (59)	
Mixed n (%)	1 (2)	
Study Design		
Cross-Sectional n (%)	24 (44)	
Longitudinal n (%)	4 (7)	
Cohort n (%)	2 (4)	
Quant. (survey) n (%)	2 (4)	

Qual. (Interview/Focus Group) n (%)	16 (31)
Phenomenological n (%)	5 (8)
Inductive n (%)	1 (2)
Continents of publication	
Europe n (%)	22 (41)
North America n (%)	29 (54)
Australasia n (%)	3 (5)
Date of publication	**n= 57 Publications●**
1990-1995	2
1996-2001	3
2002-2007	10
2008-2013	22
2014-2017	20

CAD – Coronary Artery Disease
HF – Heart Failure
COPD – Chronic Obstructive Pulmonary Disease
*** Caregiver Data based on data collected in 50 studies**
***Patient Data based on data collected in 35 studies**
● 57 publications; 54 studies. The following studies utilised the same data but produced two publications: Halm, 2006 and 2007. Saunders, 2008 and 2009. Halm 2016 and 2017.

3.4.3 Quality Assessment

Studies classified as being of insufficient quality were excluded. Qualitative papers were appraised, and only high-quality qualitative studies (as identified by MN utilising the CASP appraisal tool for guidance and in agreement with JW) were included (212, 221). A total of 21 out of 193 qualitative studies were classified as high quality (achieving a score of 4+ out of 5 in quality criteria as guided by the CASP tool (212)). Table 3.4(a) and 3.4(b) present the quality appraisal. Quantitative studies were classified as follows: 3 high quality, 12 medium quality and 17 low quality. Given the number of high-quality qualitative studies and in accord with current guidelines for the synthesis of qualitative evidence, the inclusion of qualitative studies was limited to high-quality studies only (221). In contrast, given the low number of high-quality quantitative studies, to ensure comprehensiveness of this review, all quantitative studies were included regardless of quality.

Table 3.4(a) Quality Appraisal – Qualitative Papers

First Author	Design	Recruitment	Data Collection	Data Analysis	Findings	Total
Andersen (2015)	1	1	1	0	1	**4 [H]**
Baker (2010)	1	0	1	1	1	**4 [H]**
Bove (2016)	1	1	1	1	1	**5 [H]**
Burke (2014)	1	1	1	1	1	**5 [H]**
Clark (2008)	1	1	1	1	0	**4 [H]**
Figueiredo (2015)	0	1	1	1	1	**4 [H]**
●Halm (2016)	1	1	1	1	1	**5 [H]**
●Halm (2017)	1	1	1	1	1	**5 [H]**
Hynes (2012)	1	1	1	0	1	**4 [H]**
Imes (2011)	1	1	1	1	1	**5 [H]**
Kitko (2010)	1	1	1	1	1	**5 [H]**
Liljeroos (2014)	1	1	1	1	1	**5 [H]**
Lindqvist (2013)	1	1	1	1	1	**5 [H]**
Luttik (2007)	1	1	1	1	1	**5 [H]**
Marcuccilli (2011)	1	0	1	1	1	**4 [H]**
Marcuccilli (2014)	1	1	1	1	1	**5 [H]**
*Näsström (2017)	1	1	1	1	1	**5 [H]**
Pattenden (2007)	1	1	1	1	0	**4 [H]**
Rolley (2010)	1	1	1	1	0	**4 [H]**
Spence (2008)	1	0	1	1	1	**4 [H]**
Strøm (2015)	1	1	1	1	1	**5 [H]**
Wallin (2013)	1	0	1	1	1	**4 [H]**
Wingham (2015)	1	1	1	1	1	**5 [H]**

• = same study *Mixed methods study – qualitative component

Table 3.4(b) Quality Appraisal – Quantitative Papers

First Author	**Study design**	**Participant sampling**	**Participant attrition**	**Outcome Measures**	**Data Analysis**	**Overall score**
Ågren (2010)	CS	Purp [+1]	0% [+1]	Non-V	MV [+1}	**3 [M]**
Al-Rawashdeh (2017)	CS	Purp [+1]	NS	V [+1]	MV [+1]	**3 [M]**
Badr (2017)	CS	Con	15.5% [+1]	Non-V	MV [+1]	**2 [L]**
Bakas (2006)	CS	Con	NS	V [+1]	MV [+1]	**2 [L]**
Chung (2016)	CS	Con	NS	V [+1]	UV	**1 [L]**
Cossette (1993)	CS	Con	NS	V [+1]	MV [+1]	**2 [L]**
Evangelista (2002)	CS	Con	20% [+1]	V [+1]	MV [+1]	**3 [M]**
Figueiredo (2013)	CS	Con	17% [+1]	V [+1]	MV [+1]	**3 [M]**
Figueiredo (2014)	CS	Con	11% [+1]	Non-V	MV [+1]	**2 [L]**
Grigorovich (2017)	LS [+1]	Con	NS	V [+1]	MV [+1]	**3 [M]**
●Halm (2006)	CS	Con	64%	V [+1]	MV [+1]	**2 [L]**
●Halm (2007)	CS	Con	64%	V [+1]	MV [+1]	**2 [L]**
Hess (2009)	CS	Con	NS	V [+1]	MV [+1]	**2 [L]**
Hooley (2005)	CS	Con	0% [+1]	V [+1]	UV	**2 [L]**
Hwang (2011)	CS	Con	35%	V [+1]	MV [+1]	**2 [L]**
Karmilovich (1994)	CS	Purp [+1]	24%	V [+1]	MV [+1]	**3 [M]**
Kneeshaw (1999)	LS [+1]	Con	32.7%	V [+1]	MV [+1]	**3 [M]**
Loftus (2004)	LS [+1]	Con	36%	V [+1]	MV [+1]	**3 [M]**
Lum (2014)	CS	Purp [+1]	5% [+1]	V [+1]	MV [+1]	**4 [H]**
Luttik (2009)	CS	Purp [+1]	31%	Non-V	MV [+1]	**3 [M]**
Miravitlles (2015)	CS	Rand [+1]	0% [+1]	Non-V	MV [+1]	**3 [M]**
Nakken (2017)	CS	Con	58%	Non-V	MV [+1]	**1 [L]**

*Näsström (2017)	LS [+1]	Purp [+1]	7% [+1]	V [+1]	MV [+1]	**5 [H]**
Park (2013)	CS	Con	NS	V [+1]	UV	**1 [L]**
Yeh PM (2012)	CS	Purp [+1]	39%	V [+1]	MV [+1]	**4 [H]**
Pressler (2013)	LS [+1]	Con	16% [+1]	V [+1]	MV [+1]	**4 [H]**
Riegner (1996)	CS	Con	71.8%	V [+1]	MV [+1]	**2 [L]**
●Saunders (2008)	CS	Purp [+1]	36%	V [+1]	MV [+1]	**3 [M]**
●Saunders (2009)	CS	Purp [+1]	36%	V [+1]	MV [+1]	**3 [M]**
Saunders (2010)	CS	Con	NS	V [+1]	UV	**1 [L]**
Schwarz (2003)	CS	Con	NS	V [+1]	MV [+1]	**2 [L]**
Scott (2000)	CS	Purp [+1]	10% [+1]	Non-V	MV [+1]	**3 [M]**
Takata (2008)	CS	Con	NS	V [+1]	UV	**1 [L]**
Vellone (2015)	CS	Con	NS	V [+1]	MV [+1]	**2 [L]**
Woolfe (2007)	CS	Con	37%	V [+1]	UV	**1 [L]**

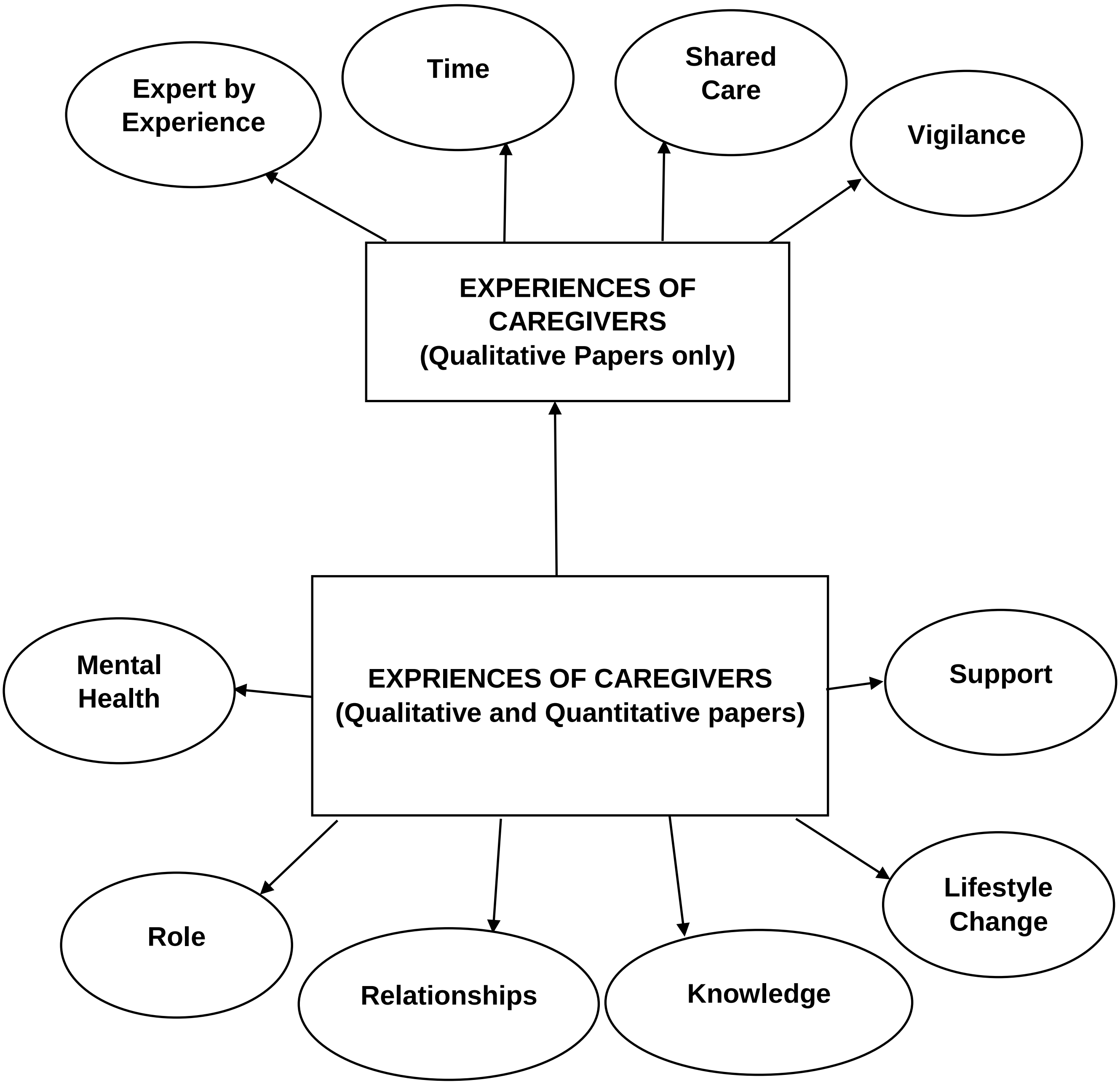
Study design - CS: cross-sectional design, LS: longitudinal design
Participant sampling – Purp: purposive, Rand: random, Cons: consecutive, Con: convenience, NS: not stated/unclear
Attrition – 20% or less = +1, NS: Not Stated
Outcome measures – V: all validated outcomes, non-V: some or all non-validated, NS: not stated/unclear
Data analysis – MV: multivariate, UV: univariate
• = same study, *Mixed method study – quantitative component
Overall quality rating – For both tables

H = High Quality. 4/5 out of 5 quality criteria achieved
M= Medium Quality. 3 out of 5 quality criteria achieved
L= Low Quality. 1 or 2 out of 5 quality criteria achieved

3.5 Findings

Six concepts relating to caregiver experience were identified: (1) mental health (2) caregiver role (3) lifestyle change (4) support for caregivers (5) knowledge and (6) relationships. Four additional concepts were identified from qualitative papers only (7) expert by experience, (8) vigilance, (9) time and (10) shared care (Figure 3.2). The concepts are reflected in caregiver quotes in Table 3.5.

Figure 3.2 Conceptual representation of the experiences of Caregivers



3.5.1 Mental Health

Twenty-five quantitative (61, 77, 187, 220, 222-243), twenty qualitative (62, 244-263) and one mixed methods (264) study addressed caregiver mental health. This concept encompassed depression and mental burden. Caregivers described an internal and external conflict of emotions, recognising a psychological change within themselves and the patient. Maintaining hope and positivity versus managing worry, fear, and anxiety was predominant (242, 244-263). The study by Pressler et al. identified that caregivers of HF patients had moderately poor health at baseline and eight months follow-up, but they had fewer depressive symptoms over time (61). Burden arose due to greater responsibilities (246, 249, 254, 262, 263). Yeh and Bull, noted the quality of the relationship and lack of family support significantly predicted greater family caregiver burden (243). Näsström et al. reported that caregiver burden was concerned with the future and their fears of potential demands (264). Those with greater resiliency appeared to adjust and cope better with the illness trajectory (245, 246, 257, 258). Caregivers described mental adjustment after an acute event (253). Living through an acute event was long lasting, and some reported experiencing traumatic symptoms after an acute event (261).

3.5.2 Caregiver Role

The role of caregivers was addressed in eighteen qualitative (62, 208, 245-253, 255-257, 259-263) and fourteen quantitative studies (61, 62, 220, 224-226, 232-234, 238, 240, 241, 265-268). The caregiver role is complex and requires coordination of patients from caregivers (62, 255, 262). Caregivers describe significant role change, such as increasing domestic tasks (244, 247, 250, 252, 257-260, 263). Role loss is prevalent (245, 246, 251), and caregivers need to reframe their identity (253, 261). Societal expectation regarding the relationship and gender, influences caregivers adjusting to their roles (246, 248, 249, 255, 260). Caregiving can be positive and rewarding. Caregivers learn about themselves and the strengths they have (62, 246, 256-258, 261, 262). Pressler et al. described the tasks involved in the caregiving role, which includes; domestic tasks, emotional support, managing dietary needs and transport (61). Pressler et al. also reported that caregivers of persons with greater HF symptoms experienced more difficulty with their role (61).

3.5.3 Lifestyle Changes

Fourteen quantitative (61, 77, 220, 223-225, 228, 235, 240-242, 266, 267, 269) and twenty-one qualitative (62, 208, 244-263) studies addressed lifestyle changes.

Caregivers experienced leisure, social, and work-related problems (220, 245, 269). Caregiving interrupted and eliminated tasks from their routine (220, 240, 245). Contrastingly, Pressler et al. reported that caregivers' perceptions of how their lives changed due to caregiving was neutral (61). This perception of caregiving improved from baseline to 4 and 8 months follow up (61). Caregivers became adaptable in their new role (208, 253, 261). There was less personal time for leisure and hobbies, either alone or with the patient (62, 248-251, 257, 258, 263). Caregivers described daily "ups and downs" and had to adjust their routines dependent on the presentation of the care recipient (62, 244, 245, 247, 252, 254, 256, 259, 260, 262).

3.5.4 Support for caregivers

Fifteen quantitative (19, 23-25, 27, 29, 30, 32, 33, 36, 37, 39, 40, 65, 67), twenty-one qualitative (62, 208, 244-263) and one mixed method (264) study examined support. This concept includes healthcare, family and social support. The weight of perceived external expectations, the necessity of being pro-active in obtaining support and maintaining a social role was described across all diagnoses (61, 77, 187, 230-233, 236-238, 243, 268). Yeh and Bull identified a lack of family support as a significant issue (243). Caregivers felt abandoned by healthcare teams. After hospital discharge they had to provide care without advice or medical support (247, 253, 259). Positive interactions were experienced and reported, specifically when having access to healthcare professionals via telephone or home support (244, 245, 257, 264).

3.5.5 Knowledge

Knowledge was addressed in seventeen qualitative (62, 208, 244, 246-257, 260, 261, 263) five quantitative (187, 233, 241, 242, 266) and one mixed method (264) study. This concept describes caregivers' understanding of the diagnosis and their need for knowledge throughout the illness (62, 208, 244, 248, 251, 256, 264). Caregivers reported information from health professionals was often inadequate (252, 254, 255). The timing of information and the format in which it was received was significant. Caregivers received information verbally or by leaflets in hospital but describe being left alone to provide care in the long term (246, 249, 250, 260, 263). Caregivers experienced difficulty understanding how to navigate the care system (253, 261). They had to make decisions without full knowledge of the consequences of their decision-making, particularly during acute exacerbations (246). The quantitative element of Näsström et al.'s mixed-methods study correlated with the qualitative studies; receipt of sufficient information was central to managing HF and was associated with better perceived health of caregivers (264).

3.5.6 Relationships

Twenty qualitative (62, 208, 245-263), twenty-two quantitative (61, 187, 220, 222, 223, 227-238, 266, 269-271) and one mixed method (264) study examined relationships. In HF studies caring for individuals with more symptoms resulted in poorer perceived experiences (61, 270). Higher relationship quality resulted in less burden and more benefit from the relationship. The relationship before diagnosis influenced the current relationship. Caregivers' perspective of the relationship was either a sense of duty (246, 255, 261, 262, 264) or that it was a valuable second chance (62, 247, 256, 263). Caregivers reported difficulty communicating about the illness leading to isolation, stress, and conflict between caregiver and patient (252, 254). The relationship requires negotiation (208, 250). Caregivers prioritised the patient over their own needs (245, 253, 255, 257, 263).

3.5.7 Expert by Experience

Twelve qualitative studies (62, 208, 246-251, 253, 256, 258, 261, 262) addressed the concept of expert by experience. Caregivers learnt new skills. They became "experts by experience" by discovering elements of the caregiving role through "doing" and by observing health professionals (62, 247, 249). They developed "proto-professional skills"; in medication administration (208, 246, 261), they were able to determine the patients' level of functioning (260) and were responsible for decision making in times of exacerbations (251). Caregivers observed the nuances of change in the patient. These changes were often not perceived by healthcare teams or other family members, for example, a change in the patient's skin colour or recognising irritability (253, 256, 262).

3.5.8 Vigilance

Vigilance was recurring in caregivers' narrative across all diagnoses and was present in nineteen qualitative studies (62, 208, 245-262). Caregivers were always on the alert observing the patient (247, 248, 251, 252, 254, 255, 257, 259, 260, 262). They lay awake at night listening for their partner's breath (208, 250, 252, 256). This state of vigilance impacted on caregivers' health, creating constant fatigue, worry and stress (208, 260). Caregivers recognised that the need to maintain alertness came from themselves and their insecurities (62, 245, 258).

3.5.9 Time

Time explores how caregivers adjusted to living with the illness and was present in fifteen qualitative studies (62, 208, 246, 248-258, 261, 263). Caregivers adapted to a new life, referring to "then", how life was, and "now", their current life (62, 250, 251, 256, 258). The duration of caregiving and severity of illness influenced caregivers' ability to adjust (247, 254, 258). Caregivers lived day by day (62) and viewed the future either with hope or uncertainty about what lay ahead (246, 251, 253, 260, 263).

3.5.10 Shared Care

Shared care was present in sixteen qualitative studies (62, 208, 244-247, 249-256, 258, 261, 262) and represents the caregiver and patient working together managing the illness. Jointly administering medication (249, 262) and attending appointments (254). The presence of illness was a process they adjusted to together (258, 261). Caregivers referred to themselves and the patient as "we" when discussing dealing with the illness (244, 252, 256). The mutual perspective between caregiver and patient served to isolate them from the world. The illness was "taking a life of its own; it's like this third person" (251).

Table 3.5 Quotes from caregivers extracted from qualitative studies

Concept	**Caregiver Quote**
Mental Health	"The mental strain is difficult. I feel so trapped" “You fall into a huge hole, then the world gets so tiny, it all gets so narrow that it is almost unbearable” “I feel like sleeping beauty. The hawthorn hedge has closed around me, and I cannot do anything about it.”
Role	“I can sum my role up in three words, I am a cheerleader, drill sergeant, and negotiator”
Lifestyle Change	“Our life has come down. The two of us used to go out dancing. We loved dancing and then it all stopped.”
Knowledge	“I wish I had had more education on the ‘what ifs’. When I was leaving the hospital nobody really said, “OK now this is what’s going to happen and this is what you’re going to have to do.” If there would’ve been any kind of complications I would’ve been totally in the dark. I didn’t know all the things I needed to know."
Relationships	“I just love him and I find that every day when I see him, what else could I do to try and make him a wee bit … better? It’s very satisfying to know that he appreciates what I do and it’s nice to know that you are helping someone.” “‘It’s like having another child sometimes because you are sort of responsible and I feel he is my responsibility. I feel that he is not anybody else’s responsibility…”
Support	“And then I really felt alone in it all. Because everybody would call and come over and ask, how is John? Hardly anyone asked “how are you doing”? “Doctors (do) not realize that 1 day your life is jut normal and then this comes and smashes everything to bits, you know- and there are so many questions.” “I would be lost without, our heart failure nurse, and, all the other input we’ve had from all the other professionals, like the podiatrist and GP … You can do it, but in partnership with everybody else.”
Vigilance	“Every morning I put my ear to his chest and listen to his heart; that is how we first discovered he was in atrial fibrillation so now I do it every morning before I leave. I monitor him very closely and there are days in which I do not feel comfortable leaving for work so those days I work at home. I call every day from work and we have our routine, if I am not aware of anything he had planned for the day, I then immediately call my neighbour to check on him”
Shared Care	“There were days I thought to myself, where are we going from here? But we mastered it together and tried to do things at his pace.”
Time	“At first it was overwhelming. I didn’t think I could do it. When they first told me I was like, “I can’t do that,” you

	know. And then they explained to me, like, yes you can. It's like getting a new baby. You know, you learn how to take care of them step by step and then it's just part of the routine. And that's really the way it was"
Expert by Experience	"It's so frustrating when she goes into hospital and the nurses and the doctors say it's her condition, you know. I'm like I'm with her twenty-four hours a day, I know how breathless she is without infection and I know how breathless she is with an infection there's a major difference" "I see him every day, they are just little subtle changes, they are not showing up in the numbers the doctors are concerned with but I see it"

3.6 Diagnosis Specific Findings

There were differences in caregiver experience for each of the diagnoses, and these are discussed below.

3.6.1 Heart Failure (HF)

Those providing care for patients with HF experienced an "ebb and flow" in caregiving; this caused underlying worry, fear and anxiety, which at times of change or illness was heightened (62, 208, 232, 234, 240, 252, 257, 262, 271). Lifestyle changes were long-lasting and sustained (62, 208, 224, 240, 245, 252, 257, 262, 271). Obtaining knowledge was necessary throughout all stages of the illness (62, 208, 233, 244, 247, 254, 271). Sourcing information and communication with health professionals was often difficult (208, 244, 247, 252, 271). In spousal relationships they frequently viewed the patient as another child or as a "duty" (233, 234, 245, 247, 252, 254, 257, 264).

3.6.2 Chronic Obstructive Pulmonary Disease (COPD)

Those providing care to patients living with COPD experienced a prolonged impact on their mental health, similar to HF caregivers (226, 228, 235, 241, 246, 251, 261). Severity of illness was influential on their experience of burden (223, 228, 241). Role change was long-lasting and profound for many (246, 248, 251, 261). They expressed concerns with a perceived lack of knowledge (242, 246, 251, 255, 261). During exacerbations, COPD caregivers experienced anxiety and fear of their loved one dying (246, 248, 251, 255). COPD caregivers highlighted the loss of social roles while trying to maintain their loved ones' dignity (246, 251, 255, 261, 268, 269). The coughing and spitting associated with COPD often left the care recipient embarrassed (246, 248, 261). The caregiver tried to avoid situations where this would happen. The dynamics of spousal relationships changed. Caregivers described losing the intimate love they had for their partner (246, 251, 255, 261).

3.6.3 Coronary Artery Disease (CAD)

Caregivers of CAD patients experienced profound role change on discharge from hospital and in the acute phase of the illness (229, 249, 260, 263, 266, 267). They initially engaged with a high volume of caregiving tasks which reduced over time (229, 230, 249, 260, 263, 266, 267). CAD caregivers experienced post-traumatic type symptoms if they witnessed the recipient experience an acute event (260, 263). Caregivers described being unable to talk about this and reliving the event in their heads. Anxiety did ease over time for many (260, 263). Caregivers experienced feelings of unpreparedness at hospital discharge and highlighted not realising how much their routine would be disrupted (249, 260, 263). Caregivers reported viewing the experience as a second chance and had a renewed sense of love and appreciation for the relationship (260, 263).

3.7 Discussion

This mixed-methods systematic review demonstrated the similarities and differences in caregiver experiences across three common cardiorespiratory illnesses. It highlighted the differences in experiences obtained from qualitative and quantitative research. Commonly occurring experiences included the exacerbation of caregiver physical and mental health due to the role. This correlates with a systematic review from Kang et al. of HF caregivers, they identified that caregiving resulted in a multitude of changes in the lives of caregivers, regardless of age, gender and ethnicity (39). Addressing both patient and caregiver needs to maintain wellbeing for both is essential as well as recognising the value of “shared-care” between patient and caregiver (24). The prevalence of mental health needs in this review demonstrates the need for psychosocial support for caregivers. This mental health impact is similar to what was reported by Aasbø et al., where it was identified that caregivers need to be in “emotional control” (272). At the same time, Wingham et al. described the “enduring anguish” experienced by caregivers (273). Lawton et al. attributed caregiver wellbeing to the commitment of the caregiver to the role and dealing with competing demands which can increase the burden and negatively impact affect. Spousal caregivers may be more ready to accept the role of caregiving than adult-children who may view it as an imposition on an already established lifestyle (274). In this review, societal expectations had an impact on how caregivers adjust to their role. Additionally, the quality of the relationship before becoming a caregiver influenced the subjective caregiver experience of burden.

Caregivers had predominantly negative experiences of support and described uncertainty of how to obtain assistance. Caregivers need more support and knowledge transfer from more experienced peers of healthcare professionals to conduct their role (275). They should be included in clinical appointments (150) to ensure they are not isolated in providing care and to allow for knowledge exchange. Caregivers in Giacomini et al.’s review of living and dying with COPD reported increasing isolation in addition to their health issues (112). They described pressure balancing their variety of roles, similar experiences to the caregivers in this synthesis across all diagnoses. Caregivers perceived a need to be vigilant. This concept of vigilance falls into five categories as defined by Mahoney’s study of caregiving in Alzheimer’s Disease: “watchful supervision”, “protective intervening”, “anticipating”, “on duty” and “being there” (276). Caregivers in this synthesis described overt vigilance, putting one’s head on the chest of the recipient to check breathing or covert vigilance observing them throughout the day (276). Healthcare professionals must begin to recognise the role they have to support caregivers and to have an understanding of the levels vigilance conducted by caregivers.

Caregivers are valuable providers of care, and their needs should be assessed systematically and in a formalised manner in healthcare settings (27). Additionally, when developing collaborative models of care, the inclusion of caregivers is imperative (12).

3.7.1 Strengths and limitations

This review demonstrates the complexity of what it means to be a caregiver and should inform the design and delivery of self-management interventions. A mixed-methods review can be contentious (277) due to the synthesis of differing paradigms. In this review, it required the transformation of quantitative data into qualitative data (198, 278). This review aimed to present a merging of paradigms concerning caregiver experiences by conducting a mixed-methods synthesis. However, it demonstrated four different concepts between the two paradigms which highlights the challenge of synthesising multiple methods. It is worth exploring how the four additional qualitative concepts could be captured quantitatively to inform self-management intervention design and delivery. This mixed-methods synthesis is, to this researcher's knowledge, the first to combine caregiver experiences in HF, COPD or CAD. It examines the differences and similarities in caregiver experiences, thus establishing a comprehensive assessment of the knowledge base of caregiver experiences in common cardiorespiratory illnesses.

There are limitations to this review, both in review methods and the nature of the included studies. First, it is acknowledged that the inclusion of lower quality quantitative studies may lead to a risk of bias: the majority of quantitative studies utilised convenience sampling had high attrition and low response rate. Non-validated outcome measures were employed in some quantitative studies with the majority of studies conducting univariate rather than multivariate analysis. However, given the limited number of high-quality quantitative studies (four studies), it is believed this broader inclusion of quantitative studies increased the scope of this review to achieve a holistic understanding of caregiver experiences. Furthermore, it is important to note that the conclusions of this review were broadly the same with consideration of only the high-quality quantitative studies. Second, studies were restricted to English language only, from high-income countries and excluding caregivers of nursing home residents. This may limit the applicability of findings to other settings. Third, converting quantitative data into a qualitative data set risks the quantitative data set being oversimplified. This was managed with regular research team meetings to review each stage of this process. Fourth, qualitative synthesis is an interpretation of other researchers' interpretations, therefore to minimise interpretative bias, a second researcher was utilised to seek confirmation of the results. Fifth, included qualitative and quantitative studies were primarily cross-sectional in design, therefore considering caregiver experience only at a single point of time. Finally, the involvement of caregivers at the conception stage and throughout this review may have generated more significant insights with regards to formulating and refining the design of this systematic review, appraising the literature and providing expert opinion on the interpretation of the results (279).

3.7.2 Implications for clinical practice

There are a number of implications following this review. It has demonstrated there are similarities and differences in the caregiver experience in HF, COPD or CAD. The impact on caregivers' lives of those with HF and COPD appears longer lasting and more turbulent than caring for patients with CAD. This review reflects the complexity of the caregiver role. The mixed-method approach indicated differences in what is being investigated. This is important in demonstrating an understanding of the caregiver experience when dealing with complex conditions. Clinically, the healthcare team need to identify who the caregiver is and be aware of their needs and utilise the use of a caregivers' needs assessment. There must be a greater understanding of caregiver supports, as well as recognising how caregivers avail of support. This can be achieved in conversation between the healthcare team and caregivers. This warrants further research as to how and whether caregivers avail of support.

3.7.3 Implications for future research

Future research should focus on involving caregivers in the design and delivery of self-management interventions for patients with cardiorespiratory illnesses. Best practice interventions for CAD caregivers in the discharge process from hospital to home must be formalised. There appears to be a focus on the mental health of caregivers of those with HF. However, further research is needed to explore this in COPD and CAD caregivers. Exploration of this, via support groups for caregivers of cardiorespiratory illnesses, is merited. Consideration needs to be given as to whether quantitative research tools to explore caregiver expertise, view of the future, experience of shared care and vigilance can be developed to capture these qualitative concepts to inform the development of self-management interventions for patients and caregivers. Repeated measures, examining perceived control and caregiver needs, may contribute to a greater understanding of the caregiver experiences which arose in qualitative studies.

Additionally, longitudinal studies with repeated assessment need to be conducted to assess the stability of caregivers' experiences and whether they are liable to much change over time. In this review, only four out of thirty-two quantitative studies examined caregivers' experiences longitudinally. Understanding whether there are caregiver changes over time will facilitate greater understanding of caregiver needs for healthcare professionals when working with this population. The emergence of additional concepts from qualitative studies emphasises the role of mixed methods research when examining lived experiences. The additional concepts also demonstrated the nuanced expertise of the caregiving experience. Researchers need to consider how to reflect this in a quantitative investigation, to inform funders when developing and trialling interventions in HF, COPD or CAD. The quality of quantitative studies in COPD and CAD were medium or low. There is a need for more empirically robust studies examining the experiences of these caregivers. Additionally, a greater understanding of caregivers' experiences with this population will facilitate the development of evidence-based guidelines for health services when working with HF, COPD or CAD.

3.8 Conclusions

This mixed-methods systematic review provides a holistic synthesis of caregiver experiences of people with HF, COPD or CAD. It demonstrates there are many implications when an individual becomes a caregiver for those with chronic cardiorespiratory illnesses. Taking on a caregiving role requires one to reframe their identity and change their life course. They learn a multitude of skills and develop expertise in their new role; thus, their expertise is invaluable. Caregivers should be acknowledged in healthcare interventions for these conditions. The quality of evidence was limited by assessment of caregiver experience at a single time point. There is a need for future studies that employ longitudinal designs examining the change in caregiver experience over time. Caregiving can be positive if caregivers have access to support, are well informed and part of the healthcare team.

Understanding the experiences of caregivers for people with these conditions allows healthcare professionals and policymakers to reflect on our approach. Healthcare services must consider caregivers in the design and delivery of interventions.

Chapter 4. The impact of involving caregivers in the delivery of self-management interventions for patients with heart failure or COPD: systematic review and meta-analysis

This chapter is an amended version of the published full paper:
Noonan, MC, Wingham, J, Dalal, HM, Taylor, RS. Involving caregivers in self-management interventions for patients with heart failure and chronic obstructive pulmonary disease. A systematic review and meta-analysis. *J Adv Nurs*. 2019; 00: 1– 15. https://doi.org/10.1111/jan.14172

4.1 Introduction

Self-management interventions form a core part of healthcare delivery for individuals living with long-term illness. Self-management is a process whereby individuals engage in behaviours which aim to enhance health by promoting the management of the signs and symptoms of ill health through behaviour change (34). Self-management interventions are comprised of one or more components in which patients (and caregivers) are responsible for implementing self-management behaviours, for example managing their diet or engaging in exercise (280, 281). Corbin and Strauss (282) proposed three key elements in the self-management of long-term illness: managing the medical requirements (such as taking medications), adapting to changes in roles and routines and managing the emotional implications of living with a long-term illness. This is of particular importance for individuals living with HF or COPD for whom engagement in self-management strategies may last a lifetime. Self-management intervention programmes which combine HF and COPD patients are being advocated by researchers and policy makers (283).

As stated in chapters 2 and 3, caregivers of HF and COPD patients are increasingly expected to provide support (150, 284). The systematic review presented in chapter 3 outlined caregivers' vast experience and expertise when providing care to adults with HF or COPD and also identified that caregivers of patients living with CAD appeared to have greater initial reliance on their caregivers but this need reduced over time. Potentially, the longer term implications of caring for someone with CAD on the health and wellbeing of caregivers, may not be as distruptive or life changing as it is for caregivers of patients with HF or COPD (Chapter 3). Both HF and COPD can be self-managed with medication and lifestyle adaptations. Two key conclusions from chapter 3 was that caregiver expertise should be acknowledged, and healthcare professionals should consider the inclusion of caregivers in intervention delivery.

However, there is a gap in the knowledge base examining the impact of involving caregivers in the delivery of self-management interventions on patient outcomes (285) . Support has been identified as a key component for patients to be successful in their self-management (91). The broader caregiver literature, discussed in chapter 2, indicated that self-management interventions that include caregivers demonstrated improved outcomes for patients. However, it is important to note the magnitude of this impact was small (98, 99, 102). Studies that specifically examined patient-caregiver dyads in HF or COPD identified that patients who had a support person sustained engagement in self-management (184) and dyads who worked together towards a common goal were more successful in maintaining self-care behaviours (177). Yet, where longitudinal research has been conducted, the influence of caregivers on patient outcomes is not sustained (183).

In order to understand and develop the efficacy of family involvement in interventions, it is suggested that research should focus on illness specific populations, with long-term follow up, to qualify the extent of family member engagement and quantify the theoretical foundations of the intervention development and the selection of outcome measures (98). A Cochrane review of interventions supporting caregivers in the terminal phase of illness recommend further research to assess interventions on the health of caregivers (286). If healthcare services are to facilitate effective self-management interventions for patients with HF and COPD there needs to be a greater understanding of the effects of caregivers with this population. Qualitative research has highlighted the needs and important contributions of HF and COPD caregivers to patient self-management (10, 62, 287-289). However, there is a paucity of quantitative evidence as to whether involving caregivers in self-management interventions positively influences HF or COPD patients' outcomes, particularly HRQoL. HRQoL is important to measure due to the long-term, enduring nature of these conditions.

The impact of involving caregivers in the delivery of self-management interventions on patient outcomes in HF or COPD has a limited evidence base. Studies that have examined caregiver involvement have had several limitations as identified in chapter

2. These include small convenience sample sizes, single centre studies, limited reporting of caregiver outcomes and a lack of rigour in the intervention development and delivery (90, 149, 169, 182). However, there is no systematic review or meta-analysis that examines the pooled effect of involving caregivers in interventions for patients with HF or COPD. This chapter presents a systematic review and meta-analysis examining the impact of involving caregivers in the delivery of self-management interventions. This systematic review utilised a quantitative approach. Randomised controlled trials (RCTs) were included for synthesis, and a meta-analysis was conducted, this is considered a robust method for informing decision making when faced with a variety of treatment options (290). Producing a review in this way is useful for healthcare professionals and researchers to determine the replicability and usability of an intervention (291).

4.2 Objectives of the systematic review and meta-analysis

The aims of this systematic review and meta-analysis of RCTs that involve caregivers in the delivery of self-management interventions for patients with HF or COPD are to:

1. Assess the methodology used by researchers to include caregivers
2. Quantify the impact on patient HRQoL
3. Compare the magnitude of impact on patient HRQoL of RCTs that do, versus those that do not involve caregivers in the delivery of self-management interventions
4. Examine the impact on the HRQoL of caregivers.

4.3 Methods

4.3.1 Design

This systematic review and meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses PRISMA statement (209). The protocol for this review was published on Prospero, the international prospective register of systematic reviews. ID number CRD 42018090748.

4.3.2 Search methods

The search strategy was designed in conjunction with Information Specialists. Search terms included condition-specific terms, i.e. “heart failure”, and “chronic obstructive pulmonary disease” and intervention related terms “self-management” and “education.” Full list of search terms are included in Appendix 5. Databases searched included: Medline Ebsco, PsycINFO, CINAHL Plus with Full Text, Embase, Web of Science, The British Library and ProQuest. Grey literature was identified using Global Dissertations and Theses and Applied Sciences Index and hand searches and citation checking of included references. To ensure the contemporary nature of the evidence considered, the search time frame was January 1990 to 30th March 2018. The lead researcher (MN) initially screened titles and abstracts. Selection of full papers was performed by two researchers (MN and RT) and cross-checked with the eligibility criteria.

4.3.3 Search outcome

Studies were included if they met the following criteria:

- Population: Adults (≥ 18 years) with HF or COPD.
- Intervention: Self-management intervention programmes which were comprised of two or more intervention components (e.g. exercise, education, support or psychotherapeutic elements). Self-management interventions in HF or COPD are typically comprised of multiple components, for example education about the condition and exercise. This type of self-management intervention can be considered as a complex intervention (34). The Medical Research Council (MRC) identifies complex interventions as those that contain “several interacting components” (292). Thus, self-management intervention programmes comprised of two or more components were part of the inclusion criteria for this systematic review and meta-analysis. The self-management interventions formally included caregivers in the delivery of the intervention.
- Outcomes: Compared to usual care or interventions that did not involve caregivers in the delivery of the intervention compared to usual care. Formal

inclusion of caregivers was classified as caregivers being explicitly included as participants in the intervention.

- Outcomes: Patient and caregiver HRQoL.
- Study design: RCTs (including individual or cluster designs).

Exclusion criteria were: studies in long-term residential care setting, and studies where caregivers were not explicitly reported as being part of the self-management intervention delivery. In order to compare HRQoL outcomes of studies involving caregivers in intervention delivery and studies that did not include caregivers in intervention delivery, a quasi-randomised sampling strategy was employed. A matching strategy was undertaken to minimise potential differences between studies, i.e. comparison of self-management intervention studies involving patients only versus self-management intervention studies involving both patient and caregiver. Studies not involving caregivers were first listed in alphabetical order and were then matched with the caregiver studies. Four study level criteria, which were consistently reported across all trials were pragmatically chosen for matching:

1) Patient diagnosis (HF or COPD)
(2) Geographical location (Europe, North America, or other)
(3) Year of publication (pre or post 2000)
(4) Inclusion of exercise as a key intervention component

4.3.4 Quality Appraisal

The Cochrane Risk of Bias Tool (293) was used to determine the methodological quality of the included studies. Study authors were contacted by the lead researcher (MN) if any required data was missing for meta-analysis. Data extraction and risk of bias assessment were initially conducted by the lead researcher (MN) and revised by a second reviewer (RT). Any disagreements were resolved through discussion and reaching consensus.

4.3.5 Data Extraction

A standardised data extraction form was used to extract details on the study, population, intervention, HRQoL outcome measures at each time point and the authors’ conclusions. Studies with multiple publications were all reviewed, and data was extracted into a single data extraction form. A bespoke data extraction tool was developed which was guided by the MRC guidelines for complex interventions (292) and the Template for Intervention Description and Replication (TiDier) checklist (291).

4.3.6 Synthesis

Results of this systematic review are presented descriptively in the form of detailed tabular summaries and a quantitative synthesis of patient HRQoL outcomes using both meta-analysis and a vote counting approach.

All relevant data available for included studies were pooled for statistical meta-analysis using Review Manager 5.3 (294). Given the variation in HRQoL outcomes reported across studies, between-group outcomes were expressed across studies as standardised mean differences (SMD). That is, the results of studies are standardised to the same scale in order to combine them. The weight of the intervention effect is expressed comparatively to the variability identified in the study (293). Studies were pooled using random-effects meta-analysis due to the clinical heterogeneity of included studies. Meta-analysis was conducted by pooling the total HRQoL score at the latest point of follow up. In studies reporting more than one HRQoL measure, the primary HRQoL measure was used (or if primacy was not stated, the outcome measure described first in the methods section of the study was utilised). A sensitivity analysis excluding COPD studies was also conducted by the lead researcher. Data was presented descriptively using tables to summarise and synthesise the findings. Meta-analysis results were reported as means and 95% confidence intervals (CIs). Missing data was imputed when possible using Stata 15.

The lead researcher conducted a vote counting assessment of HRQoL outcomes across all included trials given that all studies did not report HRQoL datum that could be included in the meta-analysis. Vote counting involves quantitatively categorising all studies according to the existence of a statistically significant ($P \leq 0.05$) effect on HRQoL between intervention and control groups (293). The advantage of the vote counting method (over meta-analysis) is that it allows the inclusion of studies irrespective of their method of quantitative reporting of outcomes. As a sensitivity analysis, conclusions of vote-counting were compared to conclusions of the meta-analysis.

4.4 Results

4.4.1 Study selection process

Following the removal of duplicates, the search strategy produced a total of 16,183 title and abstracts. Of these, 602 full papers were reviewed; this resulted in 13 studies involving caregivers for synthesis. Therefore, 13 matched studies, not including caregivers, were retained for comparative meta-analysis. The study selection process is summarised in a PRISMA Flow diagram shown in Figure 4.1.

Three pairs of studies did not meet all four criteria for the matched sampling strategy. They were instead matched on diagnosis, year, exercise as a key element of the intervention and HRQoL. The matched sampling strategy can be viewed in Appendix 6.

4.4.2 Characteristics of included caregiver studies

We synthesised thirteen studies (14 publications) which involved caregivers in the delivery of the intervention (63, 190, 295-306). A summary of the characteristics of caregiver included studies is shown in Table 4.1. Most studies (12/13) have been published since 2000. Ten studies recruited HF patients and three COPD patients. The total number of participants was 1,701 (1,439 HF and 262 COPD). The duration of interventions was a maximum of 52 weeks. The frequency of intervention sessions varied from twice per week to an eight monthly maintenance session. Health professional contact time ranged from 15 minutes (telephone call) to two hours (one to one or group sessions). The intervention setting was either a combination of home and clinic (n = 5) or clinic only (n = 5). Five studies reported caregiver mean age, 59.2 intervention and 59.2 in control. Four studies reported caregiver sex, 58% of these were female. A detailed summary of all 26 studies is presented in Appendix 7.

4.4.3 Risk of Bias

A summary of risk of bias assessment in caregiver included studies is shown in Table 4.2. Studies were of mixed quality and often poorly reported. The methodological issues most often classified as high risk were: blinding of participants/personnel (n = 12) and incomplete reporting of data (n = 6). The majority of studies were judged to be at low risk for random sequence generation (n = 12) and baseline balance (n = 13). Details of the risk of bias assessment for all 26 studies can be viewed in Appendix 8.

Figure 4.1 PRISMA Flow Diagram

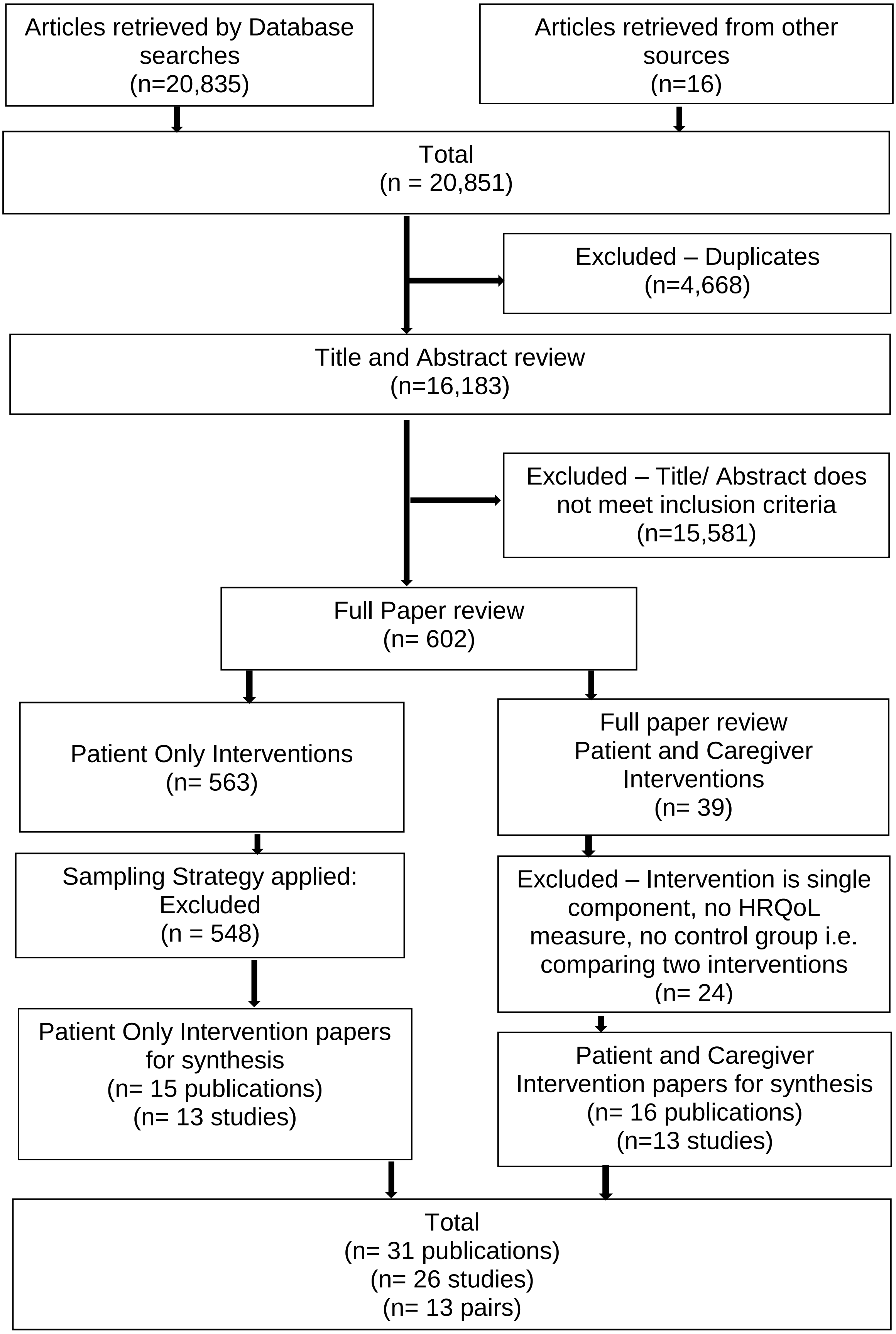


Table 4.1 Characteristics of studies that involve caregivers in intervention delivery

	Patient & Caregiver studies **N = 13**	
Study characteristics		
Publication year		
1990 - 2000	1	
2000 - 2018	12	
Study location		
Europe	8	
North America	2	
Other	3	
Sample size	**Total**	1,701
	Intervention	840
	Control	861
Single centre	6	
Duration of follow up	One month – One year	
Population characteristics		
Diagnosis		
Heart Failure	10	
COPD	3	
Age mean		
Patient	**Intervention**	70.4
	Control	70.1
Caregiver (n = 5)	**Intervention**	59.2
	Control	59.2
Sex		
Patients – Female, n = 12	682 (50%)	
Caregiver – Female, n = 4	166 (58%)	
Intervention characteristics		
Exercise as a primary component	3	
Duration of intervention	Maximum up to 52 weeks	
Frequency of intervention	Bi-weekly to 8-month maintenance session	

Length of intervention	15 minutes (telephone) – 2 hours	
Not reported	2	
Setting		
Home Based	1	
Clinic-Based	5	
Combination of home and clinic-based	5	
Not reported	2	
Risk of bias		
Random sequence generation	**High**	0
	Unclear	1
	Low	12
Allocation concealment	**High**	0
	Unclear	6
	Low	7
Blinding of participants/personnel	**High**	12
	Unclear	1
	Low	0
Blinding of outcome assessment	**High**	0
	Unclear	3
	Low	10
Incomplete data reporting	**High**	6
	Unclear	5
	Low	2
Selective reporting	**High**	2
	Unclear	2
	Low	9
Groups balanced at baseline	**High**	0
	Unclear	0
	Low	13
Did groups receive the same treatment	**High**	0
	Unclear	2
	Low	11

Table 4.2 Risk of Bias Assessment

Author (Year)	Random Sequence Allocation	Allocation concealment	Blinding of participants /personnel	Blinding of outcome assessment	Incomplete data reporting	Selective reporting	Groups balanced at baseline	Did groups receive the same treatment
Agren (2015)	Low Risk	Unclear Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
+Agren (2012) +Liljeroos (2017)	Low Risk	Unclear Risk	High Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Low Risk
Azad (2008)	Low Risk	Low Risk	High Risk	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Cline (1998)	Low Risk	Unclear Risk	High Risk	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Deek (2017)	Low Risk	Low Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
Farquhar (2016)	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	High Risk	Low Risk	Low Risk
Hasanpour (2016)	Unclear Risk	Unclear Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk	Unclear Risk
Jonsdottir (2015)	Low Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk
Marques (2015)	Low Risk	Low Risk	Unclear Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
Mårtensson (2005)	Low Risk	Unclear Risk	High Risk	Unclear Risk	High Risk	High Risk	Low Risk	Low Risk
Naylor (2004)	Low Risk	Low Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk
Srisuk (2017)	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk
Witham (2012)	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk

+ same trial

4.4.4 Methodology of caregiver involvement

Table 4.3 describes the intervention components of these studies. The predominant method of caregiver involvement was face to face (10/13 studies, 77%) with a healthcare professional and the person they were providing care for (63, 190, 295-299, 303, 305). Four studies (31%) utilised group sessions as a component of the intervention (295, 300, 302, 306). One study (8%) specifically reported that caregivers were invited to share their experiences (190). Addressing family or caregiver needs was referred to as a component of the intervention in seven studies (54%) (63, 190, 295, 298, 302, 304, 306). In two studies (15%) caregivers only participated in a part of the intervention: an educational session (306), and counselling and educational sessions on understanding heart failure (295). Three studies (23%) described the theoretical underpinnings of the intervention development (63, 297, 305):

- Stuifbergen and Pender's model of health promotion and Bandura's self-efficacy theory (63).
- Behaviour change in adults. Behaviour change wheel. Behaviour change interventions. Middle range theory of self-care of chronic illness. Orem's self-care theory. The situation-specific theory of heart failure self-care (297).
- Adult learning theory and teach-back method (305).

The remainder reported the following processes informed their intervention development: best-practice clinical guidelines (298, 303, 304), conducting a literature review (302), focus group involving family members (299), previous use of the intervention (300, 306) and previous qualitative research (190). The two studies which demonstrated the most significant gains in patient HRQoL compared to usual care were both face to face and multidisciplinary in their delivery with multi-component hard copy materials provided for patients (299, 305). Both of these studies, with the greater gains in patient HRQoL, were conducted in middle-income countries, Iran and Thailand respectively. These two studies cited theoretical underpinnings and patient and public involvement to inform their intervention development: Adult learning theory (305) and focus groups involving patient and caregivers (299).

Table 4.3 Intervention Components of studies involving caregivers

First Author Year	Theory	Material Used	Delivered by	Mode of Delivery	Setting	Tailoring of Intervention
Agren 2015	n/s	Dialogue guides Content of conversation summarised and written	Multidisciplinary	1:1 Telephone	Outpatient clinic	n/s
+Agren 2012 +Liljeroos 2017	Stuifbergen et al. Concept model based on Pender's model of health promotion Bandura's self-efficacy theory	Computer and CD ROM Written teaching materials	Nursing	1:1 Computer	Clinic Home	n/s
Azad 2008	n/s	"Partners in Care" teaching tool	Multidisciplinary	1:1 and Group	Clinic	n/s
Cline 1998	n/s	Pill Box Guidelines for HF self-mgt. Patient diary Video Presentation	Nursing	1:!	Hospital Home	Changes were made if clinically indicated
Deek 2017	Behaviour change in	Digital weighing scale Medication box	n/s	1:1	Hospital	n/s

	adults (Spring et al.) Behaviour change wheel (Michie et al.) Behaviour Change interventions (Noar et al.) Middle range theory of self-care in chronic illness (Riegel) Orem’s self-care theory The situation-specific theory of heart failure self-care (Riegel and Dickson)	Calibrated bottle Diary Bag with intervention logo				
Farquhar 2016	Medical Research Council guidelines on development and evaluation of	Mindfulness CD	Multidisciplinary	1:1 Telephone	Clinic Home	n/s

	complex interventions					
Hasanpour 2016	Family training developed from focus groups	Training material	n/s	n/s	n/s	Patients were taken to health centre/physician if required
Jonsdottir 2015	Partnership principles was the basis of the intervention	Presentations Written material	Nursing	1:1 Telephone Group	n/s	n/s
Marques 2015	Informed by a literature review	Role playing Gym access Home tasks	Multidisciplinary	1:1 Group	Primary Care Centre	n/s
Mårtensson 2005	n/s	CD ROM	Primary Health Care Physician Nursing	1:1 Telephone	Home	n/s
Naylor 2004	American Heart Association Guidelines	Audiotape Video Written summary of goal progression	Nursing	1:1 Telephone (if required)	Home Hospital (if patient hospitalised during intervention)	n/s
Srisuk 2017	Adult learning theory Teach back method	Heart Failure Manual DVD	Nursing	1:1 Telephone	Clinic Home	n/s
Witham 2012	n/s	Diary Logs	Physiotherapist	1:1 Group	Hospital Home	n/s

+ same trial

4.4.5 Meta-analysis

4.4.5.1 Impact on patient HRQoL of self-management interventions involving caregivers

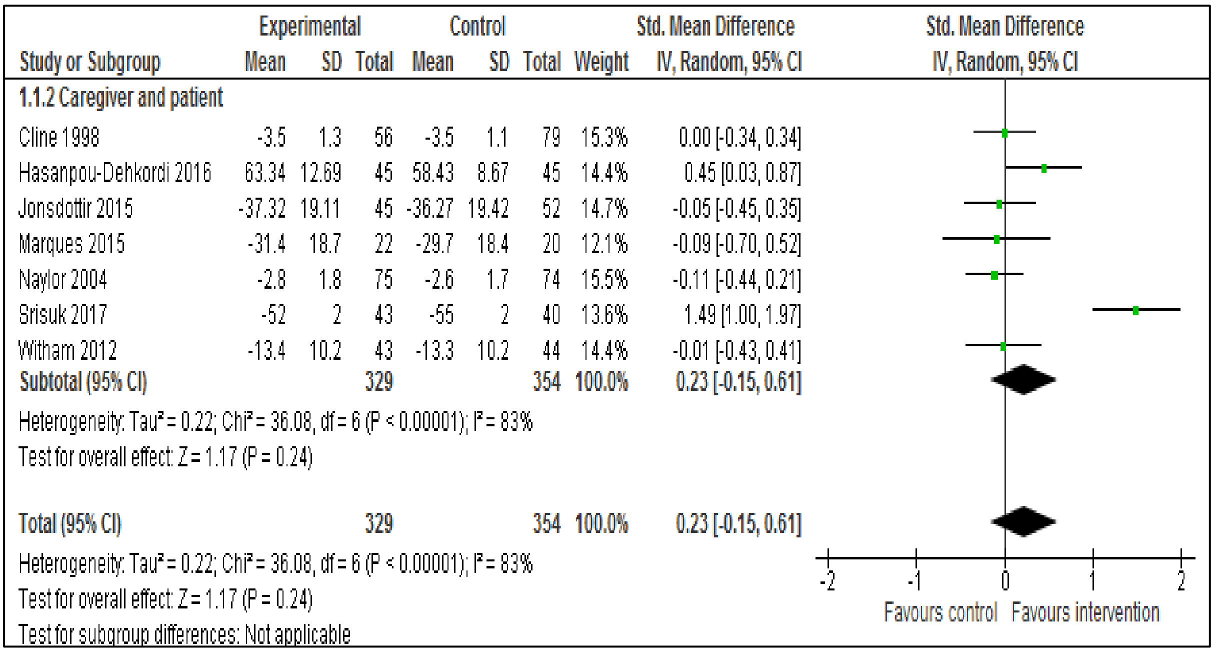
Seven studies that involved caregivers provided total HRQoL score that could be included in a meta-analysis. Outcome measures used included both disease-specific measures (i.e. Minnesota Living with Heart Failure questionnaire, St. George's respiratory questionnaire) and generic measures (Short-Form-36). While there was evidence of higher patient HRQoL with caregiver involvement in the delivery of self-management interventions compared to usual care control (mean standardised mean difference (SMD): 0.23, 95% CI: -0.15 to 0.61), this failed to reach statistical significance ($P = 0.24$).

There was evidence of a high level of statistical heterogeneity seen across studies ($I^2 = 83\%$) (Figure 4.2). A sensitivity analysis was conducted to examine caregiver included studies of HF patients only. This did not alter the interpretation of the results (mean standardised mean difference (SMD): 0.34, 95% CI: -0.16 to 0.85, $P = 0.19$, $I^2 = 88\%$). This sensitivity analysis can be viewed in Appendix 9.

Another sensitivity analysis was conducted which included studies reporting SF-36 physical and mental component subscales (PCS and MCS) (190, 297). Results remained consistent with the primary meta-analysis, i.e. PCS inclusion: SMD: 0.10, 95% CI: 0.42 to 0.62 ($P = 0.71$) and MCS inclusion: SMD: 0.19, 95% CI: -0.10 to 0.49 ($P = 0.20$). This sensitivity analysis can be viewed in Appendix 10. A high level of statistical heterogeneity was seen for both ($I^2 = 94\%$ and 79%).

A number of included studies reported >1 HRQoL domain giving a total of 136 HRQoL intervention vs control. The results of vote counting were consistent with the meta-analysis in that only 18 (13%) intervention vs control comparisons showed statistical superiority ($P<0.05$) of the intervention compared to control.

Figure 4.2 Forest plot of caregiver included studies



	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.1.2 Caregiver and patient								
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	15.3%	0.00 [-0.34, 0.34]
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	14.4%	0.45 [0.03, 0.87]
Jonsdottir 2015	-37.32	19.11	45	-36.27	19.42	52	14.7%	-0.05 [-0.45, 0.35]
Marques 2015	-31.4	18.7	22	-29.7	18.4	20	12.1%	-0.09 [-0.70, 0.52]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	15.5%	-0.11 [-0.44, 0.21]
Srisuk 2017	-52	2	43	-55	2	40	13.6%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	14.4%	-0.01 [-0.43, 0.41]
Subtotal (95% CI)			**329**			**354**	**100.0%**	**0.23 [-0.15, 0.61]**
Total (95% CI)			**329**			**354**	**100.0%**	**0.23 [-0.15, 0.61]**

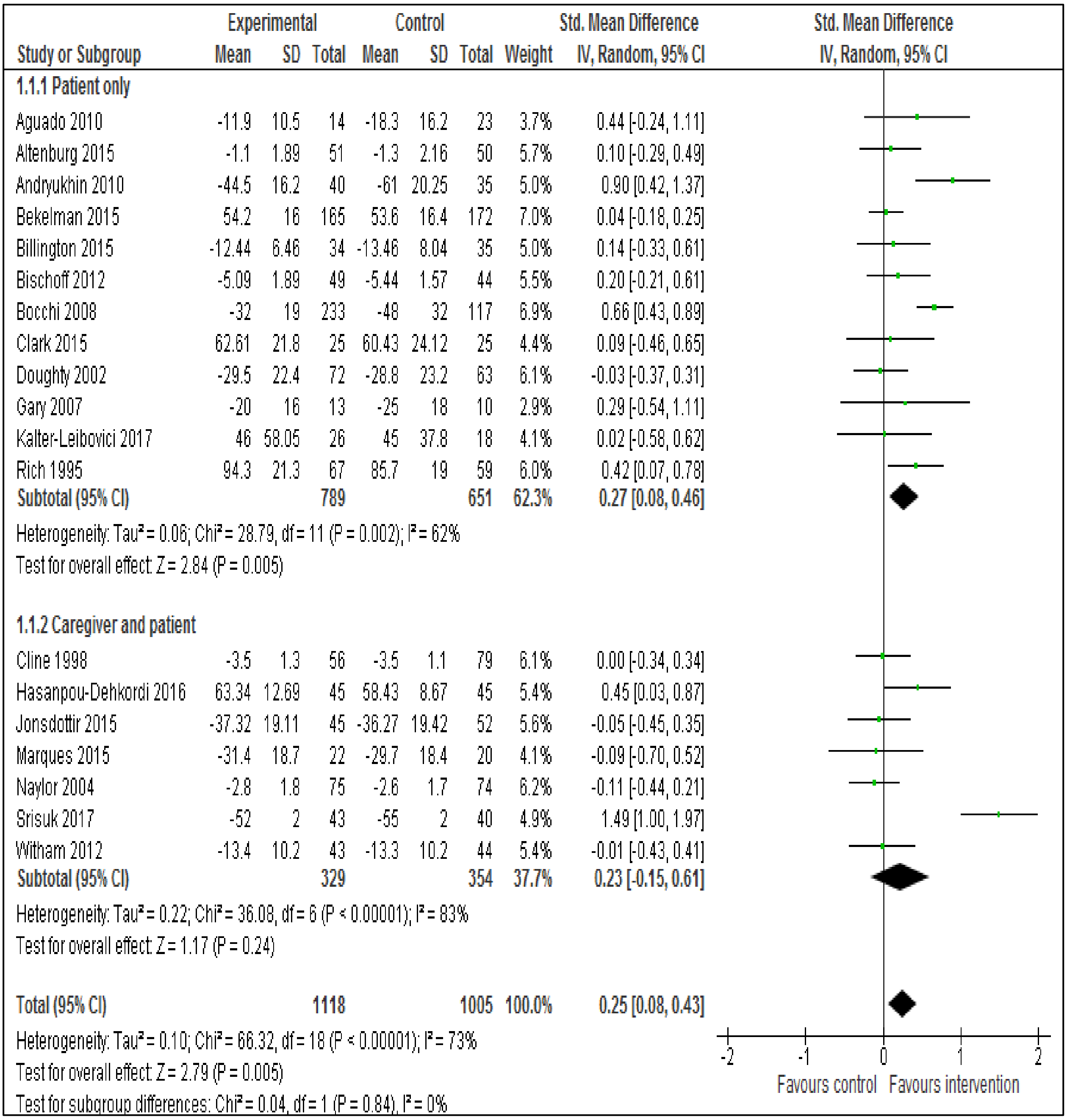
Subtotal: Heterogeneity: Tau² = 0.22; Chi² = 36.08, df = 6 (P < 0.00001); I² = 83%
Test for overall effect: Z = 1.17 (P = 0.24)

Total: Heterogeneity: Tau² = 0.22; Chi² = 36.08, df = 6 (P < 0.00001); I² = 83%
Test for overall effect: Z = 1.17 (P = 0.24)
Test for subgroup differences: Not applicable

4.4.5.2 Impact on HRQoL of self-management interventions not involving caregivers

Total HRQoL scores were provided by 12 studies that did not involve caregivers in intervention delivery. These 12 studies were included for meta-analysis. In addition to the outcome measures reported in the previous meta-analysis, patient only studies also utilised the Kansas City Cardiomyopathy Questionnaire, Clinical COPD Questionnaire, SF-12, COPD Assessment Tool, Chronic Respiratory questionnaire and a Chronic Heart Failure questionnaire. Similar to patient and caregiver studies, excluding the SF-12, all outcomes measures for HRQoL are illness-specific. Details of outcome measures are included in the summary of studies table in Appendix 7. The pooled patient HRQoL studies that included caregivers and studies that did not, were not significantly different (P = 0.84). Statistical heterogeneity was evident across both groups of studies (caregivers not involved, I^2 = 62% and caregiver included, I^2 = 83%) (Figure 4.3).

Figure 4.3 Forest plot comparing caregiver included studies with studies not involving caregivers



	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
1.1.1 Patient only								
Aguado 2010	-11.9	10.5	14	-18.3	16.2	23	3.7%	0.44 [-0.24, 1.11]
Altenburg 2015	-1.1	1.89	51	-1.3	2.16	50	5.7%	0.10 [-0.29, 0.49]
Andryukhin 2010	-44.5	16.2	40	-61	20.25	35	5.0%	0.90 [0.42, 1.37]
Bekelman 2015	54.2	16	165	53.6	16.4	172	7.0%	0.04 [-0.18, 0.25]
Billington 2015	-12.44	6.46	34	-13.46	8.04	35	5.0%	0.14 [-0.33, 0.61]
Bischoff 2012	-5.09	1.89	49	-5.44	1.57	44	5.5%	0.20 [-0.21, 0.61]
Bocchi 2008	-32	19	233	-48	32	117	6.9%	0.66 [0.43, 0.89]
Clark 2015	62.61	21.8	25	60.43	24.12	25	4.4%	0.09 [-0.46, 0.65]
Doughty 2002	-29.5	22.4	72	-28.8	23.2	63	6.1%	-0.03 [-0.37, 0.31]
Gary 2007	-20	16	13	-25	18	10	2.9%	0.29 [-0.54, 1.11]
Kalter-Leibovici 2017	46	58.05	26	45	37.8	18	4.1%	0.02 [-0.58, 0.62]
Rich 1995	94.3	21.3	67	85.7	19	59	6.0%	0.42 [0.07, 0.78]
Subtotal (95% CI)			**789**			**651**	**62.3%**	**0.27 [0.08, 0.46]**
Heterogeneity: Tau^2 = 0.06; Chi^2 = 28.79, df = 11 (P = 0.002); I^2 = 62%								
Test for overall effect: Z = 2.84 (P = 0.005)								
1.1.2 Caregiver and patient								
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	6.1%	0.00 [-0.34, 0.34]
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	5.4%	0.45 [0.03, 0.87]
Jonsdottir 2015	-37.32	19.11	45	-36.27	19.42	52	5.6%	-0.05 [-0.45, 0.35]
Marques 2015	-31.4	18.7	22	-29.7	18.4	20	4.1%	-0.09 [-0.70, 0.52]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	6.2%	-0.11 [-0.44, 0.21]
Srisuk 2017	-52	2	43	-55	2	40	4.9%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	5.4%	-0.01 [-0.43, 0.41]
Subtotal (95% CI)			**329**			**354**	**37.7%**	**0.23 [-0.15, 0.61]**
Heterogeneity: Tau^2 = 0.22; Chi^2 = 36.08, df = 6 (P < 0.00001); I^2 = 83%								
Test for overall effect: Z = 1.17 (P = 0.24)								
Total (95% CI)			**1118**			**1005**	**100.0%**	**0.25 [0.08, 0.43]**
Heterogeneity: Tau^2 = 0.10; Chi^2 = 66.32, df = 18 (P < 0.00001); I^2 = 73%								
Test for overall effect: Z = 2.79 (P = 0.005)								
Test for subgroup differences: Chi^2 = 0.04, df = 1 (P = 0.84), I^2 = 0%								

A number of included studies reported >1 HRQoL domains giving a total of 239 HRQoL intervention vs controls. The results of vote counting were consistent with the meta-analysis in that only thirteen (13%) intervention vs control comparisons showed statistical superiority (P < 0.05) compared to control. The vote counting can be viewed in Appendix 11.

4.4.5.3 Impact on caregiver HRQoL of self-management interventions involving caregivers

Due to the small sample size (n =4) reporting caregiver HRQoL in the included studies, a meta-analysis was not conducted, and instead, these findings are reported narratively. These four studies reported caregiver HRQoL outcomes (63, 190, 301, 305) using either the SF-36 or SF-12. Partners at 12 months in the psychoeducational intervention group improved their HRQoL compared to the control group (190). The study with the longest follow up at 24 months, which recorded caregiver outcomes (301), demonstrated that caregiver HRQoL scores were significantly reduced (indicating a deterioration) in physical functioning on the SF-36. A family-based education showed no difference in caregiver HRQoL between intervention and control group after six months (305). Caregiver HRQoL in this study was reported to be consistent with the general population (305).

4.5 Discussion

In accordance with the aims of this study, this review demonstrated two key findings. First, the methodology of caregiver involvement in intervention delivery was poorly reported. Second, there was no evidence from the meta-analysis of a gain in patient HRQoL in RCTs that involved caregivers in the delivery of self-management interventions for patients with HF and COPD. The pooled patient HRQoL in RCTs that included caregivers in intervention delivery compared with studies that did not include caregivers were not significantly different (P = 0.84). However, these findings need to be interpreted cautiously in the context of the methodological constraints of this study. This meta-analysis had a small number of included trials, imperfect matching between the two groups of trials and high levels of statistical heterogeneity within both groups of trials. The impact of caregiver involvement in intervention delivery on caregiver HRQoL was unable to be assessed due to lack of data.

Furthermore, patient and public involvement throughout this study may have further enhanced the formulation and interpretation of this review. Firstly by providing an insight to, and description of, formal inclusion in self-management interventions. Secondly by providing input into literature searches and search terms, and thirdly by contributing to interpretation of the meta-analysis and vote-counting (279).

These findings could be considered to be in line with Pillemer, Suitor and Wethington, who concluded that self-management interventions utilising broader theoretical evidence might have more successful outcomes and reduce the lack of clarity and inconsistent findings which occur in caregiver studies (307). They suggest that self-management intervention development should be aimed at dyads. Cho proposes a theoretical framework for understanding the effect of caregivers on elderly patients (308). Cho's framework concludes the type of caregiver, nature of the relationship, whether caregiving is direct or indirect and the internal processes of the patient (psychological, behavioural and physiological) are caregiver influences on elderly patient outcomes and should be considered in intervention development and delivery (308).

One example of comprehensive intervention development is the REACH-HF trial which will be presented later in this thesis. The intervention developers of the REACH-HF trial utilised intervention mapping to synthesise information gathered from key stakeholders: patients and caregivers, healthcare professionals, as well as theoretical frameworks (28). This intervention demonstrated a clinically significant improvement in disease-specific HRQoL (29). The depth of caregiver engagement in studies is difficult to determine as the extent of caregiver involvement is not explicitly documented. The high level of heterogeneity across caregiver studies may reflect this. The caregiver research examined in chapter 2 and 3 demonstrated that caregivers have a complex array of needs when engaging in the caregiving role (64, 309). The effects of involving caregivers in self-management interventions are variable (310). The type of intervention, the method of study and the caregiving context all need to be appreciated when involving caregivers in self-management interventions (310). The studies included in this meta-analysis adhered to some but not all of these concepts. The two studies which demonstrated statistically significant outcomes in favour of caregiver involvement (299, 305) are worth reflecting on when considering development of caregiver involved self-management interventions. Both studies were conducted in middle-income countries. Their utilisation of evidence in the intervention development, multidisciplinary delivery and provision of multi-component materials to participants are all in line with the Medical Research Council guidelines for developing and evaluating complex interventions (292). It is important to note the limitations of making any assumptions due to the small number of studies.

The indicative finding of no gain in patient HRQoL from caregiver involvement in self-management intervention delivery is in contrast to the conclusions from systematic reviews which suggest caregivers should be involved in intervention processes (64, 169, 189, 309). Zariksson et al. conducted interviews with caregivers of COPD patients two years after they participated in a one-off education session of a COPD self-management programme (311). Caregivers reported feelings of fear due to increased knowledge about the condition. They also reported feeling empowered, an increased sense of togetherness with the patient and a greater understanding of the condition. The conclusions from this intervention is that inviting caregivers to one education session is not enough, and further strategies such as psychoeducation are necessary (311). Interviews from family members who were part of a palliative care intervention for HF patients revealed how participating in the intervention resulted in feeling less worried and less responsibility as the care was shared between them and the healthcare professionals. Caregivers identified a lack of support for their own needs, concluding that interventions should also be targeted towards supporting caregivers to maintain them in their caregiving role (312).

4.5.1 Limitations

Interpreting these findings should be considered in the context of some limitations of this study. First, this review identified only a small number of studies that included caregivers in the delivery of self-management interventions. Of these, only seven reported their HRQoL outcomes so they could be included for meta-analysis. Nissen, Madsen and Zwisler reported similar findings (313). Their literature review examined health interventions targeted at relatives of HF patients. They report health service intervention studies examining patient-caregiver dyads are few in quantity and poor in quality (313). As a result, they were unable to determine the overall evidence for the effectiveness of the conducted interventions in their literature review (313).

Similar conclusions were reached from a review of research output in COPD, focusing on the burden and unmet need of caregivers (149). This review of COPD research output emphasised the high priority for more rigorous research in this area.

Second, formally involving caregivers in interventions for patients with HF or COPD is a developing area of practice and the process of caregiver engagement remains poorly reported. Descriptions of what constituted caregiver involvement in interventions differed between studies. It is important to acknowledge that caregivers may have been involved to some degree, even when not expressly reported. However, the principal aim of this review was examining the impact of explicitly and formally involving caregivers in the intervention process. Therefore, this does make a direct comparison of studies involving versus not involving caregivers difficult. A previous systematic review examining caregiver involvement in COPD patients was also limited by the lack of clarity on how caregivers were involved in interventions (314).

Third, the matching criteria had some potential limitations. While this study set out to compare the treatment effect, it was difficult due to the volume of patient only studies and the lack of caregiver included studies. A matched sampling strategy on four variables (diagnosis, publication year, geographic location and exercise as a component of the intervention) was used. However, other variables could have been applied for matching (e.g. severity of the illness, sample size and intervention duration). However, the four selected criteria were deemed to be free from bias and the most homogenous across studies facilitating a quasi-randomised sampling strategy.

Fourth, this review examined only patient outcomes in terms of HRQoL. It did not examine patient hospitalisation or mortality or caregiver burden, which may have produced different findings. However, given the lack of evidence identified by this review, it is potentially unlikely that RCTs reporting such outcomes are available. Much of the literature in this area of caregiver involvement in HF and COPD is commonly qualitative in its approach and RCTs are limited. As identified by Hartman et al. and Srisuk et al., there is a greater need for RCTs which examine patient and caregiver outcomes to determine the value of dyadic interventions in chronic illness (99, 182).

Fifth and finally, the potential for lack of efficacy of each of the individual RCT’s must be acknowledged. The RCT’s which formally included caregivers in self-management interventions may not have been as effective as may have been originally hypothesised. Additionally, intervention delivery may not have been pitched at the right level to adequately include caregivers. Lorig and Holman propose that preparatory work needs to be conducted with patients (to engage in self-management behaviour) and with service providers (to accurately pitch self-management interventions at the right population and targeting the correct needs) in order for self-management interventions to be effective (34). As identified in chapter 2, the formal inclusion of caregivers in self-management interventions is relatively new in HF and COPD research and clinical practice. Therefore, it is a possibility that in the current context of healthcare delivery, patients may be familiar with self-management interventions while caregivers might need additional preparation to engage with self-management interventions.

4.6 Conclusions

This review demonstrates that RCTs examining the impact of caregivers in interventions are limited. Additionally, those studies which have examined caregiver involvement are limited because of: poor description of the methodology of caregiver involvement, lack of recording of caregiver outcomes, lack of success in achieving anticipated outcomes in caregivers included self-management RCTs and insufficient reporting of theoretical underpinnings of the intervention development. Self-management interventions are complex and should be tailored to suit each individual’s needs (315). A key factor necessary in self-management is to facilitate the development of social support (316). This study set out to compare the impact of involving caregivers in interventions for those with HF and COPD versus interventions not involving caregivers. Within the methodological constraints of this study (i.e. relatively small number of included RCTs, imperfect matching of RCTs, and high levels of statistical heterogeneity), our results provide indicative evidence that involving caregivers in self-management interventions do not appear to further improve the HRQoL of HF or COPD patients. Greater reporting of the methodology of caregiver involvement and understanding the complexity of self-management interventions and the intricacy of the patient-caregiver dyad will facilitate the development of more robust evidence-based interventions for patients and caregivers in HF or COPD interventions. This review demonstrates the need for further empirical research involving caregivers in interventions with this population and documenting the outcomes of patients and caregiver HRQoL.

4.6.1 Implications for clinical practice

This systematic review demonstrates that while not statistically significant when compared to patient only self-management interventions, self-management interventions which include caregivers may have a positive influence on the HRQoL of HF or COPD patients. However, understanding the mechanisms as to how this can be achieved and consistently demonstrated is complex (280). From a clinical perspective, it is important that healthcare professionals acknowledge whether patients have a caregiver, and if so, whether caregivers, with the consent of patients, choose to be involved in a self-management intervention programme and in what manner they wish to be involved. Healthcare interactions involving both patients and caregivers may be challenging and require skilful communication on the behalf of the healthcare clinician (317, 318). Understanding the dynamics of the dyad can enhance healthcare clinicians' skills in how to work effectively with both patients and caregivers (247). An awareness of whether the dyad is patient-led, caregiver-led, collaborative or incongruent (172) can enhance clinicians' knowledge of how to interact with patients and caregivers in clinical appointments and orientate self-management strategies to optimise patient outcomes. These may areas of consideration for further skills training in clinical practice.

Should patients and caregivers choose to participate in healthcare appointments together, ascertaining caregiver self-efficacy is important. Caregiver confidence is one of the elements proposed as influencing caregivers in the situation specific theory of caregiver contributions to HF self-care (201). Additionally, as outlined by Bandura, a sense of mastery is key in developing skills and confidence in one's role (86). Healthcare clinicians have the skills to empower caregivers in their role which may positively influence caregiver confidence thus enhancing contributions to self-care (247, 319, 320).

4.6.2 Implications for future research

This systematic review highlights the need for further research into the involvement of caregivers in the design and development of self-management interventions for long-term illnesses. When reporting studies involving caregivers, a greater depth of information needs to be provided on what constitutes caregiver involvement and what caregiver outcomes are in addition to patient outcomes. Future studies need to be robust with greater emphasis on reporting data and consideration of how to manage risks of bias, such as blinding of participants and personnel. Addressing these issues may assist in producing a taxonomy of the type of caregiver involvement in self-management interventions for HF or COPD patients.

Chapter 5. Involvement of caregivers in a home-based self-management intervention for patients with heart failure (REACH-HF): quantitative analysis of the impact on patient and caregivers' outcomes

5.1 Introduction

The mixed-methods systematic review presented in chapter 3 concluded that, where possible, caregivers should be involved in the design and delivery of self-management interventions for patients with long-term illness such as HF or COPD (309). However, the meta-analysis reported in chapter 4 demonstrated that there is little RCT evidence currently to support that caregiver involvement improves the outcome of patients with either COPD or HF. This chapter presents a linked quantitative secondary analysis of two pooled RCTs of a home-based rehabilitation intervention (REACH-HF) for HF patients and their caregivers. HF was the focus for this secondary quantitative analysis and the subsequent qualitative analysis reported in chapter 6. This PhD was conceived to ultimately focus on the qualitative and quantitative data available from the two linked studies conducted on a home-based self-management intervention specifically designed and conducted in people with HF and their caregivers. The inclusion of patients with COPD and their caregivers (chapter 3 and 4) and patients with CAD and their caregivers (chapter 3) in the earlier parts of this research enabled an understanding of the role of caregivers in the wider context of cardiorespiratory illness.

5.1.1 The REACH-HF intervention and the involvement of caregivers

Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) is an evidence-based self-management intervention programme designed for patients with HF and their caregivers (28-30). The development of the intervention was informed by behaviour change theory (28). The REACH-HF intervention sought to improve self-management and the QoL for patients with HF and their caregivers (28, 62). The development and evaluation of REACH-HF was funded by the National Institute of Health Research (NIHR) under its Programme Grants for Applied Research scheme (Reference Number RP-PG-1210-12004) (321). There are six components of the REACH-HF intervention:

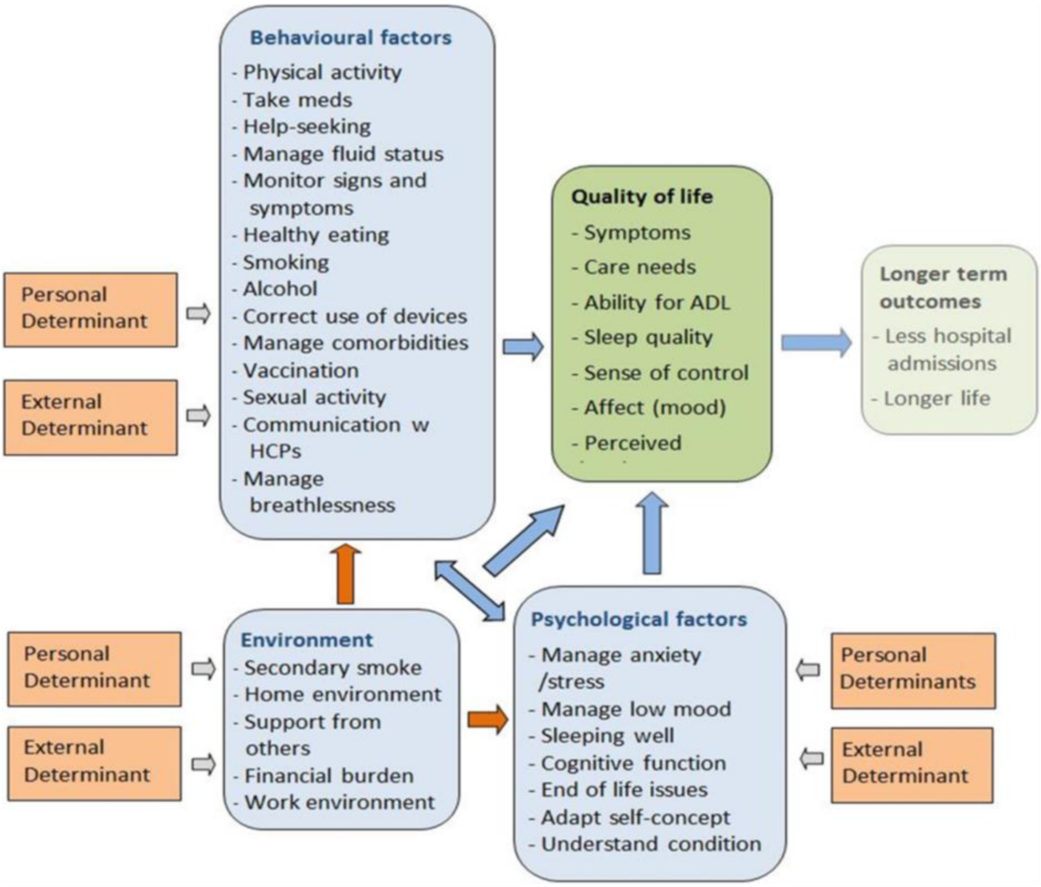
- The Heart Failure Manual (HF Manual).

- The Family and Friends Resource.
- A progress tracker.
- An exercise DVD.
- A relaxation CD.
- Facilitator intervention (face to face or telephone involving patient only or patient and caregiver).

Caregivers were key participants in the design of the REACH-HF intervention. A patient and public involvement (PPI) group consisting of caregivers and patients provided input at all stages of the intervention design. The role of the PPI group included developing the topic guide for focus groups and interviews, offering their perspective on questionnaires completed by service providers and feedback on the content of the manuals and format of the intervention delivery (28). Caregivers were also recruited to participate in semi-structured interviews and focus groups, identifying their needs and how they engage in HF self-management (62). The information gathered from these interviews and focus groups informed the content of the REACH-HF manuals (28). A logic model, which is a visual representation of the complex interlinking theoretical components demonstrating the cause and effects of an intervention (322, 323) was developed during the intervention mapping process for REACH-HF. The intervention developers referred to this as a “causal model” (28). The purpose of this model was to map the potential factors to be addressed in REACH-HF intervention sessions that could contribute to improved QoL for patients living with HF and, where present, their caregivers (28).

The REACH-HF causal model (Figure 5.1) visually depicts that behaviour, environment and psychological factors which influence QoL and which may lead to improved long-term outcomes in the management of HF (28). Personal and external determinants influence and inform patients’ and caregivers’ behaviour and psychological factors (28). These can either positively or negatively influence how patients and caregivers participate in HF self-management. Additionally, the knowledge and understanding patients and caregivers have of HF inform their approach to HF self-management. Additionally, their environment will be influenced by personal and external determinants, for example, their socioeconomic status or network of support (28). As well as personal and external circumstances informing and influencing behaviour and psychological factors, the patient and caregivers' environment influences each of these (28). Targeting behavioural factors such as medicine management, healthy eating and partaking in exercise in addition to developing strategies to manage mental health within the context of each patient and caregivers' environment was hypothesised as improving patients' and caregivers' QoL (28).

Figure 5.1 The REACH-HF logic model for the self-management of HF (Reprinted from Greaves et al. 2016, p. 4).



Healthcare professionals (with a background in nursing and physiotherapy) were trained over a 2 to 3 day course to facilitate the REACH-HF intervention over a 12-week period (28). The REACH-HF intervention was facilitated via home visits and telephone contact (28-30). Patients and caregivers were provided with the following resources: the REACH-HF main manual, a caregiver resource, a progress tracker, a pedometer, an exercise DVD and a relaxation CD (29, 30, 324). Patients were asked to track how they were feeling (physically and emotionally) using a progress tracker (324). The progress tracker was an easy to use visual guide where patients could record by circling faces that represent their emotions, physical activity and space for any further comments. Caregivers were encouraged to read the caregiver resource (324).

Facilitators were encouraged to include the following elements in the first intervention session: explain the purpose of the intervention to patients and caregivers (if present) and introduce the resources and the rationale for their inclusion in the intervention, for example using the pedometer to track steps to enhance engagement in physical activity. Facilitators were encouraged to support patients to set goals in the initial session. However, goal setting did not always occur in the initial intervention session, if this was the situation it was addressed in subsequent intervention sessions. The purpose for the subsequent intervention sessions (either home visit or via telephone) was to review or set goals, discuss what was going well and not going well and check in with caregivers regarding their knowledge, self-management and any goals they had set. The intervention sessions were underpinned by a motivational interviewing approach, which facilitators were instructed in when they attended the REACH-HF facilitator training (28, 324). An example facilitator contact sheet is presented in Appendix 12, showing what was recorded by facilitators.

The REACH-HF intervention was evaluated through two randomised controlled trials: a single centre study in patients with HF, with preserved ejection fraction (HFpEF) (ISRCTN78539530) (30) and a multicentre study in patients in HF reduced ejection fraction (HFrEF) (ISRCTN86234930) (29). A unique element of this work was the collection of data at several time points; baseline, 4 and 6 months follow-up. The REACH-HF multi-centre trial also collected data at 12 months follow-up (29, 30). This research provides a unique opportunity to understand the longitudinal experience and evolution of involving caregivers in the design and delivery of an intervention. Involving caregivers in research has been recognised by the National Institute of Health Research (325), as valuable due to the role they play within the dyad and the potential for a wider research perspective.

5.2 Research questions

This chapter addresses the following research questions:

4. Do patients with HF participating in the REACH-HF intervention, achieve a better HRQoL outcome, when they have a caregiver who is involved in the intervention delivery?
5. What are the predictors of baseline HRQoL, for caregivers of HF patients, receiving the REACH-HF intervention?
6. What is the impact of the REACH-HF intervention on caregiver outcomes?

5.3 Study design

This study used baseline data pooled from two controlled trials in HF patients, randomised to receive REACH-HF plus usual care (REACH-HF group) or usual care alone (control group): a single centre study in patients with HF, with preserved ejection fraction (HFpEF) (ISRCTN78539530) (30) and a multicentre study in patients with HF reduced ejection fraction (HFrEF) (ISRCTN86234930) (29). Patients were allocated to intervention and control in a 1:1 ratio, stratified by investigator site and minimised by baseline plasma N-terminal proB-type natriuretic peptide levels (⩽2000 vs >2000 pg/ml), to facilitate balance between the groups. Caregivers were allocated to receive the REACH-HF intervention (REACH-HF group) or not (control group), in accord with the random allocation of their patient partner.

5.3.1 Study Population

Participating HF patients were recruited from primary and secondary care settings, in five UK centres (Birmingham, Cornwall, Dundee, Gwent, and York), between January 2015 and February 2016. A total of 266 patients completed the baseline visit, 216 with HFrEF (defined as left ventricular ejection fraction <45%) and 50 with HFpEF (defined as left ventricular ejection fraction ≥45%). The patients were aged over 18 years and had a confirmed diagnosis of HF on echocardiography or angiography within the last six months. The patient inclusion criteria for the REACH-HF multi-centre RCT (HFrEF trial) were: patients over 18 years of age with left ventricular ejection fraction <45% (diagnosed via angiography or echocardiography) over the previous five years and those with no deterioration in the two weeks preceding trial enrolment which resulted in hospitalisation or changes to medication (324). Patients who participated in cardiac rehabilitation over the previous 12 months, received an implantable cardioverter defibrillator (ICD) or cardiac resynchronisation therapy (CRT) implantation or combination of both in the preceding 6 months and patients for whom participating in exercise was contraindicated as outlined by the European Society for Cardiology guidelines (326) were excluded (324). Additionally patients living in long-term care facilities, unable to travel or accommodate home visits for face to face meetings, unable to comprehend study information or outcome measures, experiencing any other significant impairments (life-limiting co-morbidities or significant psychiatric impairment) or participating in other simultaneous interventional research were excluded (324).

The inclusion details for the REACH-HF single centre pilot trial (HFpEF trial) were similar to the REACH-HF HFrEF multi-centre RCT with the key difference that patients needed to be diagnosed with left ventricular ejection fraction ≥45% 6 months prior to enrolment via echocardiography, radionuclide ventriculography or angiography (30). The exclusion criteria were as outlined in the above paragraph with the key difference being the exclusion of patients who had participated in cardiac rehabilitation 6 months prior to enrolment (30). Patients enrolled on both trials were asked to identify a caregiver (someone who provides unpaid support for them) to participate in the trial with them, if available (30, 327). Unpaid support comprised practical and emotional support, including prompting with taking medications, observing for signs and symptoms of HF, getting prescriptions, encouraging participation in social events and physical activity, helping with household tasks or providing physical care (328).

5.3.2 Data Collection

The REACH-HF trial collected both patient and caregiver outcomes. Outcome measures included in this secondary analysis are summarised below:

5.3.2.1 Patient outcome

Disease-specific HRQoL: Minnesota Living with Heart Failure Questionnaire (MLHFQ) was the primary outcome of the REACH-HF trial (29, 30). The MLHFQ is a disease-specific, patient self-reported questionnaire, examining how HF impacts the patient's daily life. Dimensions include physical and emotional health and provides a total score. Items are scored on a 0 to 5 point Likert scale. Higher ratings on the MLHFQ indicate poorer QoL. A change in score of 5 points is clinically significant on the MLHFQ. Internal consistency has been demonstrated with Cronbach's α: 0.92 for all items (329).

5.3.2.2 Caregiver outcomes

Generic HRQoL: EQ-5D-5L. The EQ-5D-5L is a generic, HRQoL, outcome measure. There are five dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Scores range from less than -0.285 to 1. Higher ratings on EQ-5D-5L indicate better QoL. The minimally significant difference in interpreting change in the UK for the EQ-5D-5L is 0.037 ± 0.008. Internal consistency has been demonstrated with Cronbach's α: 0.78 (330, 331).

Caregiver specific HRQoL: Family Quality of Life questionnaire (FAMQOL). This caregiver specific questionnaire consists of four domains examining the QoL among caregivers. Domains include: physical, psychological, social and spiritual. Higher scores on FAMQoL indicate better QoL. Internal consistency reliability has been demonstrated with Cronbach α=.89 (332).

Mental wellbeing: Hospital Anxiety and Depression Scale (HADS). HADS is a self-report scale composed of two sub-scales, one for anxiety and one for depression. Scores range from 0 to 21. Higher scores on the HADS indicates higher anxiety and depression; below 7 indicates no anxiety or depression while above 11 is an indicator of depression or anxiety (333). Cronbach's alpha for HADS-A = mean 0.83 and for HADS-D = mean 0.82 (334).

Burden: Caregiver Burden Questionnaire (CBQ). This caregiver specific questionnaire examines the impact of caregiving in HF. It has four domains, physical, social, lifestyle and emotional. Higher scores on the CBQ indicate higher burden (335). Scoring ranges from 0 to 20 = little or no burden, 21 to 40 = mild to moderate burden, 41 to 60 = moderate to severe burden, 61 to 88 = severe burden (336). Content validity has been determined for the use of the CBQ with HF caregivers (335).

Outcomes collected at baseline (pre-randomisation) and 4 and 6-months post-randomisation are included in this secondary analysis. Outcome data was collected from participants during three clinic visits at baseline and 4 months and by postal questionnaire at 6 months. At the baseline clinic visit, sociodemographic data was also collected. Data was collected by research nurses who were blinded to group allocation.

5.3.3 Ethical Considerations and data governance

Royal Cornwall Hospitals Trust (RCHT) Research Development and Innovation (RD&I) department was the sponsor of the original REACH-HF trial. The research questions addressed in this secondary analysis were within the original intentions of the REACH-HF trial. Therefore no additional ethical approvals were required (337). The initial consent obtained for the RCT and associated process evaluation was valid for the secondary analysis. This was confirmed by RCHT through the RD&I department and the College of Medicine and Health, University of Exeter Ethics Committee chair. The procedure undertaken to safeguard the management of the REACH-HF data can be viewed in Appendix 13. Data sharing and management were in line with the EU General Data Protection Regulation (GDPR) (338).

5.3.4 Patient and Public Involvement

Patient and public involvement (PPI) groups were engaged in this secondary analysis, via links with Carers Alliance Ireland and Cornwall Rural Community Charity (CRCC) Carers Team. Email communication was conducted with the Carers Alliance group in Ireland. An overview of this PhD was presented to both caregiver organisations. They informed this researcher (MN) of issues arising from working with family caregivers. Specifically, the trajectory of the illness and how caregiver needs change and are ongoing and the impact of gender, age and tension points for caregivers. The CRCC group provided information on the experiences of caregivers in rural areas, including their many challenges. These included: receiving mixed messages from health care services, changes to the welfare system, structure of public transport, the unpredictability of caring and the impact that caring has on relationships.

5.3.5 Data analysis

Stata 16 (24) was used for all statistical analysis. Initial data analysis comprised of 1) data checking, which involved analysing the mean total MLHFQ scores of both REACH-HF trials (HFpEF and HFrEF) at baseline, 4 and 6 months follow-up and comparing these to the original REACH-HF trial data, 2) baseline comparison of REACH-HF versus control group 3) analysis of dropouts by examining the demographics of completers versus dropout. There were some characteristic differences between participants who provided follow-up data at 4 and 6 months follow-up compared to those who dropped out of the intervention. These are discussed later in this chapter. The following analyses were completed for each research question:

- **Research question 1 - Do patients with HF, participating in the REACH-HF intervention, achieve a better health-related QoL outcome when a caregiver is involved in the intervention delivery?** Comparison of baseline characteristics of patients with and without caregivers using t-tests for continuous variables and chi-square analyses for binary variables. Univariate regression analysis was conducted with adjustment for baseline MLHFQ score, and stratification and centre location and minimisation variable of BNP2000 to examine whether there was an interaction between caregiver presence and effect of the REACH-HF intervention (REACH-HF vs control group) on the total MLHFQ score. The mean difference (and 95% CI) in MLHFQ total score at follow-up in the groups of patients was estimated using an interaction term (caregiver present vs no caregiver present x REACH-HF vs control). A univariate model was extended to a multivariate model, with additional adjustment of baseline patient characteristics, shown to be different between those with and without a caregiver. These characteristics were patient age, gender, main activity (employed, unemployed or unpaid occupation), number of comorbidities, number of years of heart failure diagnosis, continued education (beyond minimum school leaving age of 16), educated to degree level (or equivalent professional qualification), trial (HFpEF or HFrEF patients) and whether the patient was living alone (Table 5.4). Separate regression analyses were conducted for MLHFQ total score and MLHFQ physical and emotional sub-scores at both 4 and 6 months follow-up.

- **Research question 2 - What are the predictors of baseline health-related HRQoL for caregivers of HF patients receiving the REACH-HF intervention?** Univariate regression analysis was used to determine what baseline patient and caregiver characteristics were predictive of baseline caregiver outcome measures: HADS, FAMQoL, EQ-5D-5L, and CBQ. Higher scores on HADS indicates higher anxiety and depression. Higher scores on FAMQoL and EQ-5D-5L indicate better QoL. Higher scores on CBQ indicates an increased burden. Multivariate regression analysis was conducted, variables adjusted for included baseline patient and caregiver characteristics identified as potential confounders. Selection of patient and caregiver variables was informed by the systematic reviews completed earlier (chapter 3 and 4). These variables included: *Patient characteristics:* NYHA, years of HF diagnosis, number of comorbidities, trial (HFPEF or HFREF), age, gender, main daily activity (employed, unemployed or unpaid occupation) continued education (beyond minimum school leaving age of 16), educated to degree level (or equivalent professional qualification), living alone. *Caregiver characteristics:* Age, gender, daily activity (employed, unemployed or unpaid occupation), continued education (beyond minimum school leaving age of 16), educated to degree level (or equivalent professional qualification).

- **Research Question 3: What is the impact of the REACH-HF intervention on caregiver outcomes?** Baseline characteristics of patients and caregivers in REACH-HF vs control groups were compared using t-tests for continuous variables and chi-square analyses for binary variables. Intention-to-treat (i.e. according to baseline randomisation), all comparison of REACH-HF vs control group for caregiver outcomes of HADS, FAMQoL, EQ-5D-5L, and CBQ with complete outcome data at 4 and 6 months follow-up. Given the non-random allocation of caregivers to REACH-HF and control groups, this analysis was adjusted for both stratification and minimisation variables, baseline outcome score, patient and caregiver characteristics shown to be different between those with and without a caregiver (patient age and presence of atrial fibrillation). Secondary analyses included (1) between-group analysis of REACH-HF and control groups (2) within-group analysis of REACH-HF and control groups and (3) an exploratory subgroup analysis of predictors of change of caregiver outcomes. Three factors were estimated as potential predictors of change of caregiver outcomes; the qualitative research informed these factors (chapter 6). These included: duration of patient diagnosis (<1-year vs 1 to 2 years vs >2 years), caregiver gender (male vs female) and caregiver relationship (spouse vs non-spouse). This analysis was completed after concluding the qualitative analysis.

5.3.6 Presentation of Inferential Analyses

A p-value ≤0.05 was pre-determined to indicate statistical significance. Assuming a type 1 error of 0.05, power of 90%, a sample size of 108 patients per group for the REACH-HFrEF trial was required allowing for an attrition rate of 20% to detect clinically significant difference (324). The a minimal clinically significant difference in MLHFQ between intervention and control groups (5 points) (324). For the single centre REACH-HFpEF, a total sample size of 50 patients was recruited, this number was pre-defined to be sufficient to achieve the feasibility objectives of this trial (30).

Both REACH-HFrEF and REACH-HFpEF trial data sets were combined for the purposes of this secondary analysis giving a total of 266 patients and 118 caregivers. For this combined data set, between-group comparisons are reported as mean differences. Continuous outcomes are reported using mean 95% confidence intervals (CIs) and binary outcomes; odds ratios are reported with 95% CIs. P-values are reported to 3 decimal places. For interaction analyses, global p-values are reported for interaction effects between intervention status and covariates.

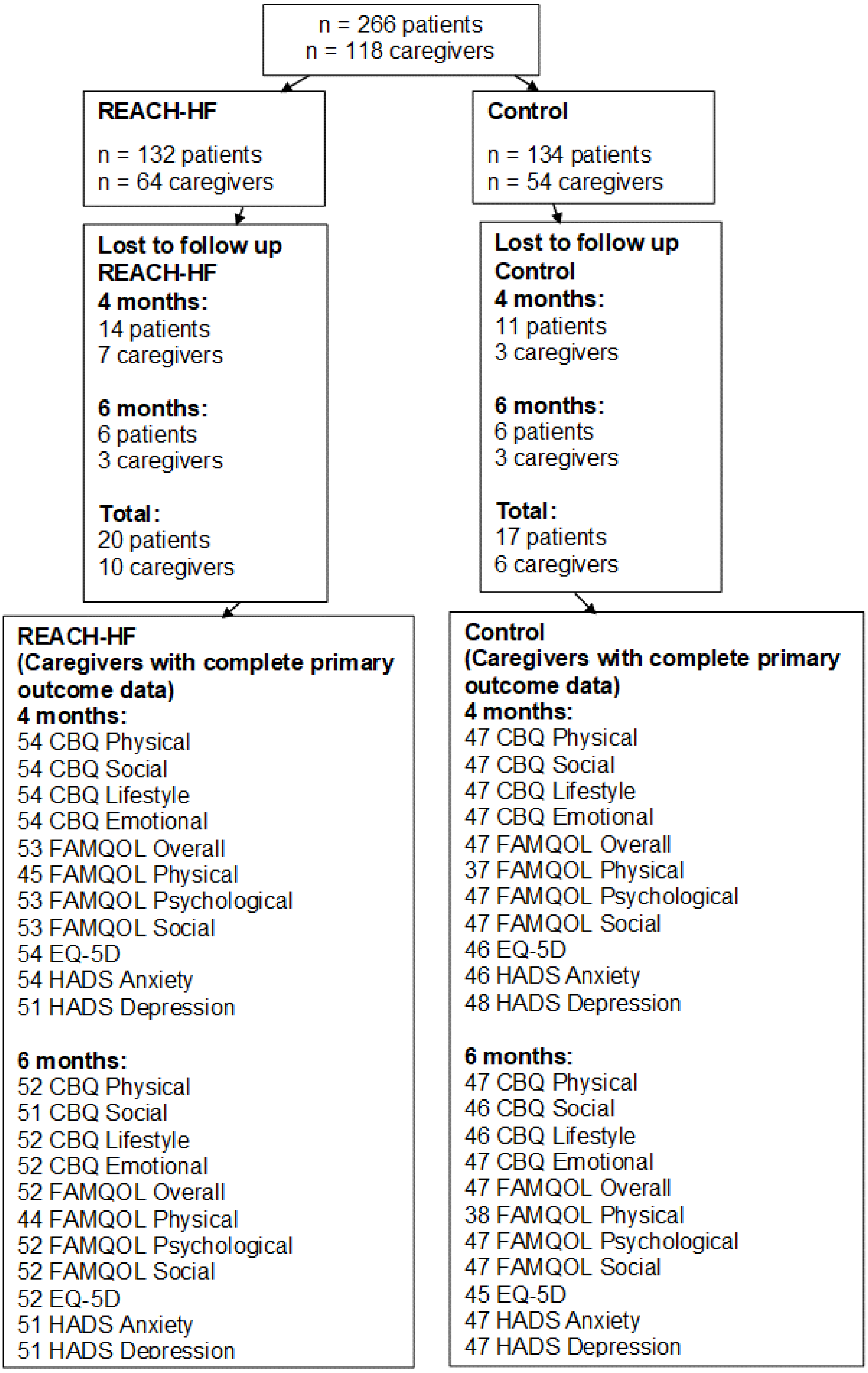
5.3.7 Missing Data

The primary research team handled missing data, therefore, any issues with missing data were addressed before receipt of the data set for secondary analysis. According to the agreed data analysis plan by the Trial Steering committee and Data Management committee primary analysis was based on a between-group, intention-to treat basis for all participants (patients and caregivers) with complete outcome data at 12 months (29, 324). Therefore, there was no imputation of missing data in the combined trial set analysed here (327).

5.4 Results

Study enrolment, allocation and follow-up of study participants are summarised in the CONSORT flow diagram in Figure 5.2.

Figure 5.2 CONSORT diagram summarising the flow of patients and caregivers across the pooled REACH-HF trials



5.4.1 Research question 1 - Do patients with HF enrolled in the REACH-HF trial achieve better health related quality of life outcomes when a caregiver is involved in the intervention delivery?

The HRQoL outcomes of patients who participated in the REACH-HF intervention versus control group are presented in section 5.4.2. The demographic data for patients enrolled in the REACH-HF trial (intervention and control groups) are presented in 5.4.3. The HRQoL outcomes of those patients who participated in REACH-HF (intervention group) with and without a caregiver are then presented in section 5.4.4.

5.4.2 Effect of REACH-HF intervention on patient MLHFQ

The between-group comparison of patients who received the intervention (REACH-HF) and patients who were in the control group across all domains of the MLHFQ at 4 and 6 months follow-up demonstrated differences in MLHFQ total score and physical and emotional sub-score in favour of the REACH-HF group at both 4 and 6 months follow-up. This indicates better HRQoL at 4 and 6 months follow-up in favour of patients who received the REACH-HF intervention compared to patients in the control group. These between-group comparisons are presented in Table 5.1.

Table 5.1 Summary of patient MLHFQ scores (total and sub-score) in REACH-HF and control group at baseline 4 and 6-months follow-up

Outcome Measure	Baseline		4 months follow-up			6 months follow-up		
	REACH-HF Mean (SD), N	Control Mean (SD), N	REACH-HF Mean (SD), N	Control Mean (SD), N	Mean between-group difference Baseline v 4 months (95% CI), p value	REACH-HF Mean (SD), N	Control Mean (SD), N	Mean between-group difference Baseline v 6 months, p value
MLHFQ Total	33.8 (24.5), 132	29.9 (22.9),133	25 (21), 117	29.6 (24.3),123	7.2 (3.2 to 11.1), < 0.0001	29.1 (21.5), 111	31.2 (23.7), 117	5.6 (1.4 to 9.9), 0.010
MLHFQ Physical	17.4 (11.9), 132	15.6 (11.5),134	13.1 (10.3), 117	15.6 (11.8),123	3.6 (1.8 to 5.5), < 0.0001	15 (10.9),111	15.9 (11.8), 117	2.2 (0.1 to 4.4), 0.042
MLHFQ Emotional	7.7 (7.6), 132	6.9 (6.9), 134	5.4 (6.4), 117	6.9 (7.2), 123	1.9 (0.7 to 3.2), 0.002	6.3 (6.6), 111	7.2 (7.2), 117	1.5 (0.2 to 2.8), 0.025

5.4.3 Demographic data of patients

Baseline patient demographic data for all patients enrolled in the REACH-HF trial are presented in Table 5.2. These patient demographic data are presented as patients with a caregiver and patients without a caregiver. Most HF patients in both groups were male, 73.1% (with a caregiver group), versus 70.9% (without a caregiver), predominantly white (92.6% and 99.1%) and diagnosed with NYHA II HF (61.7% and 55.5%). Patients were more likely to be married if they had a caregiver (78.6% vs 49.6%). Patients primarily had attained a post-school education (45.6% and 50.4%) and were retired (78.5% and 85.5%) at the time of participating in REACH-HF. There was no evidence of a statistically significant difference (p > 0.05) between the two groups of patients with and without a caregiver across the variables of gender, age, ethnicity, relationship status, domestic residence, type of HF, NYHA status, cause of HF, number of co-morbidities, previous myocardial infarction, presence of hypertension, diabetes mellitus, chronic renal impairment, time since diagnosis, main activity, education history and pro-BNP levels. There was evidence of a difference (p

< 0.05) between the groups in the proportion of patients with previous atrial fibrillation/atrial flutter 41.6% (without a caregiver) vs 55.5% (with caregiver).

Table 5.2 Comparison of patients' demographic and clinical characteristics between patients with and without a caregiver

Patients (n = 266)	Patient without a caregiver n (%) N = 149	Patient with caregiver n (%) N = 117	P-value	Total
Gender n (%)				
Male	109 (73.1)	83 (70.9)	0.149	192 (72.18)
Age (years) Mean (SD)	70.6 (10.9)	70.6 (10.1)	0.475	70.56 (0.65)
Ethnic group: white	138 (92.6)	116 (99.1)	0.492	254 (95.49)
Relationship status n (%)			0.639	
Single	22 (14.7)	9 (7.6)		31 (11.65)
Civil partnership	2 (1.3)	1 (0.8)		3 (1.13)
Widowed/surviving civil partner	35 (23.4)	11 (9.4)		46 (17.29)
Married	74 (49.6)	92 (78.6)		166 (62.41)
Divorced/civil partnership dissolved	16 (10.7)	4 (3.4)		20 (7.52)
Domestic residence n (%)				
Lives alone	58 (38.9)	15 (12.8)	0.832	73 (27.44)
Live with another	91 (61)	102 (87.1)		193 (72.56)
HFpEF diagnosis n (%)	25 (18.94)	25 (18.66)	0.953	50 (18.80)
NYHA Status:			0.621	
NYHA I	26 (17.4)	19 (16.2)		45 (16.92)
NYHA II	92 (61.7)	65 (55.5)		157 (59.02)
NYHA III	30 (20.1)	33 (28.2)		63 (23.68)
NYHA IV	1 (0.6)	-		1 (0.38)
Cause of heart failure* n (%)			0.283	
Ischaemic	64 (42.9)	58 (49.5)		122 (45.86)
Non-ischaemic	71 (47.6)	55 (47)		126 (47.37)
Unknown	5 (3.3)	3 (2.5)		8 (3.01)
Not Classified	9 (6)	1 (0.8)		10 (3.76)
Number of comorbidities n (%)			0.667	
0	82 (55)	56 (47.8)		138 (51.88)
1	45 (30.2)	45 (38.4)		90 (33.83)
2	14 (9.4)	12 (10.2)		26 (9.77)

3	8 (5.3)	2 (1.7)		10 (3.76)
4	-	2 (1.7)		2 (0.75)
Previous myocardial infarction	34 (22.8)	42 (35.9)	0.202	76 (28.57)
Previous atrial fibrillation/atrial flutter	62 (41.6)	65 (55.5)	**0.026**	127 (47.74)
Hypertension	64 (42.9)	55 (47)	0.332	119 (44.74)
Diabetes mellitus	45 (30.2)	30 (25.6)	0.628	75 (28.20)
Chronic renal impairment	27 (18.1)	19 (16.2)	0.320	46 (17.29)
Time since diagnosis of heart failure (years)			0.941	
<1	40 (26.8)	33 (28.2)		79 (29.69)
1 to 2	30 (20.1)	18 (15.3)		48 (18.04)
>2	70 (53)	66 (56.4)		136 (51.12)
Main activity n (%)			0.808	
In employment or self-employment	26 (17.4)	11 (9.4)		37 (13.91)
Unemployed	5 (3.4)	5 (4.3)		10 (3.76)
Unpaid Occupation (carer, housework, student)	1 (0.7)	1 (0.8)		2 (0.75)
Retired (medical/disability/age)	117 (78.5)	100 (85.5)		217 (81.58)
Education n (%)				
Post-school	68 (45.6)	59 (50.4)	0.459	127 (47.74)
Degree	36 (24.2)	35 (29.9)	0.372	71 (26.69)
Pro-BNP levels n(%)				
≤2000 pg/mL	120 (80.5)	95 (81.2)	0.923	215 (80.83)
>2000 pg/mL	29 (19.5)	22 (18.8)	0.923	51 (19.17)

*** Cause of HF determined by Principal Investigator**

5.4.4. Comparison of REACH-HF intervention in patients with and without a caregiver

Summary statistics (means and SDs) for MLHFQ total and sub-scores in the groups of patients with and without a caregiver at baseline and 4 and 6-months follow-up are shown in Table 5.3. Univariate analysis showed a mean difference of 10.6 points (10.6, CI 95% = 2.7 to 18.4, p = 0.008) in the MLHFQ total score, in favour of patients with a caregiver compared to those without a caregiver (Table 5.4). This indicates patients who participated in REACH-HF with a caregiver achieved better

HRQoL outcomes compared to patients participating in the intervention without a caregiver. This interaction in favour of patients with caregivers on MLHFQ total score was also seen at 6 months follow-up (9.6, CI 95% = 1.1 to 18.2, p = 0.026) and for MLHFQ physical and emotional outcomes sub-scores at 4 and 6 months follow-up (Table 5.4). Multivariate analysis demonstrated (when adjusted for variables shown to be different at baseline) this pattern of interaction effect in favour of patients with a caregiver remained at 4 months follow-up. However, this positive effect was not sustained at 6 months follow-up (2.2, -0.5 to 4.9 p = 0.113).

Table 5.3 Summary of patient MLHFQ scores (total and sub-scores) in patients without and with a caregiver at baseline 4 and 6-months follow-up

Outcome Measure	**Baseline**		**4 months follow-up**		**6 months follow-up**	
	Without a Caregiver Mean (SD),N	**With a caregiver Mean (SD),N**	**Without a Caregiver Mean (SD),N**	**With a caregiver Mean (SD),N**	**Without a Caregiver Mean (SD),N**	**With a caregiver Mean (SD),N**
MLHFQ Total	29.1 (1.8), 149	35.2 (2.3), 117	25.4, (1.8), 134	29.9, (2.4)107	27.1, (1.9), 125	33.7, (2.4), 104
MLHFQ Physical	15.5 (0.9), 149	17.8 (1.1), 117	14.0, (0.9),134	14.9 (1.1), 107	14.7, (0.9), 124	16.4 (1.1), 104
MLHFQ Emotional	6.2 (0.6), 149	8.7 (0.7), 117	5.2 (0.5), 134	7.3 (0.7), 107	5.6, (0.5), 124	8.1 (0.7), 104

Table 5.4 Comparison of REACH-HF vs control treatment effect on MLHFQ (total and sub-score) in patients with and without a caregiver

	4-months REACH-HF vs control treatment effect Mean (95% CI) N		**Interaction[1] Mean (95% CI) N, P-value**	**Adjusted Interaction[2] Mean (95% CI) N, P-value**
	Without a caregiver	**With a caregiver**		
MLHFQ Total	2.3 (-2.5 to 7.0) 134	12.7 (6.2 to 19.3) 107	10.6 (2.7 to 18.4) 241, P = 0.008	9.9 (1.9 to 18.0) 241, P = 0.015
MLHFQ Physical	1.2 (-1.1 to 3.6) 134	6.3 (3.3 to 9.2) 107	5.0 (1.3 to 8.8) 241, P = 0.009	4.6 (0.8 to 8.4) 241, P = 0.017
MLHFQ Emotional	0.5 (-0.9 to 1.9) 134	3.8 (1.8 to 5.9) 107	3.3 (0.9 to 5.7) 241, P = 0.008	3.2 (0.7 to 5.7) 241, P = 0.014
	6-month REACH-HF vs control treatment effect Mean (95% CI) N		**Interaction Mean (95% CI) N, P-value**	
	Without a caregiver	**With a caregiver**		
MLHFQ Total	1.2 (-4.4 to 6.9) 125	11.5 (4.9 to 18.1) 104	9.6 (1.1 to 18.2) 229, P = 0.026	7.4 (-1.2 to 16.0) 229, P = 0.092
MLHFQ Physical	0.01 (-2.9 to 3.0) 124	4.7 (1.6 to 7.9) 104	4.5 (0.2 to 8.9) 228, P = 0.041	3.4 (-0.9 to 7.8) 228, P = 0.125
MLHFQ Emotional	0.2 (-1.4 to 1.9) 124	3.2 (1.1 to 5.4) 104	2.9 (0.3 to 5.6) 228, P = 0.029	2.2 (-0.5 to 4.9) 228, P = 0.113

1. Interaction term for between REACH-HF control MLHFQ treatment effect at 4 or 6-months (adjusted for baseline MLHFQ difference) by caregiver presence
2. Interaction term also adjusted for baseline patient characteristics including atrial fibrillation/atrial flutter

5.4.5 Research Question 2 – What are the predictors of health related quality of life for caregivers of HF patients in REACH-HF?

5.4.6 Demographics data of caregivers

Table 5.5 provides a summary of the caregivers' demographic data for REACH-HF participants and control group participants. Caregivers were primarily female (78%), spouse/partner of the patient (77%), and retired (68%). The only statistically significant difference between intervention and control groups was caregiver age.

Table 5.5 Comparison of baseline demographics of caregivers in REACH-HF vs control groups

	REACH-HF Group (n = 63)	**Control Group (n= 54)**	**P-value**	**Total**
Caregivers (n = 117)				
Gender n (%)				
Female	50 (79.4)	41 (76)	0.658	91 (77.78)
Age (years) Mean (SD)	62.2 (1.8)	67.5 (1.5)	**0.0314**	64.67 (1.2)
Relationship to patient n (%)			0.924	
Wife	37 (58.73)	34 (62.96)		71 (60.68)
Husband	10 (15.87)	7 (12.96)		17 (14.53)
Daughter	7 (11.11)	5 (9.26)		12 (10.26)
Son	1 (1.59)	3 (3.70)		3 (2.56)
Friend	3 4.76)	1 (1.85)		5 (3.42)
Sibling	3 (4.76)	2 (3.70)		5 (4.27)
Other relative	2 (3.17)	3 (5.56)		5 (4.27)
Caregiver Main activity n (%)			0.457	
In employment or self-employment	19 (30.16)	10 (18.52)		29 (24.79)
Unemployed	2 (3.17)	3 (5.56)		5 (4.27)
Unpaid Occupation (carer, housework, student)	2 (3.17)	1 (1.85)		3 (2.56)
Retired (medical/disability/age)	40 (63.49)	40 (74.07)		80 (68.38)
Education n (%)				
Post- school	30 (47.62)	27 (50.00)	0.799	57 (48.72)
Degree	17 (26.98)	20 (37.04)	0.247	37 (31.62)
Location n (%)			0.999	
Birmingham	6 (3.78)	24 (12.96)		14 (11.97)
Cornwall	29 (18.27)	10 (5.40)		53 (45.30)
South Wales	13 (8.19)	8 (4.32)		23 (19.66)
York	15 (9.45)	12 (6.48)		27 (23.08)

5.4.7 Univariate Analysis

Variables found to be statistically significant (P<0.05) in the univariate regression analysis included: an increase in NYHA severity was associated with poorer caregiver general quality of life and burden sub-scores (EQ-5D-5L, FAMQoL overall, FAMQoL psychological and CBQ sub-scores). Each additional patient comorbidity was associated with an increase in caregiver anxiety (HADS-A) and a deterioration in quality of life sub-scores (FAMQoL Psychological). Increased years of HF diagnosis was associated with a decline in quality of life (FAMQoL overall and FAMQoL social).

Patient unemployment was associated with an increase in caregiver anxiety and CBQ sub-scores, while caregiver anxiety and depression were associated with identifying unpaid occupation as their main activity. Increased patient age was associated with improved caregiver psychological health. Furthermore, patients living alone was associated with a reduction in caregiver quality of life (EQ-5D-5L).

Caregiving of female patients was associated with better quality of life (FAMQoL overall and FAMQoL Psychological), and less burden (CBQ physical and social). Poorer psychological health on FAMQoL sub-scores was associated with being a female caregiver. The predictors of caregiver outcomes in the univariate regression analysis are presented in Appendix 14.

5.4.8 Multivariate Analysis

Variables found to be statistically significant ($p < 0.05$) in the univariate regression analysis were inputted to the multivariate regression model for each caregiver outcome. These variables included patient NYHA status, age, gender, main activity, number of comorbidities, years of heart failure diagnosis, caregiver gender and caregiver main activity. The predictors of caregiver outcomes in the multivariate regression analysis are presented in Table 5.6 to Table 5.15. Patient factors were more frequently identified as predictors of caregiver outcomes at baseline with caregiver main activity the only identified predictor of caregiver outcomes as baseline.

Patient NYHA status was a predictor ($p < 0.05$) of caregiver outcomes for anxiety, quality of life (FAMQOL and EQ5D5L) and burden (emotional, social and lifestyle). Caregivers of patients with a higher NYHA status (i.e. increasing illness severity) scored a mean of 1.5 points higher on the anxiety subsection of the HADS scale (1.5, -0.3 to 2.6, $p = 0.013$) indicating these caregivers were experiencing more anxiety than those caring for patients with a lower NYHA status. A higher NYHA status was associated with a reduction in quality of life. Caregivers of patients with a higher NYHA status scored a mean of 4.6 points less in comparison to caregivers of patients with lower NYHA status on the FAMQoL overall (-4.6, -7.4 to 1.8, p = 0.002). Caregivers of patients with a higher NYHA status also had a reduction of a mean of 2.1 points on the psychological subscale of the FAMQoL (-2.1, 3.3 to 0.9, p = 0.001) and a mean reduction of 1.3 points on the Social subscale of the FAMQoL (-1.3, 2.4 to 0.2, p = 0.017). This indicates caregivers of patients with increased illness severity reported poorer quality of life than those caregivers of patients with lower illness severity. A reduction in quality of life for caregivers of patients with increased illness severity was reported on the EQ5D5L scale. Caregivers scored a mean of -0.1 points less in comparison to caregivers of patients with lower NYHA status (-0.1, -0.1 to 0.0, p = 0.002). An increase in caregiver burden was seen across the domains of emotional, social and lifestyle burden. Caregivers of patients with higher NYHA status all reported a mean increase of 5.9 (emotional burden), 0.5 (social burden) and 1.3 (lifestyle burden) on the CBQ in comparison to caregivers of patients with lower NYHA status. The highest mean increase in burden was reported for emotional burden (5.9, 2.3 to 9.4, p = 0.002), followed by lifestyle burden (1.3, 0.1 to 2.5, p = 0.028) and finally social burden (0.5).

Other specific baseline patient and caregiver factors found to be predictive of caregiver outcomes included the following:

Patient Factors

Years of HF diagnosis: Caregivers of patients who had an additional year of diagnosis scored a mean reduction of 0.5 points on the FAMQoL overall. This indicates with each additional year of living with HF caregivers reported a reduction in quality of life (-0.5, -0.9 to -0.0, p = 0.040). A reduction was also reported on the social subscale of the FAMQoL. Caregivers of patients living with HF longer reported a reduction of 0.3 points with each additional year of living with HF (-0.3, -0.4 to -0.1, p = 0.001).

Gender: Caregivers of female patients reported a mean increase of 0.1 points on the EQ5D5L in comparison to caregivers of male patients (0.1, 00 to 0.2, p = 0.004), indicating an increase in quality of life. Additionally, caregivers of female patients reported less physical and social burden, they recorded a mean reduction of 2.7

points in physical burden on the CBQ in comparison to caregivers of male patients (-2.7, -5.1 to -0.2, p = 0031). They reported a mean reduction of 1.1 points in social burden in comparison to caregivers of male patients (-1.1, -2.0 to -0.1, p = 0.025).

Living alone status: Caregivers of patients who lived alone scored a mean of -0.2 points less than caregivers of patients who lived with someone (-0.2, -0.3 to -0.1, p = 0.001). This indicates that the caregivers of patients who lived alone reported a poorer quality of life.

Main activity status: Caregivers of patients who were unemployed reported a mean score of 2.6 higher for social burden on the CBQ social subscale in comparison to caregivers who were in employment (2.6, 0.8 to 4.4, p = 0.005). Caregivers of patients engaged in what they identified as unpaid occupation (student/housework/volunteer) reported a mean score of 3.7 points higher for social burden on the CBQ social subscale (3.7, 0.2 to 7.2, p = 0.040).

Caregiver factors

Main activity status: Caregivers who were in an unpaid occupation (student/housework/volunteer) scored a mean of 6.2 points higher on the depression subscale of the HADS in comparison to caregivers who were in employment (6.2, 0.4 to 11.9, p = 0.035). This indicates that caregivers in an unpaid occupation recorded higher mean scores for experiencing depressive symptoms in comparison to caregivers who were in paid employment.

Table 5.6 Patient and caregiver predictors of caregiver outcomes on the HADS Anxiety at baseline: Multivariate regression analysis

Variables	**Unstandardized beta coefficient (95% CI)**	**P-value**
HADS – Anxiety **N= 117**		
Patient Factors		
Patient age	-0.0 (-0.2 to 0.0)	0.295
Patient gender	0.96 (-1.2 to 3.1)	0.380
NYHA	**1.5 (-0.3 to 2.6)**	**0.013**
Patient Main activity:		
Employment	REF	REF
Unemployed	3.9 (-0.3 to 8.0)	0.068
Unpaid occupation (student/housework/volunteer)	4.3 (-3.7 to 12.4)	0.285
Retired (age/ill health)	2.6 (-0.4 to 5.5)	0.090

No. of Comorbidities	0.5 (-0.3 to 1.5)	0.217
Years of HF diagnosis	0.0 (-0.2 to 0.2)	0.933
Live alone	0.1 (-2.2 to 2.4)	0.934
Caregiver Factors		
Caregiver gender	1.6 (-0.7 to 3.9)	0.180
Caregiver main activity:		
Employment	REF	REF
Unemployed	0.0 (-4.4 to 4.4)	0.997
Unpaid occupation (student/housework/volunteer)	3.5 (-1.2 to 8.3)	0.143
Retired (age/ill health)	-1.4 (-2.1 to 1.8)	0.887

Table 5.7 Patient and caregiver predictors of caregiver outcomes on the HADS Depression at baseline: Multivariate regression analysis

HADS- Depression **N = 102**		
Patient Factors		
Patient age	0.1 (-0.0 to 0.2)	0.247
Patient gender	-1.4 (-4.2 to 1.4)	0.334
NYHA	1.2 (-0.2 to 2.7)	0.105
Patient Main activity:		
Employment	REF	REF
Unemployed	6.5 (-1.5 to 14.6)	0.108
Unpaid occupation (student/housework/ volunteer)	5.9 (-4.0 to 15.7)	0.239
Retired (age/ill health)	-3.1 (-7.0 to 0.9)	0.124
No. of Comorbidities	-0.4 (-1.5 to 0.7)	0.476
Years of HF diagnosis	0.1 (-0.2 to 0.3)	0.516
Live alone	-2.3 (-5.5 to 0.9)	0.151
Caregiver Factors		
Caregiver gender	0.5 (-2.6 to 3.6)	0.756
Caregiver main activity:		
Employment	REF	REF
Unemployed	-0.6 (-6.5 to 5.3)	0.844
Unpaid occupation (student/housework/volunteer)	**6.2 (0.4 to 11.9)**	**0.035**
Retired (age/ill health)	1.0 (-1.5 to 3.6)	0.419

Table 5.8 Patient and caregiver predictors of caregiver outcomes on the FAMQoL Overall at baseline: Multivariate regression analysis

FAMQoL Overall **N = 117**		
Patient Factors		
Patient age	0.1 (-0.1 to 0.3)	0.439
Patient gender	4.3 (-1.0 to 9.6)	0.111

NYHA	**-4.6 (-7.4 to -1.8)**	**0.002**
Patient Main activity:		
Employment	REF	REF
Unemployed	-5.9 (-16.1 to 4.3)	0.253
Unpaid occupation (student/housework/ volunteer)	10.9 (-8.8 to 30.6)	0.274
Retired (age/ill health)	4.1 (-3.1 to 11.5)	0.261
No. of Comorbidities	-0.4 (-2.6 to 1.9)	0.749
Years of HF diagnosis	**-0.5 (-0.9 to -0.0)**	**0.040**
Live alone	-1.6 (-7.3 to 4.0)	0.565
Caregiver Factors		
Caregiver gender	-1.6 (-7.3 to 4.1)	0.588
Caregiver main activity:		
Employment	REF	REF
Unemployed	5.0 (-5.8 to 15.8)	0.364
Unpaid occupation (student/housework/volunteer)	-4.1 (-15.7 to 7.5)	0.483
Retired (age/ill health)	-3.3 (-8.1 to 1.4)	0.163

Table 5.9 Patient and caregiver predictors of caregiver outcomes on the FAMQoL Psychological at baseline: Multivariate regression analysis

FAMQoL Psychological **N = 117**		
Patient Factors		
Patient age	0.1 (-0.0 to 0.2)	0.245
Patient gender	2.2 (-0.1 to 4.4)	0.060
NYHA	**-2.1 (-3.3 to -0.9)**	**0.001**
Patient Main activity:		
Employment	REF	REF
Unemployed	-3.4 (-7.8 to 1.0)	0.126
Unpaid occupation (student/housework/ volunteer)	2.6 (-5.8 to 11.1)	0.535
Retired (age/ill health)	2.0 (-1.1 to 5.1)	0.213
No. of Comorbidities	-0.3 (-1.2 to 0.7)	0.575
Years of HF diagnosis	-0.0 (-0.2 to 0.2)	0.970
Live alone	-0.5 (-3.0 to 1.9)	0.659
Caregiver Factors		
Caregiver gender	-1.9 (-4.3 to 0.6)	0.128
Caregiver main activity:		
Employment	REF	REF
Unemployed	1.2 (-3.4 to 5.9)	0.593
Unpaid occupation (student/housework/volunteer)	-2.7 (-7.7 to 2.3)	0.285
Retired (age/ill health)	-0.7 (-2.8 to 1.3)	0.463

Table 5.10 Patient and caregiver predictors of caregiver outcomes on the FAMQoL Social at baseline: Multivariate regression analysis

FAMQoL Social **N = 117**		
Patient Factors		
Patient age	0.1 (-0.0 to 0.1)	0.210
Patient gender	0.9 (-1.1 to 2.9)	0.375
NYHA	**-1.3 (-2.4 to -0.2)**	**0.017**
Patient Main activity: Employment Unemployed Unpaid occupation (student/housework/ volunteer) Retired (age/ill health)	 REF -0.7 (-4.6 to 3.1) 4.1 (-3.3 to 11.5) 0.7 (-2.1 to 3.4)	 REF 0.704 0.274 0.635
No. of Comorbidities	0.0 (-0.8 to 0.8)	0.965
Years of HF diagnosis	**-0.3 (-0.4 to -0.1)**	**0.001**
Live alone	-0.4 (-1.9 to 2.3)	0.718
Caregiver Factors		
Caregiver gender	0.2 (-1.9 to 2.3)	0.859
Caregiver main activity: Employment Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 REF 0.2 (-3.9 to 4.2) -1.5 (-5.8 to 2.9) -1.0 (-2.8 to 0.8)	 REF 0.929 0.505 0.272

Table 5.11 Patient and caregiver predictors of caregiver outcomes on the EQ5D5L at baseline: Multivariate regression analysis

EQ5D5L **N = 117**		
Patient Factors		
Patient age	-0.0 (-0.0 to 0.0)	0.535
Patient gender	**0.1 (0.0 to 0.2)**	**0.004**
NYHA	**-0.1 (-0.1 to -0.0)**	**0.002**
Patient Main activity: Employment Unemployed Unpaid occupation (student/housework/ volunteer) Retired (age/ill health)	 REF -0.0 (-0.2 to 0.2) -0.1 (-0.5 to 0.2) 0.1 (-0.0 to 0.2)	 REF 0.742 0.527 0.130
No. of Comorbidities	-0.0 (-0.0 to 0.0)	0.681
Years of HF diagnosis	-0.0 (-0.0 to 0.0)	0.879
Live alone	**-0.2 (-0.3 to -0.1)**	**0.001**
Caregiver Factors		
Caregiver gender	0.1 (-0.0 to 0.2)	0.152

Caregiver main activity:		
Employment	REF	REF
Unemployed	0.1 (-0.1 to 0.3)	0.511
Unpaid occupation (student/housework/volunteer)	-0.0 (-0.2 to 0.2)	0.788
Retired (age/ill health)	-0.1 (-0.2 to 0.0)	0.082

Table 5.12 Patient and caregiver predictors of caregiver outcomes on the CBQ Physical at baseline: Multivariate regression analysis

CBQ PHYSICAL **N = 117**		
Patient Factors		
Patient age	0.0 (-0.1 to 0.1)	0.897
Patient gender	**-2.7 (-5.1 to -0.2)**	**0.031**
NYHA	2.6 (1.3 to 3.9)	0.000
Patient Main activity:		
Employment	REF	REF
Unemployed	4.6 (-0.1 to 9.3)	0.054
Unpaid occupation (student/housework/ volunteer)	-0.8 (-9.9 to 8.2)	0.855
Retired (age/ill health)	-2.3 (-5.6 to 1.1)	0.188
No. of Comorbidities	0.1 (-0.9 to 1.1)	0.895
Years of HF diagnosis	0.0 (-0.1 to 0.2)	0.605
Live alone	0.9 (-1.7 to 3.5)	0.487
Caregiver Factors		
Caregiver gender	-0.0 (-2.7 to 2.6)	0.968
Caregiver main activity:		
Employment	REF	REF
Unemployed	-2.5 (-7.5 to 2.5)	0.324
Unpaid occupation (student/housework/volunteer)	2.1 (-3.3 to 7.5)	0.440
Retired (age/ill health)	1.2 (-0.9 to 3.4)	0.262

Table 5.13 Patient and caregiver predictors of caregiver outcomes on the CBQ Emotional at baseline: Multivariate regression analysis

CBQ EMOTIONAL **N = 117**		
Patient Factors		
Patient age	-0.2 (-0.5 to 0.1)	0.234
Patient gender	-5.5 (-12.2 to 1.2)	0.108
NYHA	**5.9 (2.3 to 9.4)**	**0.002**
Patient Main activity:		
Employment	REF	REF
Unemployed	9.3 (-3.6 to 22.2)	0.154
Unpaid occupation (student/housework/	0.9 (-24.0 to 25.8)	0.942

volunteer) Retired (age/ill health)	-0.6 (-9.9 to 8.6)	0.892
No. of Comorbidities	0.2 (-2.6 to 3.0)	0.881
Years of HF diagnosis	0.2 (-0.3 to 0.8)	0.433
Live alone	2.7 (-4.4 to 9.9)	0.452
Caregiver Factors		
Caregiver gender	0.5 (-6.7 to 7.7)	0.886
Caregiver main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	-4.4 (-18.1 to 9.2) 5.9 (-8.8 to 20.6) 3.3 (-2.6 to 9.3)	0.523 0.426 0.271

Table 5.14 Patient and caregiver predictors of caregiver outcomes on the CBQ Social at baseline: Multivariate regression analysis

CBQ SOCIAL N = 117		
Patient Factors		
Patient age	-0.0 (-0.1 to 0.0)	0.535
Patient gender	**-1.1 (-2.0 to -0.1)**	**0.025**
NYHA	**0.5 (0.0 to 1.0)**	**0.037**
Patient Main activity:		
Employment	REF	REF
Unemployed	**2.6 (0.8 to 4.4)**	**0.005**
Unpaid occupation (student/housework/ volunteer)	**3.7 (0.2 to 7.2)**	**0.040**
Retired (age/ill health)	0.1 (-1.2 to 1.4)	0.838
No. of Comorbidities	-0.0 (-0.4 to 0.3)	0.819
Years of HF diagnosis	-0.0 (-0.1 to 0.0)	0.190
Live alone	0.4 (-0.6 to 1.5)	0.382
Caregiver Factors		
Caregiver gender	0.1 (-1.0 to 1.1)	0.901
Caregiver main activity:		
Employment	REF	REF
Unemployed	-0.6 (-2.5 to 1.3)	0.531
Unpaid occupation (student/housework/volunteer)	0.7 (-1.4 to 2.7)	0.530
Retired (age/ill health)	0.4 (-0.4 to 1.3)	0.294

Table 5.15 Patient and caregiver predictors of caregiver outcomes on the CBQ Lifestyle at baseline: Multivariate regression analysis

CBQ LIFESTYLE **N = 117**		
Patient Factors		
Patient age	0.0 (-0.1 to 0.1)	0.813
Patient gender	-2.0 (-4.2 to 0.2)	0.076
NYHA	**1.3 (0.1 to 2.5)**	**0.028**
Patient Main activity:		
Employment	REF	REF
Unemployed	3.2 (-0.9 to 7.5)	0.128
Unpaid occupation (student/housework/ volunteer)	-1.6 (-9.8 to 6.5)	0.691
Retired (age/ill health)	-0.2 (-3.2 to 2.8)	0.901
No. of Comorbidities	-0.2 (-1.1 to 0.7)	0.608
Years of HF diagnosis	0.0 (-0.1 to 0.2)	0.648
Live alone	0.8 (-1.5 to 3.1)	0.492
Caregiver Factors		
Caregiver gender	-0.9 (-3.2 to 1.5)	0.467
Caregiver main activity:		
Employment	REF	REF
Unemployed	-3.2 (-7.7 to 1.2)	0.156
Unpaid occupation (student/housework/ volunteer)	3.0 (-1.8 to 7.8)	0.221
Retired (age/ill health)	0.2 (-1.8 to 2.1)	0.864

5.4.9 Research Question 3 - What is the impact of the REACH-HF intervention on caregiver outcomes?

Table 5.16 shows the comparison between caregiver outcomes in REACH-HF versus control groups. In summary, there appeared to be a positive direction of effect of the REACH-HF intervention on caregiver outcomes. Caregivers reported a reduction in social burden scores CBQ Social at 6 month follow-up (-0.6, CI 95%, -1.14 to -0.03, p = 0.038) indicating that caregivers in the intervention group experienced less social burden subscale of the CBQ, scoring a mean of 0.6 points less on the social burden scale at 6 months in comparison to caregivers in the control group. Caregivers reported a mean reduction of 1.1 points and 1.7 points on the lifestyle burden subscale of the CBQ at 4 and 6 months follow up indicating that caregivers in the intervention group experienced less lifestyle burden at 4 (-1.1, CI 95%, -1.97 to -0.22, p = 0.014) and 6 months follow-up (-1.7, CI 95%, -2.73 to -0.75, p = 0.001). Caregivers reported a mean reduction of 0.9 points on the HADS anxiety subscale, indicating less caregiver anxiety for caregivers in the intervention group in comparison to those in the control group at 6 months follow up (-0.9, CI 95% -1.93 to -0.06, p = 0.036).

A secondary analysis compared within-group changes in caregiver outcomes from baseline to 4 and 6 months follow-up (Appendix 15). There was a mean increase of 1.2 points in caregiver lifestyle burden within the control group at 6 months follow up (1.2, 0.35 to 2.06, p = 0.007). This indicates that within the control group caregivers experienced an increase in lifestyle burden at 6 months follow up. Caregivers within the control group experienced increased quality of life outcomes scores on the FAMQoL overall. This indicates a higher quality of life overall outcome score for caregivers within the control group at 4 months follow up (2.8, 0.33 to 5.32, p = 0.027). Finally caregivers within the control group at 4 months follow up had a mean increase score of 1.8 points on the HADS depression subscale (1.8, 0.71 to 2.90, p = 0.002) indicating an increase in depressive symptoms. Caregivers in REACH-HF reported a mean reduction of 1.1 points on the HADS depression subscale (-1.1, -1.99 to 0.23, p = 0.014) indicating a reduction of depressive symptoms at 6 months

Table 5.16 Comparison of caregiver outcomes between REACH-HF and control groups

Outcome Measure (Score range)	**Baseline**		**4 months follow-up**			**6 months follow-up**		
	REACH-HF Mean (SD), N	**Control Mean (SD), N**	**REACH-HF Mean (SD), N**	**Control Mean (SD), N**	**Between-group difference Baseline v 4-months Mean (95% CI), p value***	**REACH-HF Mean (SD), N**	**Control Mean (SD), N**	**Between-group difference Baseline v 6-months Mean (95% CI), p value***
CBQ Physical (0 – 88)	3.8 (4.6),63	3.6 (4.4), 54	2.7 (3.9), 54	3.2 (4.2),47	-0.5 (-1.72 to 0.62), 0.356	2.9 (4.0), 52	3.8 (4.2), 47	-0.9 (-2.02 to 0.09), 0.073
CBQ Emotional (0 – 88)	15.9 (12.5), 63	16.5 (11.2), 54	14.4 (11.0), 54	14.1 (11.7), 47	-0.1 (-2.64 to 2.41), 0.926	14.2 (10.9), 52	16.2 (11.3), 47	-2.6 (-5.50 to 0.19), 0.067
CBQ Social (0 – 88)	1.2 (1.9), 63	1.0 (1.6), 54	0.7 (1.2), 54	0.9 (1.5), 47	-0.3 (-0.81 to 0.13), 0.161	1.0 (1.4), 51	1.3 (2.0), 46	**-0.6 (-1.14 to -0.03) 0.038**
CBQ Lifestyle (0 – 88)	3.1 (4.2), 63	3.3 (3.1), 54	2.4 (2.9), 54	3.3 (3.5), 47	**-1.1 (-1.97 to -0.22) 0.014**	2.4 (2.9), 52	4.0 (4.2), 46	**-1.7 (-2.73 to -0.75) 0.001**
FAMQoL Psych (1- 25)	14.1 (4.6), 63	13.6 (4.1),54	15.0 (4.5), 53	14.9 (4.4), 47	0.1 (-1.20 to 1.40) 0.878	14.5 (4.3), 52	14 (3.3), 37	0.5 (-0.58 to 1.70) 0.335
FAMQoL Social (1-25)	16.6 (3.0), 62	15.5 (4.0), 54	16.8 (3.1), 53	16.7 (3.2), 47	-0.0 (-1.19 to 1.10) 0.938	16.2 (2.9), 52	16.2 (2.9), 52	0.3 (-0.62 to 1.39) 0.447

FAMQoL Physical (1-25)	16.4 (3.0), 53	16.6 (2.6), 44	17.0 (3.0), 45	17.7 (2.8), 37	-0.2 (-1.20 to 0.84) 0.729	16.5 (2.8), 44	16.7 (2.4), 38	0.2 (-0.66 to 1.11) 0.615
FAMQoL Overall (1-100)	60.0 (9.9), 63	59.4 (9.5), 54	62.1 (10.7), 53	62.8 (11.9), 47	-0.0 (-3.19 to 3.08) 0.972	60.6 (10.0), 52	59.8 (9.1), 47	1.1 (-1.70 to 4.01) 0.426
HADS Anxiety (0-21)	4.1 (4.1), 63	4.4 (3.6), 54	3.6 (4.4), 54	3.5 (3.2), 46	0.2 (-0.75 to 1.25) 0.622	3.3 (4.0), 51	4.5 (3.7), 47	**-0.9 (-1.93 to -0.06), 0.036**
HADS Depression (0-21)	5.2 (4.8), 56	6.4 (4.1), 46	4.9 (4.6), 51	6 (3.7), 48	-0.5 (-2.27 to 1.17) 0.529	2.8 (3.2), 51	4.2 (3.2), 47	-0.8 (-2.18 to 0.41) 0.181
EQ-5D-5L (−0.285 to 1.00)	76.0 (19.3), 57	77.5 (17.6), 43	81.7 (15.7), 45	78.2 (16.3), 41	3.6 (-1.68 to 8.95) 0.178	78.3 (14.3), 43	78.4 (17.2), 36	-0.9 (-7.18 to 5.28) 0.762

An additional exploratory analysis was undertaken to examine if specific patient or caregiver baseline characteristics were predictive of the REACH-HF versus control effect on caregiver outcomes. Three factors were tested based on the results of the qualitative analysis of the REACH-HF trial (chapter 6), i.e. duration of patient diagnosis, caregiver gender, and caregiver relationship (Table 5.17 to Table 5.19).

Table 5.17 Comparison of caregiver outcomes between REACH-HF and control across subgroup groups: Caregiver gender

Caregiver Gender interaction analysis (difference in outcome between male vs females)		
Outcome Measure	**4-months follow-up Mean (95% CI) N, P-value**	**6-months follow-up Mean (95% CI) N, P-value**
CBQ Physical	0.68 (-1.4 to 2.8), 101, 0.519	-0.76 (-2.7 to 1.2), 99, 0.447
CBQ Emotional	-1.44 (-6.0 to 3.1), 101, 0.530	-1.65 (-7.2 to 3.9), 99, 0.557
CBQ Social	-0.04 (-0.9 to 0.8), 101, 0.912	0.09 (-0.9 to 1.1), 97, 0.862
CBQ Lifestyle	0.89 (-0.7 to 2.5), 101, 0.267	0.78 (-1.1 to 2.7), 98, 0.413
FAMQoL Psych.	0.53 (-1.8 to 2.9), 100, 0.658	-0.04 (-2.2 to 2.1),99, 0.965
FAMQoL Social	-0.20 (-2.2 to 1.8), 99, 0.844	0.14 (-1.7 to 1.9), 98, 0.877
FAMQoL Physical	0.28 (-1.5 to 2.0), 82, 0.753	0.70 (-0.9 to 2.3), 82, 0.388
FAMQoL Overall	0.61 (-5.3 to 6.6), 100, 0.838	0.12 (-5.3 to 5.6), 99, 0.964
HADS Anxiety	-0.81 (-2.6 to 0.9), 100, 0.365	-1.22 (-2.9 to 0.4), 98, 0.158
HADS Depression	-2.91 (-6.0 to 0.2), 97, 0.067	-2.12 (-4.4 to 0.2), 96, 0.072
EQ-5D-5L	-4.62 (-13.7 to 4.5), 73, 0.317	-3.08 (-15.0 to 8.9), 71, 0.610

Table 5.18 Comparison of caregiver outcomes between REACH-HF and control across subgroup groups: Years of patient HF diagnosis

Year of patient HF diagnosis (<1, 1 to 2, >2 years) interaction analysis		
Outcome Measure	**4-months follow-up Mean (95% CI) N, P-value**	**6-months follow-up Mean (95% CI) N, P-value**
CBQ Physical	0.20 (-0.6 to 1.0), 101, 0.641	-0.11 (-0.9 to 0.7), 99, 0.774
CBQ Emotional	-0.01 (-1.8 to 1.8), 101, 0.988	0.10 (-2.1 to 2.3), 99, 0.928
CBQ Social	0.07 (-0.3 to 0.4), 101, 0.667	-0.11 (-0.5 to 0.3), 97, 0.579
CBQ Lifestyle	-0.35 (-1.0 to 0.3), 101, 0.281	0.00 (-0.7 to 0.7), 98, 0.998
FAMQoL Psych.	0.39 (-0.6 to 1.4), 100, 0.425	0.26 (-0.6 to 1.1), 0.553
FAMQoL Social	0.52 (-0.3 to 1.3), 99, 0.218	-0.00 (-0.7 to 0.7), 0.985
FAMQoL Physical	0.44 (-0.3 to 1.2), 82, 0.227	0.15 (-0.5 to 0.8), 82, 0.640
FAMQoL Overall	1.73 (-0.7 to 4.2), 100, 0.160	0.39 (-1.8 to 2.6), 99, 0.723
HADS Anxiety	-0.15 (-0.9 to 0.6), 100, 0.686	-0.32 (-1.0 to 0.3), 98, 0.351
HADS Depression	-0.18 (-1.4 to 1.1), 97, 0.772	0.07 (-0.8 to 1.0), 96, 0.870
EQ-5D-5L	-0.50 (-4.4 to 3.4), 73, 0.798	-2.1 (-6.4 to 2.3), 71, 0.349

Table 5.19 Comparison of caregiver outcomes between REACH-HF and control across subgroup groups: Caregiver spouse v non-spouse

Spouse v Non-spouse interaction analysis		
Outcome Measure	**4-months follow-up Mean (95% CI) N, P-value**	**6-months follow-up Mean (95% CI) N, P-value**
CBQ Physical	-0.42 (-2.2 to 1.4), 101, 0.643	0.35 (-1.3 to 2.0), 99, 0.680
CBQ Emotional	**3.80 (-0.7 to 7.6), 101, 0.054**	1.98 (-27 to 6.7), 99, 0.408
CBQ Social	0.27 (-0.4 to 1.0), 101, 0.462	0.25 (-0.6 to 1.1), 97, 0.582
CBQ Lifestyle	0.49 (-0.9 to 1.9), 101, 0.480	0.14 (-1.4 to 1.7), 98, 0.861
FAMQoL Psych.	-1.73 (-3.7 to 0.3), 100, 0.095	**-2.13 (-3.9 to -0.3), 99, 0.022**
FAMQoL Social	-0.38 (-2.1 to 1.3), 99, 0.664	-0.35 (-1.9 to 1.2), 98, 0.655
FAMQoL Physical	-0.60 (-2.3 to 1.1), 82, 0.504	-0.51 (-2.1 to 1.1), 82, 0.528
FAMQoL Overall	-3.89 (-9.1 to 1.3), 100, 0.142	-4.37 (-9.0 to 0.3), 99, 0.067
HADS Anxiety	-0.85 (-2.4 to 0.7), 100, 0.277	0.47 (-1.9 to 1.0), 98, 0.526
HADS Depression	-2.08 (-4.8 to 0.6), 97, 0.126	**-2.45 (-4.4 to -0.5), 96, 0.015**
EQ-5D-5L	3.58 (-5.6 to 12.7), 73, 0.439	4.7 (-4.4 to 13.8), 71, 0.307

The only factor found to be statistically significant was caregiver relationship. Larger treatment (REACH-HF vs control) benefits in HADS-D scores at 6 months follow-up, were seen for non-spousal caregivers (i.e. child, sibling, friend or other relative) than spousal caregivers. Larger treatment (REACH-HF vs control) benefits in FAMQoL psychological health, was seen at 6 months follow-up for spousal caregivers than non-spousal caregivers.

5.5 Discussion

This secondary quantitative analysis of the REACH-HF (home-based cardiac rehabilitation self-management intervention) trial data had three key findings. First, the involvement of a caregiver in the delivery of the REACH-HF intervention was found to improve the HRQoL of patients with HF receiving the REACH-HF intervention. Second, a number of patient factors were predictors of caregiver outcomes. The most consistent of these was increased patient HF severity as defined by NYHA status. This was identified as the most consistent predictor of increased caregiver burden and reduced HRQoL at baseline. Third, participating in the REACH-HF intervention demonstrated the potential to improve caregiver anxiety as well as social and lifestyle burden. Each of these key findings are elaborated upon in the sections that follow (5.5.1 – 5.5.3).

5.5.1 The impact of caregivers in REACH-HF

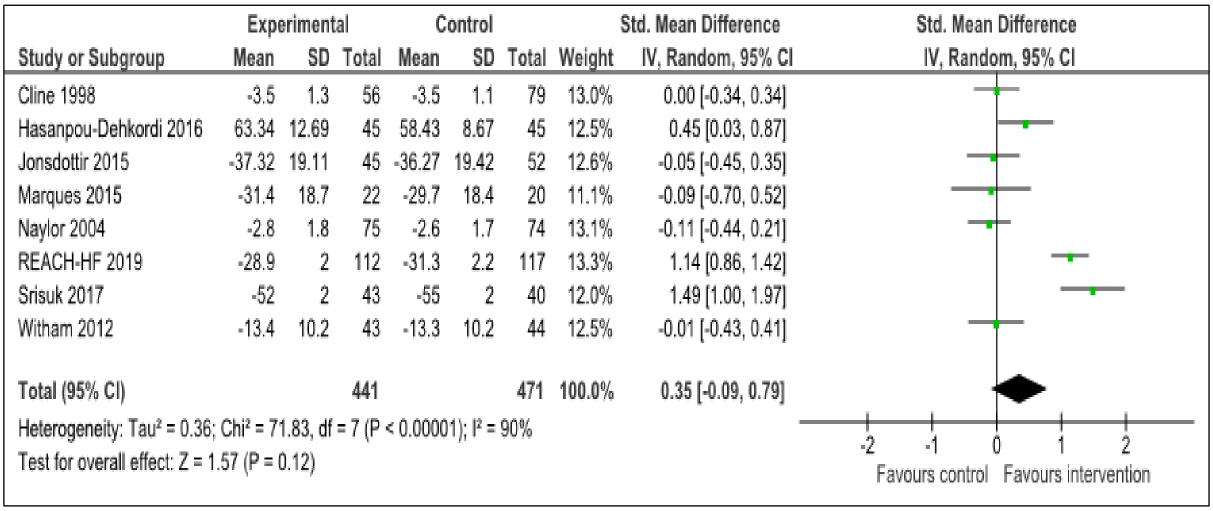
This study demonstrated the significant influence of the presence of when including them in the REACH-HF self-management intervention. The finding that patients had greater improvements in HRQoL when caregivers were involved in the REACH-HF trial contributes important evidence to the body of RCT research reviewed in chapter 4. The systematic review and meta-analysis in chapter 4 identified that involving caregivers in interventions for patients living with long-term illness had limited additional benefits on patient outcomes. The conclusions reached in the meta-analysis in chapter 4 suggested that the inclusion of caregivers in the delivery of self-management interventions was potentially limited due to the lack of efficacy of the intervention delivery. Furthermore, it was concluded that in order to understand the impact of caregivers on patients, theory-driven, evidence-informed interventions were required. Additionally, a clear description of the methodology of involving caregivers in the intervention design and delivery and recording of caregiver outcomes were identified as essential to understanding the mechanisms of the caregiver role with HF patients (339). REACH-HF was designed to address each of these elements: informed by theory, use of literature and key stakeholders to gather evidence, as well as having the active involvement of patients and caregivers living with HF from inception through to the delivery of the intervention (28, 62). Figure 5.3

presents the updated meta-analysis from chapter 4 to include the REACH-HF trial data.

Inclusion of REACH-HF does not alter the overall findings with regard to including caregivers in self-management interventions (mean standardised mean difference (SMD): 0.35, 95% CI: -0.09 to 0.79). It is also important to note in this research that while the conducted multivariate analysis demonstrated that caregiver presence was statistically significant on patient HRQoL at 4 months follow up, this was no longer statistically significant on patient HRQoL at 6 months follow up in the multivariate analysis. This more neutral finding is in line with what has been identified in the wider HF and caregiver literature identified and discussed in Chapter 4.

The methodology of caregiver involvement in REACH-HF and the mechanisms of the impact of REACH-HF on the caregiver role are discussed further in Chapter 6, which may contribute to understanding these findings. Caregiver participation in intervention studies has demonstrated sustained improvements over time for some patient outcomes. An RCT conducted by Srisuk et al. (2016) demonstrated that the emotional quality of life impact on patients was sustained at 6 months follow up in their trial (182). Other HF caregiver research has demonstrated that caregivers have a positive impact on patient outcomes including adherence to medication (185), positive impact on patient confidence and motivation towards improving and maintaining a healthy diet (340, 341) and overall self-care (12, 342, 343). While not all RCTs, these studies included intervention delivery which was evidence-based and theory-informed. This quantitative analysis of the pooled REACH-HF RCTs provides a methodologically robust example of the positive impacts of caregiver involvement on patient HRQoL outcomes.

Figure 5.3 Meta-analysis of the impact of involving caregivers in interventions updated with REACH-HF findings



	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	13.0%	0.00 [-0.34, 0.34]
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	12.5%	0.45 [0.03, 0.87]
Jonsdottir 2015	-37.32	19.11	45	-36.27	19.42	52	12.6%	-0.05 [-0.45, 0.35]
Marques 2015	-31.4	18.7	22	-29.7	18.4	20	11.1%	-0.09 [-0.70, 0.52]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	13.1%	-0.11 [-0.44, 0.21]
REACH-HF 2019	-28.9	2	112	-31.3	2.2	117	13.3%	1.14 [0.86, 1.42]
Srisuk 2017	-52	2	43	-55	2	40	12.0%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	12.5%	-0.01 [-0.43, 0.41]
Total (95% CI)			**441**			**471**	**100.0%**	**0.35 [-0.09, 0.79]**

Heterogeneity: $Tau^2 = 0.36$; $Chi^2 = 71.83$, $df = 7$ ($P < 0.00001$); $I^2 = 90\%$
Test for overall effect: $Z = 1.57$ ($P = 0.12$)

5.5.2 Predictors of caregiver outcomes

The finding that increased patient NYHA (disease severity) was the main predictor of caregiver outcomes for anxiety (HADS-A), quality of life (FAMQOL and EQ5D5L) and burden (CBQ emotional, social and lifestyle) is consistent with previous studies examining the association between patient health status and caregiver outcomes in HF caregiver research (227, 237, 344). However, much of the research examining predictors of caregiver outcomes has largely focused on caregiver emotional health, quality of life and burden (222, 227) with little reference in the HF literature to caregiver anxiety specifically. Pressler et al. conducted a longitudinal study of caregiver experience over time and reported that caregivers of patients who were more symptomatic described higher anxiety. However, data on changes in patient health at eight months follow-up were not collected (61). One cross-sectional study which does consider caregiver anxiety was undertaken by Burton et al. (2012). In their study examining the relationship between patient and caregiver outcomes in HF, COPD, and cancer, they emphasised that the support and resources available to caregivers were predictors of caregiver outcomes as opposed to patient diagnosis or illness severity (345). It is noteworthy that patients and caregivers living with HF who participated in this study were classified as having low disease severity and NYHA status was not provided (345). Examining caregivers of patients with increasing illness severity may have yielded differing outcomes as seen in this secondary analysis of the REACH-HF data. A meta-analysis of primarily cross-sectional studies examining caregiver wellbeing and patient outcomes in HF, found that higher caregiver strain was associated with an increase in patient illness severity (344). Whilst the strength of this work is the ability to pool the effect of these trials, the lack of longitudinal follow up is consistent with previously reported methodological constraints of HF and caregiver literature (344). Of note, Grigorovich et al. reported that patient HRQoL was not associated with caregiver emotional wellbeing over the long-term (77).

Similar to what has been found in this empirical research, other predictors of caregiver HRQoL are not consistent across the literature. Predictors of caregiver HRQoL that have been reported in the research include increased age of the patient (346), caregivers' own perception of caregiving (225), time spent on caregiving tasks (347, 348), caregivers' own health and wellbeing (347) and caregiver gender (349). It has been suggested that self-management interventions need to be targeted at caregivers' needs, facilitating the provision of education and support (and not solely on patient needs), with particular focus on providing the caregiver with the opportunity for engaging in their own interests outside of caregiving (77, 222). Caregiver inclusion in self-management interventions requires an individualised approach and perhaps only then we can begin to more fully evaluate predictors of caregiver outcomes, enabling further refinement of intervention design and delivery (25, 301). It is evident that the relationship between patient HRQoL and caregiver quality of life is not a simple one but rather mediated by a multitude of patient, caregiver and dyad factors as well as cultural influences as proposed in the situation specific theory of caregiver contributions to HF self-care (201). This demonstrates the importance of observing caregiver changes in HRQoL and the predictors of caregiver changes over time, and within the context of the environment in which caregiving is taking place (26).

Other factors found to be inconsistent predictors of caregiver outcome measures in this analysis included, patient factors: gender, main activity comorbidities and living status and caregiver factors: gender and main activity. While these predictors of caregiver factors were statistically significant in the various multivariate models, the meaningfulness of these findings needs to be interpreted with caution. An important consideration in the identification of factors was the large number of analyses conducted and hence the play of chance. The finding of lack of consistency in predictors of caregiver outcomes is identified across the HF caregiving literature and is reflected in the variety of predictors examined and reported upon in HF caregiver research (25). This leads to difficulty in identifying consistent variables that are predictive of caregiving health and wellbeing. This is also evidenced in research conducted in other long-term conditions, including caregivers of stroke patients (350, 351), dementia caregiving (352) and caregivers of patients living with Parkinson’s disease (353). These various considerations mean that the prediction of caregiver outcomes is much more nuanced than those which may be captured on a simple statistical basis alone. The variables which were found not to be statistically significant as predictors of caregiver outcomes included patient age, retirement status of the patient or caregiver, caregiver gender and number of patient comorbidities are important to note. Patient age is less reported in the caregiver literature, instead duration of living with HF is commonly reported when discussing patient illness and the relationship with HF. Caregiver age has been examined and how this impacts on caregiver health and wellbeing. Caregivers of a younger age perceive greater role strain (225) which may be associated with increased social demands, such as having a family or being in paid employment, as identified by the impact on the mental health needs of the sandwich caregiver generation discussed in chapter 2 (60, 354). Patients and caregivers who identified as being in an unpaid occupation might have classified themselves in this category as opposed to the retired category. Caregiver gender may not have been significant as this trial consisted of predominantly female caregivers (discussed further in section 5 of this chapter). Patient comorbidities may not have been a significant predictor because HF was the focus of this trial and perhaps less consideration of the functional implications of these conditions may have been noted (i.e. these conditions were in the background) by patients and caregivers when completing outcome measures.

5.5.3 The impact of REACH-HF on caregiver outcomes

REACH-HF had a positive impact on caregiver social and lifestyle burden, as well as caregiver anxiety. A similar finding has been reported in other research which has evaluated supporting caregivers with education and knowledge exchange interventions (355-357). Similar to REACH-HF, each of these interventions provided patients and caregivers with a variety of resources, including both multimedia and written guidebooks to facilitate the intervention (355-357). The Stress process model suggests that caregivers effectively use coping mechanisms in their caregiving role when they perceive they have social supports and access to systems where they feel included (80). Participating in REACH-HF, having access to a facilitator, and the caregiver resource may have provided these perceived social supports and systems for caregivers. Hence lessening the anxiety as well as social and lifestyle burden experienced. A cross sectional study examining caregiver burden in 135 patient-caregiver dyads reported one of the factors associated with caregiver burden was patient physical health (222). These improved outcomes may be attributed to the patients' positive health behaviour change as identified in the middle range theory of self-care of chronic illness (358). It can be hypothesised that patients who participated in REACH-HF with their caregiver may have improved their skills, specifically in self-management of HF as a result of increased knowledge and understanding obtained during REACH-HF. Patients may have improved their ability to make decisions about their health behaviour, improve their motivation, habits, functional ability and overall self-care skills. Thus, this may have had secondary benefits of reducing caregiver anxiety as well as social and lifestyle burden.

However, REACH-HF did not consistently demonstrate improvements across all caregiver outcomes. Of note, physical and emotional burden (CBQ), quality of life (FAMQoL and EQ-5D-5L) and depression (HADS-D) were not impacted. The lack of improvements seen for these outcomes measures may indicate limited efficacy in the delivery of the intervention. For example, whether the duration of the intervention delivery was sufficient to effect change in caregiver depression, quality of life or physical and emotional burden. Another consideration is whether REACH-HF was delivered as it was designed, i.e. as a dyadic intervention where caregivers were formally included in the intervention delivery. This lack of consistency in outcomes is in line with HF research and the wider caregiver literature, where caregiver outcomes have been reported as not being definitive due to the heterogeneity of intervention studies and the lack of evaluation of HF intervention studies which involve caregivers (359-361).

The noteworthy finding that non-spousal caregivers experience larger treatment benefits on HADS-D depression scores following participation in REACH-HF is important as it contributes important evidence to the caregiver evidence base by explicitly demonstrating the differences between spousal and non-spousal dyads. This outcome has not previously been identified consistently in the caregiver research in HF. A review examining psychological outcomes of caregivers following participation in interventions (psychoeducation, support, transitional care, coaching and tele-monitoring) identified eight studies that included the outcome measure of depression (186). Only one of these studies reported a reduction in caregiver depression (362). It is of importance to note the one study which reported a decrease in caregiver depression involved weekly automated support telephone calls with an email generated and sent to the participants after the telephone call (362). This intervention provided the most regular input and longest duration of intervention, in comparison to the other interventions included in the review (186). The lack of evaluated caregiver outcomes in HF interventions has been emphasised in a number of literature reviews, and further research examining caregiver outcomes in HF research is recognised as a high priority (90, 182, 186, 363).

5.6 Strengths and limitations

Access to the pooled REACH-HF RCT data provided a unique opportunity to analyse individual HF patient and caregiver outcomes from an evidence-informed intervention (19). A key strength of this research was the engagement of patients and caregivers at all stages of the intervention, from planning right through to implementation and evaluation (339).

There are some limitations to this analysis. First, the comparison of patient outcomes sorted into groupings of patients with or without a caregiver was not a randomised comparison. Therefore, adjusting for patient and caregiver characteristics which were found to be different between the two groups sought to overcome this non-randomised comparison. Second, there is a risk of attrition bias due to differences in the characteristics of patients and caregivers who completed the intervention compared to those who dropped out at 4 and 6 months follow-up. Furthermore, there was no imputation of missing data in the combined REACH-HF data sets, which may have added to the potential risk of bias in patient and caregiver outcomes (327). A qualitative secondary analysis of patients and caregivers was completed to explain the results of this quantitative analysis (chapter 6).

Third, the sample included predominantly white, female, spousal caregivers, educated to second level. Thus, the socioeconomic status and cultural experiences and expectations of caregiving and engaging with self-management and healthcare professionals for this group of caregivers may be very different to those with differing demographic characteristics. Research has identified that higher caregiver burden is primarily associated with being Caucasian and a female caregiver (193, 236). Hence, the caregivers participating in REACH-HF may have had higher baseline burden scores thus leading to potentially greater improvements seen following participation in the intervention than may have been observed in other ethnic groups. Literacy levels may have influenced whether caregivers used the patient manual, caregiver resource or other tools provided as part of the intervention. This has implications for anticipated patient and caregiver outcomes as the design of the intervention was targeted at adults who are literate and confident with using multimedia (for use of the relaxation CD and exercise DVD). A strong spousal relationship between the patient and caregiver may have informed why the caregiving role was undertaken and also the willingness of caregivers to be available to attend intervention sessions together. In contrast, child caregivers, other relatives or friend caregivers may have different experiences when participating in self-management programmes such as REACH-HF and may have differing reasons for undertaking a caregiving role which will influence caregiver outcomes such as burden and quality of life. This needs to be considered when interpreting these findings. These factors potentially limit the generalisability of these findings to social or cultural groups outside of consideration of Caucasian, gender, spousal relationship, and education status.

Fourth, analyses of outcomes were limited to 4 and 6 months follow-up. Longer-term follow-up at 12 months was collected for the multicentre RCT in HFrEF patients and caregivers. However, as this longer follow-up was not available for the single centre RCT in HFpEF patients and caregivers, it was therefore decided that this secondary analysis was limited to 4 and 6 months follow-up. Fifth, the REACH-HFrEF trial was powered on a between-group difference in patient outcome (i.e. MLHFQ). Therefore, even when combined with the single arm REACH-HFrEF study, the overall sample size trial may have been insufficient to detect between group differences in caregiver outcomes. For example, a minimally significant difference in the HADS of 1.5 (364) would require 112 caregivers per group at 90% power and 5% alpha (365).

5.7 Implications for clinical practice

The results of this analysis have important implications for current clinical practice. Firstly, including caregivers in self-management interventions has the potential to positively influence patient HRQoL outcomes, as well as caregivers' perceived burden and anxiety. It is therefore important that healthcare professionals, in consultation with the patient, identify if they have a caregiver assisting in their self-management. A discussion with caregivers either alone or with the patient as a starting point is merited to determine if they are willing and able to participate, and whether they have any needs that might require addressing or signposting for further support. Considering the potential impact of increasing NYHA severity as a predictor of caregiver quality of life burden and anxiety, it is important for clinicians to consider caregivers' needs throughout the progression of the illness. Caregivers may require targeted support with regards to anxiety management and prompts to engage in their own self-care.

Implications for clinical practice must be considered with regards to the demographic details of the sample in this study, predominantly female, spousal, white caregivers. Female spousal caregivers may adopt a more traditional role, i.e. caring for the male spouse, which may influence the dynamics of the patient-caregiver dyad and how they engage in HF self-care maintenance and management. Understanding the role of the caregiver in supporting the patient, determining the extent of caregiver involvement and the influence of the caregiver in patient self-management can inform clinicians and potentially enhance their interactions with patients and caregivers.

Furthermore, consideration of caregivers' education and literacy levels may also influence how they engage with resources such as those provided in REACH-HF. Consideration may need to be given to providing intervention resources which may be auditory or easy read formats to facilitate equitable access to clinical interventions. Recognising if a patient has a caregiver and whether the patient consents for the caregiver to be a part of their illness management is an important starting point for ensuring an inclusive healthcare approach.

5.8 Implications for future research

This research has highlighted areas for future research. Future RCTs of self-management interventions are needed that collect both patient and caregiver outcomes, as there is also a need to further determine whether the content and delivery of self-management programmes are designed and aligned to optimally meet the needs of both patients and caregivers. While there is indication of the positive influence of joint involvement of caregivers on patient outcomes, this research was not consistent with regards to the benefits of this involvement on caregiver outcomes. Further exploration of caregiver involvement on caregiver outcomes is therefore merited; specifically in terms of the selection of caregiver outcome measures which accurately understand and reflect caregiver experiences as well as health and wellbeing outcomes when caregivers are involved in the delivery of self-management interventions. Further research is required to determine whether individual patient and caregiver outcome measures can accurately reflect the dyadic aims of dyadic self-management interventions or whether dyad specific outcome measures are more appropriate to capture and accurately reflect the health and wellbeing outcomes of patient-caregiver dyads.

Further research is needed to develop and implement interventions which address the needs of caregivers of patients with greater illness severity in order to understand how to target interventions towards those with the greatest need. Further examination into the timing and duration of intervention delivery may provide insight into how to consistently maintain patient and caregiver wellbeing as they transition through the stages of HF. Considering the implications of increased NYHA on caregiver burden and caregiver quality of life, exploration of the amount of self-management support required at the differing stages of HF could help inform the level of facilitation and support required by patients and caregivers throughout the stages of HF. While a unique aspect of this research is the collection of data at 4 and 6 months follow up. Further longitudinal research is required to determine whether this impact on patient quality of life and caregiver outcomes is sustained or diminishes after 12 and 24 months.

Caregivers in this trial primarily reported their ethnicity as white and were predominantly educated to secondary level. This has implications in terms of the applicability of these findings to heterogeneous groups who may have other cultural experiences (for example familial obligations to caregiving or not), their social environment, socioeconomic status and literacy levels. Each of which can influence and determine the caregiving experience, caregiver wellbeing, and the ability or interest to engage with self-management interventions such as REACH-HF. Thus ongoing research is required to examine the impact of REACH-HF in more diverse population specifically Black, Asian and minority ethnic groups.

5.9 Conclusions

This quantitative secondary analysis establishes that involving caregivers in a rehabilitation programme for HF patients (REACH-HF) can improve patient HRQoL, lead to improvement and reductions in caregiver anxiety and social and lifestyle burden. This study emphasises the importance of involving caregivers in the delivery of rehabilitation and self-management interventions for patients with long-term illnesses. However, due to risk of attrition bias, interpreting the results with caution is warranted. Further research is needed to demonstrate self-management interventions that involve caregivers in their design and delivery, can lead to sustained improvement in patient and caregiver outcomes.

CHAPTER 6. The impact of REACH-HF on the nature of caregiving and how it contributes to improved patient health-related quality of life. A qualitative study of caregiver contributions to HF self-management following participation in REACH-HF

6.1 Introduction

The quantitative analysis conducted and discussed in chapter 5 demonstrated that patients who had a caregiver also participating in REACH-HF achieved a better HRQoL outcome on the Minnesota Living with HF questionnaire (MLHFQ) when compared with patients participating in REACH-HF without a caregiver. HRQoL is concerned with the influence of an individual's health status on their day to day functioning (161). The aim of this chapter was to further explain this finding by conducting a secondary analysis of qualitative data to identify how the components of REACH-HF influenced caregivers in their role and consequent caregiver actions which supported patients' HF self-management. The concept of self-management in REACH-HF was the process of engaging in medical and behavioural strategies to enhance or maintain day-to-day life when living with HF. Caregivers were formally included in REACH-HF as they were identified as having a key role in supporting self-management. Caregiver actions were considered as any overt or discreet activities which caregivers engaged in as a result of participating in REACH-HF. The concept of overt and discreet caregiving has previously been reported in caregiver literature. Clark et al. (2008) identified the concept of visible and invisible caregiving following a systematic review of home based caregiving in HF management. Visible caregiving consists of actions which are observable, for example caregivers in REACH-HF attending facilitated intervention sessions (366). Invisible caregiving consists of unobservable actions, for example the caregiver monitoring the patients breathing or subtly checking for fluid retention (366). The analysis sought to elicit this information from the qualitative data in order to explain our understanding of the complexity of caregiving in HF by identifying which specific components of REACH-HF enabled caregivers to enhance patient HRQoL.

6.1.1 Research Question

What is the impact of REACH-HF on the nature of caregiving which contributed to improved patient outcomes on the Minnesota Living with HF Questionnaire (MLHFQ)?

6.2 Methodology

6.2.1 Study Design

This study was a secondary qualitative analysis of patients and their caregivers who participated in the REACH-HF fully randomised controlled trial (HFrEF trial). A cross case analysis of patients and their caregivers at 4 and 12 months follow-up was conducted.

6.2.2 Data set included in this analysis

The qualitative data set was comprised of patient and caregiver data from the mixed methods process evaluation of the REACH-HF trial (367). The patients and caregivers included in this secondary analysis all received the REACH-HF intervention. The data available and included for analysis for this research question were:

1) Semi-structured interviews completed at 4 and 12 months follow-up. Primarily, these interviews were conducted with the patient or the caregiver individually. However, in some of these interviews, the patient and caregiver were together in the room when the other person was being interviewed. Interviews were conducted by experienced qualitative researchers. The interview topic guide was used to conduct patient and caregiver interviews, which was reviewed throughout the study to ensure that questions being asked were relevant and informed by any emerging topics (280) (Appendix 16). Research questions that were asked were guided by interviewees and in order to further enhance interviews, interviewers used techniques such as seeking clarification and asking probing questions to further expand on answers provided by participants.

Interviews were audio-recorded and transcribed, and any identifying data were anonymised.

2) Interviewer Field notes at 4 and 12 months follow-up (Appendix 17). These field notes were written by the interviewer and recorded who was present in the household, first impressions of the interviewer, atmosphere, any interruptions during the interviews, caregiver and patient relationship (verbal and non-verbal communication), how the interview went and interviewers' assessment of their performance and influence, how patient or caregiver responded and main points arising from the interview. Key points were summarised at the end of the field notes.

3) Facilitator contact sheets (Appendix 12). These were written by facilitators delivering the intervention after each episode of intervention delivery. The information recorded in these sheets included: date, whether the session was face to face or via telephone who was present, what physical activity was completed by the patient, an overall discussion of what went well, what worked less well and how this could have been done differently.

4) REACH-HF fidelity measure (Appendix 18). This rated facilitator competence in the delivery of the REACH-HF intervention. The facilitator rating was completed by two researchers who were involved in the development of REACH-HF. The rating scale assessing facilitator competence was scored using a six-point Likert scale based on the Dreyfus system (281), a five-stage model for skill acquisition. The rating scale was scored from 0 (facilitator did not deliver the intervention element appropriately, low fidelity) to 6 (intervention element was delivered appropriately, high fidelity). There were 13 items which were assessed for fidelity. In addition to patient related items, these also included: caregiver involvement (as applicable), addressing emotional consequences of being a caregiver (as applicable), caregiver health and well-being (as applicable), bringing the programme to a close and a content checklist for both patient and caregiver.

5) A one page summary of patient and caregiver demographic data (Appendices 19 and 20).

6.2.3 Sampling

The full qualitative data set was comprised of 19 patient only interviews at 4 months follow-up and 14 patient only interviews at 12 months follow-up. There were 18 caregiver only interviews at 4 months follow-up, and 15 caregiver only interviews at 12 months follow-up. A purposive sampling strategy of patient-caregiver dyads who received the REACH-HF intervention was applied for this secondary analysis. The rationale for using a purposive sampling approach was to ensure that the selection of patient-caregiver dyads provided a rich data set that facilitated analysis of a range of patient-caregiver dyads. This included: spousal and non-spousal patient-caregiver dyads, both male and female caregivers patient-caregiver dyads who had data available at both time points (4 and 12 months follow-up) (368). This approach to sampling facilitated the identification of critical insights and provided greater explanatory power of the impact and influence of REACH-HF.

Additionally, the limited research that has been conducted into male caregivers has demonstrated that male caregivers are less likely than female caregivers to seek support (286). Selecting both male and female caregivers allowed a more in-depth analysis to identify whether there were any differences between what male and female caregivers were doing, both during and after participation in REACH-HF which contributed to improved patient outcomes. Finally, patient-caregiver dyads, who had data available at both time points (4 and 12 months follow-up) were included. This was to enable comparison of any changes over time within dyads before, during and after participating in REACH-HF. Therefore, in this analysis, purposive sampling was appropriate as it facilitated an understanding of different experiences of caregiving in HF and how REACH-HF impacts differing caregiving dyads (287).

Each patient and caregiver dyad was considered as one case. This resulted in 36 interviews for analysis (9 cases at two time points). Table 6.1 outlines the sample included in this analysis.

Table 6.1 Demographic details of participants

PT/ CG ID	Patient Illness Severity	Relationship between dyad (Pt/Cg)	Living together or separately	Age		CG Gender	Time since Diagnosis	Caregiver Main activity	Patient Comorbidity
				PT	CG				
4015	NYHA II	Father/ Son	Separately	73	49	M	<5 years	Employed	Hypertension Diabetes
2016	NYHA II	Mother/ Daughter	Separately	74	40	F	>5 years	Employed	Arthritis Chronic Back pain Hypertension
2020	NYHA II	Husband/ Wife	Together	52	45	F	>15 years	Housework	Arthritis Depression
1091	NYHA III	Wife/ Husband	Together	68	68	M	<5 years	Employed	Arthritis Chronic Back Pain Hypertension Depression Heart disease
1172	NYHA III	Wife/ Husband	Together	45	45	M	>5 years	Employed	Angina Depression Arthritis Heart disease
2049	NYHA II	Friend/ Friend	Separately	85	68	F	<5 years	Retired	Arthritis Atrial Fibrillation
4012	NYHA II	Husband/ Wife	Together	67	67	F	>5 years	Retired	Arthritis Atrial Fibrillation

1130	NYHA II	Mother/ Daughter	Together	51	31	F	<5 years	Employed	Arthritis Chronic Back Pain Depression
4061	NYHA II	Husband/ Wife	Together	73	65	F	<5 years	Retired	Angina Atrial Fibrillation Chronic Renal Impairment Past MI

PT = Patient, CG = Caregiver, F = Female, M = Male, MI = Myocardial Infarction

6.2.4 Secondary Data Analysis in Qualitative Research

The purpose of this secondary analysis was to further explore this data set and answer a new question distinct from the original piece of work (369-371). The original purpose of the REACH-HF trial was to evaluate the clinical effectiveness and cost effectiveness of a facilitated home-based self-management intervention for patients with HF and their caregivers. The REACH-HF trial, including the outcomes has been discussed in greater detail in chapter 5. The mixed-methods process evaluation of the REACH-HF trial was completed parallel to the RCT and aimed to identify and understand what change processes took place that explained the effects of REACH-HF and whether the intervention was delivered as designed (280). The purpose of this secondary analysis was to re-use existing data from the process evaluation to understand the impact of REACH-HF on what caregivers were doing that resulted in improved patient HRQoL outcomes (chapter 5).

Conducting a secondary analysis of the REACH-HF process evaluation data set was an opportunity for this researcher to construct a new interpretation of the data with an emphasis on the caregiver perspective. This was achieved by exploring how REACH-HF facilitated caregivers in their role to enhance patient HRQoL outcomes as recorded on the MLHFQ. The data set was shared following completion of the procedures outlined in the data sharing protocol (Appendix 13) devised by the Co-Chief Investigators. Primary data was shared directly with this researcher (MN). Members of the supervisory team for this PhD were involved in the REACH-HF trial (RT and NB) and the process evaluation (JF and NB). They were able to share their knowledge on the development, aims, and analysis of the REACH-HF trial as well as the process evaluation.

Secondary analysis of qualitative data is a method which has become established in practice over the last decade and it has the potential to be a rich source of valuable information (370, 372). There are methodological concerns with regard to secondary analysis, however, by addressing these concerns in a robust and transparent manner the benefits of having access to this data rich source should outweigh any ethical or researcher bias, as well as any epistemological concerns (373). Epistemological concerns, researcher bias and ethical issues are addressed later in this section. This secondary analysis remains in line with the original research question. A cross-case analysis approach (discussed in greater detail later in sections 6.2.6 to 6.2.9) (374) was consistent with the qualitative analysis conducted in the primary process evaluation and RCT (367). It was important to maintain an awareness of the influence of the relationship between the researcher and the participant in primary qualitative data collection while completing this secondary analysis (292, 294). This was achieved by MN keeping reflective notes and discussions with the supervision team for this PhD (JF, NB and RST), all of whom were key researchers from the REACH-HF trial and process evaluation.

Epistemological concerns were addressed by reading and understanding any documents related to the study protocols and intervention development processes of the REACH-HF intervention (375, 376). Additionally, these were addressed through regular supervision meetings where ideas were discussed, queries clarified and an understanding of the primary research aims and objectives was further embedded. It was also important to acknowledge the influence of this researcher’s (MN) clinical background (occupational therapist) throughout the process. This was discussed in supervision with regard to values held by MN as both a healthcare professional and PhD student and how this in turn informed interpretation of the data. Discussions with JF and NB guided MN on how to conduct qualitative research in a rigorous manner encouraging reflection on the purpose of conducting qualitative research within the REACH-HF trial, sampling and analysis decisions, as well as MN’s interpretations and representation of the perspectives of patient-caregiver dyads (377). It is argued that secondary analysis should be conducted by experienced researchers if the person conducting the secondary analysis was not a member of the original research team (378). However, in this instance, regular supervision meetings as outlined above, mediated this concern.

Ethical considerations have been discussed in greater detail in chapter 5. It is worth noting again, with regard to this secondary analysis, the research question being asked is directly related to the intention of the primary research. Thus, the initial consent obtained for the REACH-HF RCT and associated process evaluation was valid for this secondary analysis. This was confirmed by the Royal Cornwall Hospital Trust via the Research Development and Innovation Department and the College of Medicine and Health, University of Exeter ethics committee chair.

6.2.5 Methodological Approach

The pragmatist paradigm guided this research, the underlying belief being that experience informs knowledge (379-381)**.** This paradigm places primary importance on the research question and the outcomes of the research question as opposed to the methods used (380). Pragmatism permits moving from induction to deduction and transitioning from objectivity to subjectivity in the pursuit of knowledge (382). Knowledge from the perspective of pragmatism is understood to be socially constructed, and elements of these social constructions are informed by experience (381, 383). As a philosophical approach, pragmatism has been criticised for placing too much emphasis on the research question and is perceived as ignoring the underpinning paradigm, theory and methods (384, 385). Thus it must be considered that this approach has the potential to be at odds with a theory-driven intervention. However, a characteristic of the pragmatist approach is that theories are true to varying degrees based on how well they work with regards to their applicability and predictability (386). The pluralist approach in pragmatism is endorsed as useful to gain an understanding of people and the world they live in (386). It is the responsibility of the researcher to be reflexive, acknowledge the implications of underlying philosophical approaches and to report transparently how the theoretical foundations of the intervention have been applied and interpreted (386).

Intervention development for REACH-HF utilised a behaviour taxonomy to identify strategies and techniques for behaviour change (28). The literature informed this as well as the expert opinion of PPI group members (28). The purpose of this taxonomy was to provide an intervention based upon a source of ideas as opposed to having a definitive list of behaviour which needs to be adhered to, to achieve outcomes (28). The pragmatism paradigm understands that knowledge is based on real-world experiences, these may be complementary or contradictory (387). The development of the multi-component delivery of REACH-HF recognised the diverse needs of patients and caregivers living with HF, thereby providing a variety of options to engage with the intervention (28). Thus the pragmatic paradigm enables exploration of complex questions to address the complexity of the real world (388), which is pertinent in health services research. This aligns with understanding the complexities of the multi-component intervention that is REACH-HF.

6.2.6 Data Analysis

This qualitative analysis comprised a cross-case analysis approach (374). This approach is grounded in case study research which entails examining a case in depth to provide a detailed understanding of the complexities of that case (389, 390). It can be singular, examining one case study or collective, such as in this qualitative analysis, examining multiple cases (390). Each patient-caregiver dyad was categorised by MN as one case. Analysis of multiple cases facilitated MN to develop an understanding of the similarities and differences across cases and identify themes in relation to the processes and outcomes of caregiver involvement in REACH-HF (374, 391). This approach provided critical insights and greater explanatory power of what caregivers were doing in their role in the context of participating in REACH-HF which led to improved patient outcomes. While cross-case analysis facilitates identification and explanation of similarities and differences across cases, it is important to note that comparing cases is not a straightforward matter of finding patterns and synthesising cases (392). There is a risk of over generalising what has been identified across cases and losing the context of each case (392). Therefore, it was important to conduct within-case analysis in order to have an understanding of the processes and outcomes of each individual case (374, 389, 393).

Once ethical approval and general data protection measures were in place (discussed in chapter 5), the qualitative data set was shared with MN. A member of the supervision team, an experienced qualitative researcher (JF), who was a key member of the REACH-HF project management team, exported the qualitative data set to MN, in accordance with the REACH-HF data sharing protocol (Appendix 13). Once this was received MN imported the data set to NVivo 12 Plus. A GDPR compliant independent transcriber had already completed the transcribed the data (327). The first step upon receipt of the data was to become familiar with the content of the interviews, field notes, fidelity scores and patient and caregiver demographic data. This immersion in the data involved reading the primary data several times (377, 394), which was important as MN was not involved with the collection of the primary data. Therefore, this stage enabled MN to establish familiarity with, and an understanding of, the contents of the data (394). The aim at this point was to get a holistic sense of what patients and caregivers were reporting as well as primary researcher impressions following interviews with participants. During the immersion stage, MN began simultaneously coding the data. In addition to becoming familiar with the data and developing an understanding of the context of what patients and caregivers were reporting, this was a method of organising the data. (376, 391, 394, 395) MN established a list of a priori codes which were informed by both the REACH-HF interview topic guide and the research conducted up to this point in this thesis (chapters 2, 3, 4 & 5). This list of codes was documented in NVivo 12 Plus with a descriptor of the meaning applied to each code. This ensured MN maintained consistency in coding data throughout this analysis process (376, 396). Figure 6.1 presents these a priori codes.

Figure 6.1 A priori codes

HF affects more than just the patient	Difficulty getting out and about in the community	Cg. does not live with patient	Length of diagnosis	Understanding of HF pre-REACH-HF
Positive relationship - United dyad, close, "we"	Hilly terrain versus flat terrain	Financial strain on pt. and Cg.	Pt. Health status at 4 months	Obtained new knowledge in REACH-HF
Do not discuss HF with rest of family	Living in a rural environment	In paid employment – Pt. or Cg.	Pt. Health at 12 months	Purpose for participating in REACH-HF
Reported tension/Strain in Pt.- Cg. relationship	Living in an urban environment	Retired – Pt. or Cg.	Pt. living with comorbidities	
Observation (i.e. nuanced changes in patient health)		Pt. as Cg. (i.e. participant in REACH-HF with caring responsibility for others)	Unpredictability of HF symptoms	
Relationship type (spousal, friend, parent/child)		Family in household (i.e. children, other relatives)	Caregiving requirements changing (i.e. Pt. health improving/decreasing)	

Cg. motivating Pt. active/passive self-management		Family geographic location (near/far)	Cg. health needs (physical and emotional)	
Cg. descriptor of role (spouse, parent, friend)		Social engagement (i.e. support groups)	HF management (i.e. treatment approaches – ICD, Transplant, Pacemaker)	
Cg. promoting Pt. independence		Cg. Hobbies – leisure/self-care		
Pt. dependence on Cg.		Pt. and Cg. Loss of past roles	Interactions with Healthcare professionals	
Cg. facilitating pt. decision-making		Pt. and Cg. new roles		
Future (post-REACH-HF)				
Coping strategies (Pt. /Cg.)				
Patient Goals				

Pt. = Patient, Cg. = Caregiver

The process of coding was iterative and entailed reading and re-reading the data to facilitate reflection and deeper thinking about the content and context of the data (397). This process allowed the opportunity to revise, reaffirm and refine the codes already identified (394). An additional code, also known as an inductive code (374), was identified at this time. Inductive codes are created when patterns or key features are identified in the data set which were not previously considered by the researcher (395). At this stage this additional code was “the meaningfulness of self-management tasks”. MN identified patterns in the data which provided an insight as to whether patients sustained engagement in self-management tasks even when supported by a caregiver. An example of this was evidenced in the patient-caregiver dyads 4061 and 2020. The caregivers in these dyads participated in exercise with the patient, specifically the walking programme as recommended in REACH-HF. The patient in the dyad 4061 was vocal in stating he did not enjoy walking and it did not hold any interest for him. The caregiver (wife) in this dyad, attempted to motivate the patient to engage in this activity by going on walks with him. However, caregiver participation in this instance was not sufficient to effect sustained change for this patient beyond REACH-HF. In contrast, for the patient in the dyad 2020, walking was sustained as it was something he enjoyed doing and he could participate in it with his caregiver (wife). Therefore, because it was meaningful to him, unlike the patient in the dyad 4061, he sustained his engagement in this activity beyond completion of the REACH-HF intervention.

On completion of familiarising oneself with the data and the exploratory stage of coding, MN completed the quantitative analysis of the REACH-HF data set (chapter 5). The rationale for this was multifaceted. Firstly, the exploratory stage of coding the qualitative data informed research questions one and two as discussed in the quantitative analysis (chapter 5). Secondly, taking time away from the qualitative data enabled MN to be reflective of the data analysis process and the position of MN within this process (398). Reflections on the data analysis process included deeper thinking with regard to the aims of the research question in relation to theoretical concepts in the caregiver HF literature (201) and the constructs of the REACH-HF logic model (discussed in chapter 5), which was the conceptual framework underpinning the REACH-HF intervention (28). The position of MN within the qualitative analysis process was managed by writing reflective notes to bracket assumptions and minimise researcher bias (399). In particular acknowledging the duality of MN’s perspectives: the clinical position as an occupational therapist and the researcher position as a PhD student (399). Thirdly, given that this research was examining both quantitative and qualitative data, further training in mixed methods research was accessed during this time away from the qualitative data. This enhanced MN’s understanding of completing mixed methods research, in particular sequential exploratory and explanatory designed research (400).

Informed by the results of chapter 5, that patients with caregivers achieved better HRQoL outcomes following participation in REACH-HF, MN then returned to the qualitative data. Previously identified codes (Figure 6.1) were retained, but in order to minimise any researcher bias, previously identified codes were held lightly to enable facilitation of new analysis of the secondary data (374, 401). This process encouraged MN to be reflexive in the analysis approach which in turn facilitated minimisation of bias and preconceptions to ensure an accurate representation of the data (374, 402, 403). This meant that the list of codes previously identified were flexible and were a starting point for MN as a novice qualitative researcher, however, they were not being rigidly retained at this stage of data analysis (374, 402). Guided by supervision discussions, informed by the quantitative data outcomes, and with a greater understanding of the qualitative data, cross case analysis, using both a case and variable oriented approach was identified as appropriate (374, 404, 405). A combination of case and variable oriented analysis is advocated by Miles, Huberman and Saldana (2014) when attempting to understand processes and outcomes across a multitude of cases (374). The rationale for this approach, as outlined earlier in this chapter, was to understand the ways in which REACH-HF either enabled or impeded caregivers in their role to facilitate patient self-management of HF, thus resulting in improved patient HRQoL.

6.2.7 Variable oriented approach

The variable oriented approach involves writing up each case using a standard set of variables informed by a conceptual framework (405, 406). The REACH-HF causal model for the self-management of HF (chapter 5) was the conceptual framework which informed the variable oriented approach (28). As a starting point, interviews, field notes and fidelity scores from two patient-caregiver dyads were coded under each variable using this conceptual framework. These two patient-caregiver dyads were selected at this stage of analysis based upon their contrasting reported experiences of REACH-HF, as identified by MN. In case study research, this can be described as an instrumental approach to case study analysis (404). That is, using particular cases to understand the context within which the elements of the REACH-HF logic model operated. This included the personal, environmental, psychological and behavioural factors which were identified targets for change according to the REACH-HF logic model (28). In this instance to understand how REACH-HF enabled caregivers in their role to positively influence patient HRQoL. The first of these patient-caregiver dyads, was a father-son dyad (Participants 4015) who reported improved lifestyle changes following participation in REACH-HF. This dyad identified that they did not communicate about HF prior to participating in REACH-HF, but that the patient manual and caregiver resource enhanced their knowledge about HF self-management. Explicitly, the caregiver (son) was able to utilise the knowledge he obtained about HF to assess the patient's (father) breathing and fatigue. Based on his assessment, he then tailored the amount of assistance he provided for chores around the house. The patient (father) was aware of this monitoring. Both the caregiver (son) and patient (father) reported that they discussed the signs, symptoms of and management of HF as a result of REACH-HF, which enabled the caregiver (son) to adjust his level of input dependent upon the patient's (father) needs. A key external determinant for this father-son dyad in HF management was the father's motivation to care for his wife who had dementia. This demonstrated the influence of the external determinants on the patient and caregiver motivations for engaging in HF self-management. The patient-caregiver dyad who reported a differing experience to this was a mother-daughter dyad (Participants 1130). The caregiver (daughter) in this dyad identified that she did not participate in REACH-HF. Although she was present for the baseline visit and did initially assist with completing the progress tracker, she did not associate what she was doing in her role to REACH-HF. This caregiver (daughter) viewed the facilitator in REACH-HF as providing a support to the patient (mother) which enabled the caregiver (daughter) to take a step back and focus on external demands such as her wedding and starting a family. At the 12 month interview it was evident this caregiver was trying to step back into the supporter role, however due to balancing parenting and work, she did not believe she had the time to engage with the REACH-HF resources or source information about HF. The patient (mother) reported she was still struggling to come to terms with HF and the self-management strategies she needed to engage in. This potentially indicates that the time or duration of the intervention was insufficiently tailored to the needs of this patient-caregiver dyad.

The variables included: personal determinants (intrinsic factors for participating in REACH-HF), external determinants (factors outside of patient or caregiver control), behavioural factors, environment, QoL psychological factors, and long-term outcomes. The data from these patient-caregiver dyads was mapped by MN onto a Microsoft Word document under each of the aforementioned variable headings. As these interviews, field notes and fidelity scores were revisited MN's interpretations of these two patient-caregiver dyads were mapped onto the Microsoft Word document (Appendix 21) (392, 407). Once these cases were reviewed and interpreted, all other patient-caregiver dyad interviews, field notes and fidelity scores were re-read and interpreted and displayed in a Microsoft Word document as per the example in Appendix 21. This process facilitated comparisons across cases by MN - to identify any similarities or differences across the patient-caregiver dyads (393).

6.2.8 Case oriented approach

The rationale for utilising a case oriented approach in addition to the variable oriented approach was to understand the specific processes within each case as well as identifying how these processes apply to the wider patient-caregiver population (404). This approach is identified as “stacking comparable cases” and is advocated by Miles, Huberman and Saldana (374). A case analysis was constructed by MN on each case and was completed in NVivo 12 Plus. This case-oriented approach documented the characteristics of patient-caregiver dyads, the context of the dyad and whether there were any similarities or differences with other dyads. Displaying the data in this manner facilitated MN to analyse each case in depth. This was a process of understanding the essence of each patient-caregiver dyad and recognising within each case the processes of what caregivers were doing and the outcomes experienced by each patient-caregiver dyad, thus enabling the presentation of a case-oriented approach to analysis (374).

6.2.9 Cross-case analysis

As each case was examined, MN moved back and forth between the variable oriented data (Appendix 21), the case oriented data (Appendix 22) and the data in its original imported form. The purpose of this was to compare and contrast across cases but also return to the original data to find the evidence for any assumptions and test the interpretations of MN (408). The original list of a priori codes was referred to again at this stage of the analysis process (376) to identify if there were any data included in the a priori list of codes that were overlooked in the variable or case oriented analysis (409). This comparative approach enabled MN to interrogate the data and identify patterns (i.e. what parts of the data fit together and whether there were recurring data) and outliers (i.e. inconsistencies in the data set when compared with other cases) in the data (404, 407, 410, 411).

After deconstructing the data, the interpretation and refinement stage was about comparing cases and constructing MN’s interpretations of each patient-caregiver dyad and synthesising this data (377, 412). This was a process of creating meaning out of the data. Strategies such as reflective notes and critical discussions in supervision meetings aided this interpretation process (413). In order to understand the impact of REACH-HF, MN categorised data into three overarching themes: before REACH-HF, during REACH-HF or after REACH-HF. Sub-themes were constructed by clustering patterns and building a chain of evidence (374) to demonstrate the sub-theme. A chain of evidence is a method of identifying differing sources in the data which support or challenge a theme (374). These overarching themes and sub-themes were mapped onto a meta-matrix (Table 6.2), the visual representation of the data in Table 6.2 was another tool employed by MN to assist with making sense of the data (374). It is a process of constructing a holistic picture from deconstructed parts (374). An example of constructing one of the sub-themes is described in the following paragraph.

In the process of examining the mapped out data, a pattern was noted regarding the theme of communication. This was identified as communication described by the patient or caregiver about HF to each other, observed communication between the patient-caregiver dyad by the primary researcher, and direct communication within the interview between the patient and caregiver. Text regarding the theme of communication was clustered together and a visual chain of evidence was constructed (Appendices 24 and 25). Within the context of the logic model, it was expected that by participating in REACH-HF together, caregivers would communicate about HF management with patients. To achieve this one of the assumptions was that both the patient and caregiver would be present for facilitated intervention sessions. An example of this was one of the spousal-dyads (participants 4061), where the caregiver (wife) was keen for her husband to engage in healthier eating and utilised the information from the patient manual and facilitator support to discuss this with him. The patient (husband) in this dyad recognised that he struggled with healthy eating but identified that his wife supported him and was very “patient” him. However, it was identified that REACH-HF also enhanced communication about HF for caregivers who were not present at the facilitated intervention sessions. These caregivers were able to apply what they learned from reading either the patient manual or the caregiver resource and discuss this with the patient. An example of this was the father-son dyad (participants 4015). From the caregiver resource, the caregiver (son) identified that he learned what advice he should give his father (patient) if he identified any signs or symptoms of HF. The patient (father) identified that he was more receptive to hearing what his caregiver (son) had to say about his HF management. The father (patient) attributed this to their learning from participation in REACH-HF. The patient (father) in this dyad further reported at his 12 month interview that any discussions about his HF management happened together as a family. Visually representing the data by constructing a chain of evidence (Appendices 24 and 25) made it apparent that REACH-HF was an instigator in facilitating communication. REACH-HF did not always explicitly facilitate discussion about HF, it is worth noting this may have been more implicit and was not accurately captured in the data. One of these examples was a spousal dyad (Participants 1091) whereby the patient (female) identified that she preferred to talk about her HF management with the REACH-HF facilitator and did not engage with much discussion with her caregiver about this. The caregiver (male) concurred and identified his role as primarily completing the domestic tasks around the house, assuming that the role of the REACH-HF facilitator was to talk to the patient (wife) about her needs.

To ensure reliability and a robust approach to data analysis, multiple strategies were employed. Keeping informed of the literature, reading the REACH-HF interview topic guide and understanding the REACH-HF logic model ensured this research was underpinned by the evidence base of HF and caregiver literature (413). A paper trail was kept throughout the data analysis process in NVivo 12 Plus and Microsoft Word to present visual displays including variable mapping and the chain of evidence (Appendices 24 and 25) (395). The methods and data analysis process from importing data to conclusions identified has been transparently outlined in this chapter to enhance replicability (374). Supervision meeting discussions were a source of guidance for MN in ensuring a reflexive and critical approach to data analysis. This included acknowledging subjective bias, reflections on themes and justifying decision making throughout the process (399, 413).

Table 6.2 Meta Matrix – Cross Case Analysis

Overarching Preliminary theme	Sub-theme	Pre-REACH-HF	Outcomes reported at 4 months	Outcomes reported at 6 months	Interpretation by MN (Dyads where this was evidenced)
Operational characteristics of caregiving before REACH-HF	Pre-REACH – HF Direct and Indirect Caregiving	Diagnosis (how long), access to services, needs of the patient, caregiver perspective of HF, tasks they do, what patients and caregiver knew/ understood about	Re-framing of roles within the dyad	Patients taking responsibility for direct tasks (i.e. exercise)	Experience of HF management informing caregivers in their current approaches to HF management (Dyads 4012, 4061, 1091, 2016) Experience of healthcare services contributes to caregiver knowledge pre-REACH-HF (Dyads 2020, 4012, 2049, 4061) Caregivers actively sourcing (either selves or via healthcare services) knowledge on HF management (Dyads 4015, 2016) Caregivers' developing a strategic understanding of how and why they do specific

					tasks in HF self-management e.g. encouraging weighing (Dyads 2020, 4015, 2016, 2049)
Operational characteristics of caregiving before REACH-HF Impact of caregiving in REACH-HF and the context of caregiving in REACH-HF Impact of caregiving in REACH-HF and the context of caregiving in REACH-HF	Patient-Caregiver dyad relationship Relationship type and locus of control	Parent-child; difficulty telling a parent what to do Spouses, friend – primarily open, understanding communication	Spousal, friend relationship – natural transitions Taking a step back after crisis. Parent-child more overt in change in locus of control after crisis	Spousal relationship changing between who is providing care dependent on who is most in need Parent–child communications	The proximity of patient and caregiver, i.e. whether they live together or apart and the nature of the relationship before REACH-HF. (Dyads 1130, 2049, 1172, 2020, 2016, 4015) Role of gender: impact of this on caregivers approach to caregiving (Dyads 4015, 1091)The dynamics in the relationship inform the caregiving role – how much does the patient allow the caregiver to take a caring role (Dyads 4061, 4012, 4015, 2016, 1091)

	REACH-HF intervention - expectations Engagement with the intervention	N/A	Patient - Giving back to the research. Caregiver - patient to achieve goals Caregivers present or absent for intervention sessions Patient using resources Caregiver using Family and Friends resource	Interviews prompted some patients and caregivers to review manuals Keeping manuals in view or hidden	Caregivers understanding of the intervention (Dyads 4015, 2016, 2020, 1091, 1172, 2049, 4012, 1130, 4061) Facilitator contact sheets and fidelity scores indicate lack of caregiver involvement in sessions or when caregiver involved focus was on patient needs only (Dyads 1172, 1091, 1130, 2049, 2016, 4015) Patient engaging with facilitator had an indirect effect on caregiver. Caregiver manual was enough for caregivers when patients were engaged with facilitator and caregivers perceived patients were obtaining benefits from this (Dyads 4015, 1091, 2049, 1130) Caregivers who sought input from facilitator were vocal

					about lack of knowledge they had at the beginning of the intervention (Dyads 2020, 2016) Mainly spouses reported presence in sessions with a facilitator. (Dyads 2020, 1091, 4012, 4061) Adult-child caregivers with multiple other roles (i.e. working and young children) struggled to engage with REACH-HF – the impact of “sandwich carer” generation and balancing multiple obligations (Dyads 1130, 2016, 4015)
Impact of caregiving in REACH-HF and the context of caregiving in REACH-HF	Tangible Measures for HF self-management	N/A	Caregiver manual and/or Present for sessions with the facilitator	Continuing physical activity encouragement – some continuing to do with cha	Observable measures for patient and caregiver of change. Pedometer and Chair Based Exercise DVD were spoken of by both patients and caregivers in terms of measurement – achieving steps/ levels and increasing steps/ levels

			Exercise with the patient – pedometer and DVD – describing in numbers		(Dyads 4015, 2016, 2020, 1091, 1172, 2049, 4012, 4061) Surgery as a measure of change – providing hope (Dyads 1130, 1172)
	REACH-HF facilitated communication about HF	N/A	Able to communicate about HF by asking about REACH-HF	Greater sharing between patient and caregiver about their needs	REACH-HF was a tool that facilitated communication between patient and caregiver by reading patient manual and caregiver resource and sharing knowledge with each other or discussing HF signs, symptoms, and management strategies. (Dyads 1172, 1091, 2020, 2016, 4015) Initially, concrete checking regarding task engagement for REACH-HF, expanded at 12 months more subtle checking but normalised part of a conversation (most notable between child-parent dyads)

					(Dyads 4015, 2016, 2049, 4061) REACH-HF facilitated communication for the patient but with the facilitator as opposed to caregiver/family (Dyads 1091, 1130) Role of gender in communication (Dyads 4015, 1091)
	The family approach in REACH-HF	N/A	Reluctance among spousal caregivers to interrupt the lives of adult-children. Adult-child caregivers more likely to involve others	Adult-child caregivers involving siblings and supporting each other in caregiving Sharing REACH-HF with family	The multiple roles of adult-child caregivers necessitate involving siblings (or other family and friends) in order to share the duty, take the pressure off (Dyads 4015, 2016, 1130) Spousal caregivers' role is a natural part of the relationship; do not see the need to be involving their children in hands-on management of HF. (Dyads 4061, 4012, 1091)

					Patients who had wider family involved appeared to do better with engagement (i.e. completing progress tracker) and maintenance (still using exercise, a form of tracking) post-REACH-HF. (Dyads 4015, 2016) Nature of REACH-HF intervention (i.e. checking steps, encouraging exercise, quizzes in manual) encourages the involvement of wider family (Dyads 4015, 2016)
	Patient health Caregiver well-being	Patient health stable before REACH-HF A mix of new and longer diagnoses (duration) Caregiver not viewing their	Caregiver describing if the patients' mood is low/patient health not good, they don't feel good	Describe coping techniques to manage patient health and identify REACH-HF facilitated seeking support sooner	Nature of the relationship between patient and caregiver, the intensity of caregiving, caregiver coping skills and the stability of patients' health are all contextual factors which inform how the caregivers engaged in REACH-HF (e.g. whether they attended facilitated sessions, read the manuals, engaged in exercise) and in turn how this

		own health needs			informed their role and enabled patients in HF self-management. (Dyads 4015, 2016, 2020, 1091, 1172, 2049, 4012, 1130, 4061) REACH-HF informing response to escalation of signs and symptoms of HF (Dyads 2049, 2020, 2016, 4015)
After REACH-HF	Caregiver & patient perspective of REACH-HF	N/A	Discrepancy and/or agreement between patients and caregivers as to the benefits of REACH-HF	Behaviour change maintained by most, not by some	Caregivers individualising the resources for patients, taking ownership of the intervention (Dyads 2016, 2049) Meaningfulness of goals for patients and their understanding of REACH-HF was an influencing factor in whether behaviour change was maintained, for example if walking was valued (spousal-dyad) time with wife

					to talk, versus walking being a chore (spousal-dyad) where walking was not an activity they enjoyed together (Dyads 4012, 4061, 1130) Behaviour change interrupted by health change in patient (Dyads 1091, 4012, 4061, 1130) Age – the message of REACH-HF, translating to younger versus older. (Dyads 1172, 2020) Lack of fidelity in caregiver involvement as they weren't assessed to find out what their needs were. (Dyads 4061, 1130, 4012, 2049, 1172, 1091) Characteristics of those who benefitted from REACH-HF - Congruency of dyads (Dyads 4015, 2016, 2020, 2049)

After REACH-HF	Knowledge from REACH-HF Caregiver skills	Lived experience, duration of diagnosis Access to services all inform starting point of caregivers and patients	Expert (spousal and friend) – novice (children)	Increased knowledge obtained and maintained for most who participated in some element of REACH-HF Confirmation for caregivers on what they were doing	Increased knowledge led to a positive change in patient and caregiver understanding of patient – strength of relationship (Dyads 4015, 2016, 2020, 2049) Taking a step back from the patient and encouraging independence and greater understanding of patients' needs thus checking in more (Dyads 4015, 1172, 1091, 2016) Caregivers of patients' stable/long-term diagnosis cited no change. (Dyads 4012, 4061) Patient and caregiver perspective of knowledge from REACH-HF (Dyads 4015, 2016, 2020, 1091, 4012)

					Source of new knowledge (Dyads 2049, 1130, 1172, 1091, 2020, 2016, 4015, 4061) Operationalising this new knowledge (Dyads (Dyads 2049, 1130, 1172, 1091, 2020, 2016, 4015, 4061) Aspects of REACH-HF that allow the locus of control to change – caregivers having more knowledge, feeling more confident to step back. (Dyads 2049, 2016, 1130, 1091, 2020, 4015) Patients having more confidence in their self-management and health remaining stable (Dyads 4015, 2016, 2049)

The sub-themes identified in Table 6.2 were continually examined to ensure they were applicable and congruent with the research question and the underpinning evidence base (374). These sub-themes were further refined to capture the essence of these patient-caregiver dyads and the impact of REACH-HF on what caregivers were doing (414). This rigorous analytical approach enabled this researcher to create a visual schematic representation of the themes and sub-themes which characterise caregiver behaviour and activities during and after participating in REACH-HF which contributed to improved patient outcomes on the MLHFQ (Figure 6.2).

6.3 Results

Three core themes which demonstrate the temporal trajectory of how caregivers enabled patient HF self-management as a result of participating in REACH-HF were identified: “Setting the scene: Caregiving pre-REACH-HF”, “The impact of REACH-HF within the context of caregiving in HF”, and “The Aftermath: Caregiving post-REACH-HF”.

The first theme: “Setting the scene: Caregiving pre REACH-HF” was constructed by MN as a descriptive theme. This theme presents the context in which patient-caregiver HF self-management is taking place and provides an understanding of the background and the diversity of the experience of caregivers in HF self-management. This theme consists of one sub-theme:

1) Pre-REACH-HF experiences of caregiving.

The second theme: “The impact of REACH-HF on the context of caregiving” presents the mechanisms of REACH-HF which influenced and informed how caregivers supported patients in HF self-management:

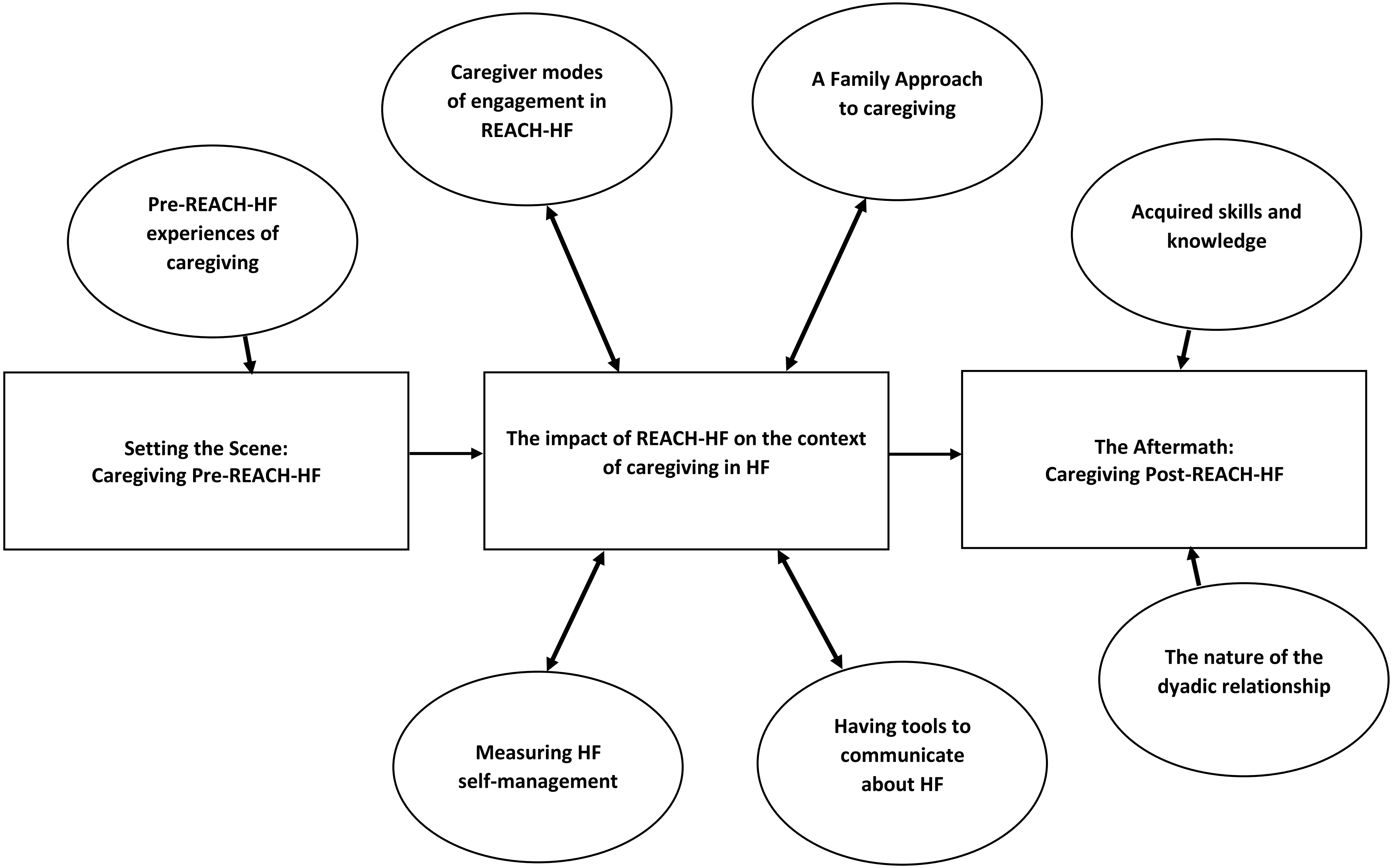
1) Caregiver modes of engagement in REACH-HF
2) A family approach to caregiving
3) Measuring HF self-management
4) Having tools to communicate about HF

This theme presents the impact of these mechanisms on what caregivers were doing. The purpose of understanding these mechanisms of REACH-HF was twofold. First, to identify if REACH-HF achieved its primary objective in terms of engaging caregivers in the intervention delivery for the benefit of patients. Second, to understand how REACH-HF informed caregivers in their role, and subsequently how these caregiver actions impacted on patients to achieve improved patient HRQoL outcomes. Caregiver actions were noted as being overt (observable behaviour, such as changing medication) or discreet (listening to breathing or observing for colour change). The arrows in Figure 6.2 are bi-directional to indicate that not only does REACH-HF impact and inform these sub-themes, they also impact and inform how patients and caregivers participated in REACH-HF. Caregivers participation in REACH-HF was informed by their physical and social environment.

The third theme: “The Aftermath: Caregiving post-REACH-HF” presents the skills, knowledge and understanding of HF obtained by caregivers and how this influenced caregivers in their role after REACH-HF. This theme identified what actions (overt or discreet) caregivers were engaging in to facilitate patient HF self-management and the context in which this caregiving was taking place on completion of REACH-HF. This theme has two sub-themes:

1) Acquired skills and knowledge
2) The nature of the dyadic relationship.

Figure 6.2 Schematic representation of Themes and Sub-themes



6.3.1 Setting the scene: Caregiving pre-REACH-HF

6.3.1.1 Pre-REACH-HF experiences of caregiving

As illustrated in Figure 6.2, the starting point for many caregivers participating in REACH-HF varied greatly. This was due to caregivers' past experience and context of HF informing their current lived experience. Caregivers ranged in age from 31 to 68 years of age and were comprised of spousal (n= 5), adult-child (n=3) and a friend caregiver (n=1). Patients' duration of HF diagnosis ranged from 2 months to 13 years, and the onset of HF was both gradual and sudden as described by caregivers. Caregivers reported that they learned how to manage HF through lived experience.

Caregivers of patients living with HF for a longer duration (5 years+) described confidence in their role, knowing what to do and when. These caregivers could be characterised as having expert skills, becoming experts through their lived experiences of caregiving before REACH-HF (366). This concept has been recognised in the HF caregiver literature (247). Many of these expert caregivers described making decisions in times of crisis. These ranged from adjusting medications, phoning for an ambulance, and dealing with hospital admissions. These crises were not a regular occurrence but did equip caregivers with skills and knowledge for coping in any potential future crises:

> "I do look for signs that he's unwell and there have been o-occasions, erm, when I've had to dial 999 and get the ambulance in"…. "So we just deal with it, bu-but having said all that it doesn't, it doesn't faze me about going on holiday with him."…."Erm, I know what to do and we'll just deal with it." (Female, spousal caregiver, 4012, 4 months)

All caregivers described actions to support HF self-management. These actions were direct such as sourcing HF information for the patient and themselves, cooking meals and taking over tasks the patient once completed, such as finances or cleaning, or indirect, for example, monitoring patients for symptoms. Understanding the clinical rationale of completing these indirect monitoring tasks was limited among some caregivers:

> Interviewer: "Do you look for any cardiac symptoms at all?"

> Caregiver: “Not-, ha ha, oh well I’ll have to say yes, but everything is just a general – if she had blue lips you’d notice it but I wouldn’t start thinking… as I walked through the back door I wouldn’t start thinking, cardiology, cardiology, look for heart symptoms. I’d walk through the back door and think, oh, you’ve got blue lips.” (Female, friend caregiver, 2049, 4 months)

Lack of access to a HF nurse, due to lack of staffing in services, impacted caregivers’ perceived knowledge about HF despite the long-term duration of the diagnosis:

> “He wasn’t, he wasn’t referred to a cardiac nurse, basically”… “Because had I had that support, I probably would be better off in the long run….”Um, I would have had the support from my cardiology – his cardiology nurse and advice and all I had at the time was my GP”…..” I need to understand more about it” (managing HF). (Female, spousal caregiver, 2020, 4 months)

Living with HF resulted in lifestyle changes for all caregivers. These changes varied from less disruptive to daily roles and routines (i.e. taking over tasks such as managing finances and planning holidays) to significant adjustments to daily roles and routines (i.e. caregiver needing to take time off work to provide care, considering geographic relocation to be closer to services). The knowledge and understanding caregivers had of HF prior to participating in REACH-HF informed their perspective of living with HF. This development of caregivers’ knowledge and understanding was influenced by the onset and timing of diagnosis (i.e. younger versus older age at diagnosis and the type of relationship between patient and caregiver).

6.3.2 The impact of REACH-HF on the context of caregiving in HF

6.3.2.1 Caregiver modes of engagement in REACH-HF

As previously suggested caregivers engaged in both overt and discreet caregiving tasks. Caregiver actions which were overt and were completed with the purpose of supporting the patient to engage in self-management tasks suggested in REACH-HF included: participating in the exercises with the patient, asking direct questions about the patients’ engagement with REACH-HF, checking that the patient was completing the progress tracker, being present at facilitator home visits and reading the patient manual or caregiver resource. Participating in exercise with the patient included completing the chair based exercise programme and ensuring they were completing it correctly, or going for walks together and utilising the pedometer so the patient could monitor their steps. For many caregivers, particularly non-spousal caregivers, participating in HF self-management tasks in such a direct way was new for them:

> “we’ve gone and done the exercising with her and done the steps per minute, so we’ve kind of done an awful lot more with her.” (Female, adult-child caregiver, 2016, 4 months)

> “the REACH programme came along and he was put on the walking programme and then he found that ‘Yeah, go for a walk early morning, it’s great!’ And he’d go off walking and I’d be going ‘Hang on a minute, wait for me!’…I like to think I helped him along, to be honest. I like to think that I was the one who was encouraging him, ‘Come on, you’ve got to go a bit further’ and ‘Don’t slow down for me, you just keep going.’” (Female, spousal caregiver, 2020, 4 months).

> “if you couldn’t see her for a particular day we could just phone her ‘What exercises have you been doing?’ and ‘What level is it now?’ and ‘How often have you been doing it this week?’ and that sort of thing …” (Female, adult-child caregiver, 2016, 4 months)

Patients who participated with their caregiver in the exercises prescribed in REACH-HF (chair based exercise or walking programme with a pedometer) were positive about this experience:

> “actually once I started it and, err, started doing the exercises and things like that but, err, the first one we done is my daughter and my, err, my husband came up…the first day I started it I did honestly hand on heart say I could tell I could feel a difference right from the time I started.” (Female, parent patient, 2016, 4 months)

> “I was feeling better in myself. I wasn’t – I didn’t want to be sat down in the house, I wanted to be up and out. I’d get up, get washed, get showered, get the kids ready for school, see the kids off to school, and then I’d say to MC2020 ‘Come on then, we’ll go and have a walk.’” (Male spousal patient, 2020, 4 months).

However, this was not applicable to all patients and caregivers. For some caregivers, trying to encourage the patient to engage in the walking programme was a source of tension at times:

> “I do try and encourage him to walk but it’s not his favourite occupation, so that’s a little bit of a slight bone of contention sometimes isn’t it?” (Female spousal caregiver, 4061, 4 months)

> “It’s, it’s not something that motivates me, you know exercise, you know. You know to go for a walk, I don’t go for a walk to look at the scenery, I only go for a walk, to go from A to B. And my wife’s said to me, “You must, you must look at the scenery and enjoy it.” I don’t enjoy scenery, I just want to get there and get back, then I’ve done my walk, you know, and that’s, that’s… I don’t know how I can overcome that one.” (Male, spousal patient, 4061, 12 months)

For the male patient in dyad 4061, walking was not an activity he enjoyed, and thus he did not identify the benefits of participating in this with his wife (caregiver) as a method of engaging in HF self-management. Whereas the male patient in dyad 2020 identified that he enjoyed walking and this was a valued activity he did with his wife (caregiver) as part of REACH-HF. This indicates the value or meaning that someone ascribes to the activity is an important indicator of their level of engagement or motivation to do that activity.

Another aspect of caregiver activities in terms of direct actions was their participation in facilitated intervention sessions. An important point to note about caregivers’ participation in intervention sessions is that for many of them, their skills and knowledge of the patient were identified for the first time and acknowledged by REACH-HF facilitators. Thus REACH-HF facilitators utilised these caregivers as co-facilitators during intervention sessions. Caregivers, when engaged as co-facilitators, can have an essential role in enhancing and consolidating behaviour change in HF self-management (415). This demonstrated the value of engaging caregivers in intervention delivery:

> I noted that the facilitator and the caregiver seemed to be working together to promote the exercise as part of REACH-HF… she has worked out her own role as a co-facilitator. (Fieldwork note, friend dyad, both female 2049, 4 months)

Enabling the caregiver to participate as a co-facilitator required expertise from REACH-HF facilitators to recognise these skills in the caregivers and structure the session in a way that allowed this. This demonstrated respect for caregiver expertise and potentially contributed to enhanced caregiver confidence. Enhancing caregiver confidence can positively impact caregiver actions to support HF self-management, thus enhancing patient HRQoL (187). This was clearly evidenced for one spousal dyad, where the female caregiver was present at all facilitator sessions and was vocal about the impact of REACH-HF on her confidence and subsequently informed how she dealt with a crisis which resulted in the patient avoiding being hospitalised. The following is an excerpt from the Fieldnotes after the 12 month follow-up interview:

> “She was the one who took action when he was unwell and this was using learning from the intervention. Her husband didn’t think they got help any earlier than they usually would have done but she does. She put into practice what she had learnt without referring to the resources and when she noticed her husband was swelling – around his waist as well as his ankles she asked what he weighed, got him to weigh and then called the GP.” (Fieldnotes, female spousal caregiver 2020, 12 months)

Caregivers mostly read both the patient HF manual and the Family and Friends resource. The knowledge they obtained from their engagement with these resources enabled them to prompt patients to use the other resources such as the pedometer, CD or DVD. The volume of the HF manual, progress tracker and accompanying CD and DVD were deemed to contain too much information and difficult to follow for two patients, as a result the caregivers individualised the resources for the patient. This included adapting the progress tracker into one page with key pointers for the patient (Appendix 26) and colour coding what they identified as important sections of the HF manual (mother-adult-child dyad 2016). Another caregiver purchased a DVD player for the patient and taught her how to use it. This caregiver wrote out and printed the exercises for the patient to make it easier for her to follow the instructions and enabled her to complete the exercises independently if the caregiver was not present (friend-friend dyad 2049). These dyads described undertaking these activities to ensure the patients could maintain these behaviour changes beyond the duration of the REACH-HF intervention:

> Regarding the progress tracker: “I found it sometimes quite frustrating going back and forth …… so in the end [name of daughter] put little stickers at the top, yellow for one thing¸ green for another, red for another so I could just go to those….”The way it’s set out. It’s brilliantly done …” (Female, parent patient 2016, 4 months).

> “So this one pager we did was just something very, very snappy, and easy for her to sort of look at. Because we want her to continue, because…… it

> had such an impact on her, um, not so much, uh, one is her breath, and being able to sort of, she's not getting so tired with moving around…… but um, also with her sort of, uh, confidence as well, in relation that she could go further. (Female, adult-child caregiver, 2016, 12 months)

Caregiving did not always consist of direct actions or direct questions about REACH-HF. At times caregivers employed what they perceived as a discreet approach to ensure their loved one was participating in the suggested self-management tasks in REACH-HF:

> "I drive through *** [pt 1130] sometimes on the way home and I've actually seen her walking. And she wouldn't have known what time I would have driven home, so I know that she's doing it unprompted, so…" (Female, adult-child caregiver, 1130, 4 months)

> "This caregiver assesses condition from afar when he calls – usually every other day and visits several times a week. He listens to his father's voice and how he sounds – assessing tiredness and breathlessness and then tailors care accordingly. (Fieldnote 12 months, male, adult child caregiver 4015)

> "'I'm far more proactive in asking questions so… she might not realise where I'm digging. But, um…so even though I might be sending her a message in relation to my daughter, say for instance…she's gone in to nursery okay and she'll be ready like at one. But it's like, "How are you by the way?", you know. There is that checking without her knowing, you know, and, um, uh, and so I think, uh, I've changed that sort of way" (Female, adult-child caregiver, 2016, 12 months)

Observing the patients from afar then empowered caregivers to take action if required or maintain their observing from afar thus letting the patient maintain their independence as necessary. Patients may not have always been aware of this surveillance but having a caregiver as a formal part of REACH-HF enabled them to feel supported, accept help or talk with their caregiver about how they were feeling:

> "it does make a massive difference to have that support net-, network around you." (Female, parent patient, 1172, 4 months)

> "the son (caregiver) rings every day. He's a shrewd old cookie. He, he's watching what's going on. Erm, I, I know he is. And if he, if he thinks it's- I'm gonna do- "What are you going to do be doing today?" And I says, right, "No, leave that. I'll do that when I come over." (Male, parent patient, 4015, 12 months)

> “Like [name of daughter] this morning, she knew when she spoke to me on the phone that I wasn’t feeling right. I said to her ‘The ring came out last night’ and she just knew that – ‘OK’, she said ‘I’ll get Dad up to bring you over, I’ll go do the shopping’. They are really, really good. “I’m probably more open about how I’m feeling than I was.” (Female parent patient, 2016, 4 months)

The nature of the relationship the caregiver had with the patient influenced whether the nature of caregiving was direct or indirect. For example, adult-child caregivers and one spousal caregiver had multiple roles in addition to caregiving. This included full-time employment and parenting young children. This impacted on some adult-child caregivers’ ability to engage with REACH-HF as they reported not having the time to be present in appointments with the facilitator or the time to read the Family and Friends resource. One of the spousal dyads for whom this was an issue described their dyadic approach to HF management; the patient read all the REACH-HF resources, and she would tell the caregiver essential pieces of information from the manuals and, if necessary, prompt him to read elements of the HF manual. The design of REACH-HF enabled caregivers to use the resources provided and engage in the intervention in a manner best suited to their circumstance. This approach was viewed positively by patients, many of them reported that knowing they had a support person provided reassurance to them in their management of HF:

> “it’s much easier if you’ve got somebody else that you can, er... Talk to about things and so on as well.” “Erm, you know, she, she sort of, er, was, was here, er, er, if I needed, erm, any help on anything. But MC4012 didn’t really get involved very much, no.” “It’s just, just, it, it, she’s, she’s, it’s nice that she’s there” (Male, spousal patient, 4012, 4 months)
>
> “I mean, he, he's been a, a, moral support, you know.” (Female, spousal patient, 1091, 4 months)”
>
> “I couldn’t manage without her helping” (Female, friend patient dyad 2049, 12 months)

Most spousal and friend caregivers were retired and therefore were more likely to be present for appointments with the facilitator and had time to read through the resources. Some spousal dyads had to take responsibility for caring for grandchildren. In these spousal dyads, the caregivers took on a co-ordinator role, arranging this childcare duty for times they (caregiver) were present with grandchildren in the house. This ensured patients were able to maintain their role as a grandparent but also minimising any additional stress on the patient:

> This couple support with childcare. This is difficult as (patient) should not really be lifting children. Where possible, (caregiver) is present or makes sure someone else is to help….. (Field notes, spousal dyad, female patient, male caregiver 1172, 4 months)

Reasons for participating in REACH-HF varied from wanting to understand more about HF to needing support in motivating the patient in order to positively influence patients' HRQoL, and an opportunity for the patient to set themselves goals. All of the patients in this sample were positive about the involvement of their caregiver in the intervention:

> "I just wanted to support Mum and understand a little bit more about what was going on, 'cause it is a brand new subject to us." (Female, adult-child caregiver, 1130, 4 months)
>
> "Um, well C and my friend ***, who lives three doors along were probably the, the closest… uh, family members or…whatever you want to put it, um, that were sort of in on the very beginning and, and right the way through, um, and I, I think it, you know, useful that they had as much information as I did… uh, so they knew what to expect out of me…um, and what I could or couldn't do, what I should or shouldn't do (laughs)…" (Female, parent patient, 1130, 4 months)
>
> "Well I was hoping that it might encourage [MP4061] to set some little goals for himself"…."Erm, in, in exercise and, and, and weight control. That's what I was hoping for." (Female, spousal caregiver, 4061, 4 months)
>
> "Yeah, she's, er, she nags me a bit, but, er, but I have to say that, all in all, that I value it greatly" (Male, spousal patient, 4061, 4 months)

Patients who were pro-active in engaging in HF self-management independently of their caregiver required minimal caregiver input. In these situations caregiving required a less active stance and engaged in more covert observing. One adult-child caregiver described a relief when he recognised the patient was making lifestyle changes and engaging in HF self-management as a result of REACH-HF:

> "he has taken pressure off me without really knowing it" "because getting his own act in gear." (Male, adult-child caregiver, 4015, 12 months)

Some caregivers and patients reported reading REACH-HF resources once (either the HF manual and or the Family and Friends resource) and not going back to re-read any of the resources over the following 12 months. Caregivers and patients knew where the resources were kept to reference them if they needed to access them. Keeping the resources provided reassurance about any potential future crises and provided a resource of knowledge which they could return to if needed:

> “So if the situation were to come again, here we are, we would go through the resources again, we would go through the CDs again, and we will work our way through it again. So there’s the future.” (Female friend caregiver, 2049, 12 months)

The social context of caregivers dictated their ability to be present for facilitated intervention sessions. Retired spousal and friend caregivers were most likely to be present in intervention sessions. One adult-child caregiver was present for intervention delivery sessions as she was on maternity leave. Trying to engage caregivers in a face-to-face intervention requires an awareness of the time demands on these caregivers. REACH-HF was designed with this awareness, thus providing an intervention that was home-based and included a resource for caregivers to read in their own time, as well as telephone interventions (28). While this was an identified element of the intervention delivery, not all facilitators utilised this mode of caregiver engagement. One facilitator did make several attempts but was unable to make any telephone contact with one of the adult-child caregivers. Another facilitator contacted one of the adult-child caregivers via telephone. These two facilitators were the exception in this data set and having telephone contact with caregivers was not standard practice within this sample.

6.3.2.2 The Family Approach to caregiving

Caregivers who had other family members also engaged in REACH-HF (i.e. reading the Family and Friends resource and/or the HF main manual) reported significant gains from REACH-HF. This was amongst both spousal and adult-child caregivers regardless of gender, age or severity of illness. Having a shared goal broader than REACH-HF united the family and the REACH-HF resources were an enabler for achieving these goals.

> “we’re doing better than we probably did because we’ve got a common goal” (Male, adult-child caregiver, 4015, 12 months)

Goals varied from, the whole family wanting to understand HF, reducing anxiety about HF amongst the wider family, to patients wishing to be able to support their adult-child caregivers by caring for their grandchildren. One parent-adult-child dyad identified behaviour change was necessary due to the patient being a caregiver for his wife. Family involvement in REACH-HF included methods such as all family members participating in the chair based exercise, adult-children sharing observations and discussions with each other about the patients’ health, grandchildren asking about the pedometer and making memories together by going on trips. Some patients in the adult-child-parent dyad identified that having grandchildren motivated them to get out for a walk, thus encouraging engagement with physical activity:

> “My daughter’s gone back to work so I’m looking after her on, um, Tuesday and Wednesday afternoon and all day on a Thursday. And they’re often here on a Monday afternoon as well and sometimes over the weekends, so I see quite a bit of her…and she has literally got me, you know, moving around a lot more than I did before. I can look after my granddaughter, um, play with her, take her out for walks, um, shopping with her. You name it, we can do it like, you know.” (Female, parent patient, 2016, 12 months)
>
> “Now, the little one, the eight year old – she checked the pedometer every day, to start with, to make sure I were doing it. And she’d say ‘How many steps have you taken today, Grandad?’ I’ll say so-and-so, ‘Right, walk around twice’ then she set me off from that corner and I had to walk right up there in the property, right the way round, and then ‘And again, Grandad, you’re all right.’ And I’ll go round again. Silly as it sounds, you do it! You do it! [laughter].” (Male, parent patient, 4015, 4 months)

Keeping the manuals in the home environment and the facilitator visiting the patient and caregiver at home provided a forum for the wider family to become engaged in the caregiving process. The value of the family approach was particularly evident in two of the parent-adult-child dyads:

> “they’ve all got their own sort of role”…” we’ve all come together, erm, really because we’re conscious of each other’s commitments and what we’ve got to do, and that way, you know, we, we all take a part without one being dominant and above the other.” (Male patient, 4015, 12 months)

> “anything we do out of the norm is properly discussed as a family.” (Male patient 4015, 12 months)

> “the family have come together, so that’s been a bigger support for her as well.”….. “I’ve been grateful of the family, er, coming forward.” (Female adult-child caregiver, 1130, 12 months)

> “my one sister would often do the exercises with her. One time we ended up with my Dad, myself and my Mum were doing the exercises together [laugh], and, um, but, you know, which was good for Dad really, because I think it’s good for general fitness, you know! But, um, you know, we would try and do it with her. But my sister would often, you know [lowers voice here], Mum’s, I don’t know whether it’s a generation thing or – [back to normal volume] Mum wasn’t and, you know, she isn’t big for – she’ll, like most people I presume, set up with exercise and then after a few weeks, like a New Year’s resolution, isn’t it, and after a few weeks – phew gone, you know. And Mum will do exercise, and she’ll do it at ninety miles an hour, where my sister’ll be like ‘You’ve got to slow down, it’s the quality of it, not the speed of it, to do exercises’, so she’ll often do things with her …” (Female adult-child caregiver, 2016, 4 months)

The value of a family approach was highlighted when one of the parent-adult-child dyads had a change of facilitator during the REACH-HF intervention process. Additionally, due to illness, intervention sessions were primarily over the telephone, which did not appear to impact the benefits this family obtained from REACH-HF. This is likely because all family members were involved in REACH-HF and the facilitator was pro-active in contacting the adult-child caregiver in this dyad by telephone:

> “She may have had a disjointed facilitator experience due to illness but it has not affected her. I have heard the first session and so much was covered then and this family are engaged with the intervention”….. “The family believe in taking responsibility for yourself as the health service has limited resource.” (Fieldwork note, adult-child parent dyad, both female, 2016, 12 months)

Not all families engaged in REACH-HF, but the younger spousal dyads both encouraged their teenage/young adult-children to read the Family and Friends resource. However, both reported that their children were not keen to do this. This may have been due to fear of HF, or HF being present for most of their lives and therefore not feeling a need to read any more about it.

Caregivers who utilised a family approach when participating in REACH-HF, supported the patient's participation in the elements of REACH-HF by jointly completing tasks such as the progress tracker or completing the chair based exercise together. The wider family being involved also supported the caregiver in their role. When visible in the patients' home the REACH-HF manuals facilitated the wider family to be included as they were readily accessible in the home environment for other family members to read the resources and become involved in the conversation around HF management. These dyads who involved wider family spoke positively of the benefits they had obtained from REACH-HF and identified behaviour change within the patient.

6.3.2.3 Measuring HF self-management

The concept of measuring the patient's HF progress was discussed repeatedly in interviews by both patients and caregivers. The REACH-HF intervention provided patients and caregivers with physical items to monitor and measure HF self-management. Caregivers referenced the pedometer, the progress tracker and the chair based exercise DVD as ways of tracking patients' progress and indicators of whether the patient was improving or not. Patients wore the pedometer or had it placed in their pocket, and this counted their steps when walking throughout the day. When queried in interviews about their progress and experience of REACH-HF both patients and caregivers referenced the pedometer, making statements about how many steps the patient was achieving per day or whether they weren't achieving as many steps as they would like. This was a method for caregivers to monitor patient progress. The number of steps a patient was taking per day was a benchmark to monitor progress and to discuss HF self-management with each other and the facilitator:

> "he's doing his, his walking and he's got his pedometer, he wears it everywhere, it's great, 'cause he puts it on, if we went to (name of city) he'd put it on 'I'll see how many steps I'm going to do today.' (Female, spousal caregiver, 2020, 4 months)

Post-intervention, the majority of patients were maintaining physical activity. Some patients continued using the pedometer and referenced their physical activity in terms of their number of steps daily. Therefore, the ability to quantifiably measure progress independent and sustained behaviour change was enabled:

> Patient “I’ve still – I’ve still got my pedometer.”
> Interviewer: “So how far are you able to walk now?”
> Patient: “Erm, I'm doing about between five and a half and seven and a half thousand paces a day.”
> Interviewer: “Good grief. That’s a lot.”
> Patient: “Well, I'm aiming for a bit more because I thought 10,000 paces was, was, erm, just an average” (Female patient, 1091, 12 months)

All patients made note of their progress in the tracker; this included their weight, HF symptoms, and exercise. Each week they recorded how they were feeling physically and mentally and what it was that made them feel better or worse. Included in the progress tracker and the HF manual was a traffic light action plan. This was to aid decision-making for both patient and caregiver with recommended actions in response to HF symptoms. Green indicated patients were good to continue with their daily routine if signs and symptoms were the same as usual, amber signified patients or caregivers needed to take some action if the patient was feeling worse than usual and red indicated that a caregiver or patient should seek immediate help from medical professionals. Patients identified this as a useful tool in supporting them to make decisions about their symptoms and when to act, for example, phoning a doctor when breathless. There was an absence of evidence to interpret caregivers’ perspective of the traffic light action plan. In contrast, caregivers reported benefitting from having the progress tracker to view the daily and weekly progress as recorded by the patient, which enabled them to monitor the patient’s progress. This was particularly useful for adult-child caregivers who were not living with the patient:

> “seeing her, and the, the, the-, how her Progress Tracker went. You could, you could see it on paper as well so we wanted to…be sure that she, uh, she kept it up as much as possible” (Female, adult-child caregiver, 2016, 12 months)

The chair-based exercise DVD was spoken about by patients and caregivers to a lesser extent than the pedometer and progress tracker. However, when patients used the DVD, patients and caregivers described progress in terms of the level of exercise the patient achieved:

> “You know, that it was, and it was quite nice to come down some mornings and see him sitting on the chair and doing the exercises and things, ‘cause I’ve never seen him doing anything like that before. So he was obviously taking seriously…But I know he’s pushed himself up. [Facilitator] started him on level three and he’s pushed himself up to level five.” (Female spousal caregiver, 4012, 4 months)

Having tools to measure progress, such as the pedometer, progress tracker or a weighing scales provided caregivers with resources to encourage behaviour change and provided a tangible goal to work towards (28). Measuring progress encouraged individuals to take ownership of their HF management and provided caregivers with knowledge and understanding of the patient's HF and how to support them. In the uncertainty and ever-changing nature of HF, having something tangible such as a reference point to measure health status can provide motivation and offer hope to patients and their caregivers in a life touched by HF and a motivation tool for caregivers to use in their role. REACH-HF provided this function for the dyads in this sample (28).

6.3.2.4 Having tools to communicate about HF

REACH-HF was designed to facilitate communication between patients and caregivers about HF and how to manage it. That it achieved this was demonstrated in patient-caregiver dyads who were parent and adult-child. Adult-child caregivers described the initial change in the relationship dynamic after the HF diagnosis and how this impacted on their ability to communicate. One of these adult-child caregivers identified that it was challenging to tell a parent what to do, while another reflected that it is now like having another child. One patient identified that her adult-children were doing too much for her and had difficulty communicating this until they participated in REACH-HF:

> “it’s the girls, it’s, you know, er, my daughters, they say ‘Don’t do this, don’t do that’ and now I just say ‘I can do it, it’s all right, I know …’”(Female parent patient, 2016, 4 months)

The facilitator-led sessions which engaged both patient and caregiver, the manuals and the progress tracker were all tools which enabled discussion about HF. Firstly by enhancing participants' understanding of HF and secondly by consolidating their knowledge in HF self-management activities and focusing on a shared goal which was to live well with HF. For example, in one of the younger spousal dyads was a caregiving husband concerned about his wife's exercise habits. The facilitated sessions enabled discussion about the caregivers concerns about the patient swimming, the facilitator emphasised the health risks of this to the patient. The patient subsequently identified that swimming was not a health promoting activity for her to engage in. Caregivers perceived the facilitator as a source of support to them in encouraging and promote behaviour change. Patients also recognised there were times that it was easier to take advice about HF management from a healthcare professional rather than a family member:

> "You should see her coming out of the swimming pool, I brought her a chair, which is wicked really, she can go into town when she wants. And I brought this to stop her going purple. And that's exactly how she came out the swimming pool the other day. So when she wasn't in the room I talked to, who was the other lady that come round?..to [facilitator] about it". (Male younger spousal caregiver, 1172 4 months)

> "'cause '[caregiver] kept going on about, you know, no, no, you shouldn't do this, you shouldn't, I'm not happy about it, blahdy blah, because I was coming out purple, red, purple.So listen to your family really, and listen to someone that knows what they're talking about you'll probably listen better. But she didn't do – like he would say you're not allowed to swim anymore…but [facilitator] was, you know, make it – tell me the risks, quite big risks, which you don't think about that." (Female patient, spousal patient, 1172, 4 months)

REACH-HF did not always facilitate communication between patient and caregiver for all spousal dyads. For some spousal dyads, REACH-HF was something for the patient to engage in, and the facilitator was the person to communicate with about HF. In one spousal dyad a male caregiver spoke of difficulty speaking with his wife (patient) as he did not think she would be comfortable discussing things with him. Another spousal dyad where the female caregiver was keen to keep HF in the background of their lives and did not want to consider the future, purposely chose not to discuss the implications of living with HF with her husband (patient):

> “we don’t have deep discussions about things. We, I don’t feel we need to do that” (Female spousal caregiver, 4012, 4 months)

> Interviewer: “Do you, have you ever had any, sort of, discussions about your health and expectations for the future and..?”
> Patient: “No. No, I, erm…no, and nothing really about the health really.” (Male spousal patient, 4012, 4 months)

> As a couple they have not had a ‘deep’ discussion about the future – he doesn’t feel they need too. I got a sense that they ‘live in the moment’ rather than plan ahead. Their focus is on enjoying life today while they can. I sense that they are not ready to face an ill future. (Fieldnote, spousal dyad, 4012, 4 months)

By 12 months, components of REACH-HF facilitated communication amongst the wider family in some spousal dyads who had not shared REACH-HF with the wider family at 4 months follow-up. The accumulated components of REACH-HF which facilitated communication were most likely to be: the patient manual, facilitator home visits, the pedometer and the chair based exercise DVD. Facilitator home visits were vital in enabling communication. This was particularly pertinent for male caregivers who reported that the patient was more likely to tell the truth about their circumstances to the facilitator as opposed to them:

> “She can't like talk to me so much as she can to a stranger” (Male, spousal caregiver, 1091, 4 months)

Caregivers’ knowledge of the patient also influenced how and when they communicated about self-management actions and behaviours learned from REACH-HF. All caregivers described knowing when and how to approach the patient about healthcare issues. This innate knowledge of the patient was a key skill of caregivers in promoting and encouraging engagement in HF self-management:

> “it's just picking the right time to ring, or pop across. Ones where he's in a, he's, er, in a reasonable mood, or if he's in a more receptive mood, I think is the best way of describing” (Male adult-child caregiver, 4015, 4 months)

All patients and caregivers who were present for intervention sessions and had the opportunity to engage with the facilitator spoke positively about REACH-HF facilitators and the value of having a health professional come to their home who had the time to talk. This indicates that REACH-HF, by its design, was successful from the perspective of caregivers who felt supported by the presence of a healthcare professional in their home. Caregivers who were present in the facilitated intervention sessions viewed their role as communicating truths between patient and facilitator, this included comments on the patients' health and whether they were engaging with REACH-HF:

> "he kept saying to him he has X, Y and Z, and I knew that that wasn't right. So I said to the specialist, "He's not really telling the truth there." Then he looked at me, as if to say that I'd broken a golden rule.
>
> I said, "Well, you do. You've got to be honest, especially at this time." I said" (Male adult-child caregiver, 4015, 4 months)

This secondary qualitative data analysis indicates that REACH-HF created an outlet for patients and caregivers to communicate about HF self-management, as it was purposefully designed to do (via the patient manual, facilitated intervention sessions, DVD and pedometer). The combined and cumulative impact of the REACH-HF resources prompted conversations between patients and caregivers about HF. This was particularly important for male caregivers who struggled in the past to be heard when trying to engage in conversations with the patient (Dyads: female spouse, male parent) about HF self-management. REACH-HF provided them with this opportunity as they had the REACH-HF manual and facilitator conversations to utilise as evidence or to be the cornerstone for their discussions. Those spousal dyads for whom REACH-HF did not facilitate further discussions about HF self-management were keen for HF to live in the background of their lives. These spousal caregivers viewed REACH-HF as an outlet for patients to discuss HF with the facilitator but not for the patient and caregiver to discuss HF with each other.

6.3.3 The Aftermath: Caregiving post-REACH-HF

Caregiving post-REACH-HF is the key theme in understanding the sustained impact of REACH-HF on patient and caregiver outcomes. The skills and knowledge obtained as a result of participating in REACH-HF, and the extent of this impact on the nature of caregiver contributions in HF self-management and sustained behaviour change are presented in this theme.

6.3.3.1 Acquired knowledge and skills

Caregivers in this sample reported an increase in knowledge as a result of participating in REACH-HF. This knowledge was two-fold, an increase in knowledge about HF and an increased knowledge in understanding the patient's needs. Caregivers of patients who were living with HF over a longer duration of time (Five or more years) were more likely to report this knowledge consolidated what they previously knew. Caregivers obtained this knowledge from the REACH-HF manuals, from information the patient shared with them, and from the facilitator when caregivers were present during intervention sessions:

> "the simplest of things, like Mum was poorly halfway through it, um, I didn't know quite what she could take with the medication you know, naturally just go to the medical cabinet and get something out, you know. But that awareness from this package, um…they would just think, right, we need to speak to somebody. So I just went off down the chemist with the list of medication" (Female adult-child caregiver, 2016, 12 months)

Knowledge acquired from REACH-HF confirmed what caregivers either already knew or provided them with an understanding of HF self-management, thus enhancing the value and meaning they placed on the patient engaging with HF self-management tasks. Having access to an evidence-informed resource which was enhanced by facilitator sessions provided reassurance to caregivers. Caregivers' identified increased confidence in their decision-making during times of HF exacerbations, and interviewers also noted this observation in field notes. Increased caregiver confidence in these times of crisis resulted in taking action sooner and could minimise the likelihood of greater exacerbations leading to hospitalisation (416, 417):

> "She was the one who took action when he was unwell and this was using learning from the intervention. Her husband didn't think they got help any earlier than they usually would have done but she does. She put into practice what she had learnt without referring to the resources and when she noticed her husband was swelling – around his waist as well as his ankles she asked what he weighed, got him to weigh and then called the GP….I believe her prompt action may have saved a hospital admission." (Field notes, spousal dyad 2020, 12 months)

Having access to REACH-HF resources at home enabled caregivers to use the resources as and when they needed or wanted to. When patients were engaging with the health behaviour change strategies which were integral to the design of REACH-HF, caregivers, who were not living with the patient reported being able to reduce their input. This reduced the intensity of caregiving and at times re-invigorated patients to maintain a sense of autonomy over their health:

> "if I'll be honest with, like I keep going back to. He's taken a lot of pressure off me without really knowing it. Because getting his own act in, in gear. He's basically identified his own signs." (Male, caregiver, son, 4015, 12 months).
>
> "I changed. So having realised where I was, erm, it couldn't go on. So I had to do something about it...Stick to it rigidly. Stick to a sensible time of going to bed and getting up and your diet and things like that, and you seem to go on without any problems. I wouldn't say I have good days and bad days by any means. They're mostly manageable and, and, er, nothing really changes. Which I'm, I'm pleased with. But I can only put that down to sticking to what I've read and sticking to a diet. And sticking to a, a way of life." (Male, parent patient, 4015, 12 months)
>
> Interviewer: "So how's your role changed, if it has at all, since January, when I was last here?
> Caregiver: "I'm going to say in a way it's diminished in as much that [MP2049] is so much better. She's so much more confident. She can get around so much better." (Female, friend caregiver, 2049, 12 months)
>
> "I do all that I want to do but I don't forget that I've got a wonky heart."
> (Female, friend patient, 2049, 12 months)

Living in a different household to patients was identified by some caregivers as a stressor pre-REACH-HF, and they identified difficulties with trying to support the patient at times from afar. However, post-REACH-HF when patient health remained stable and caregivers were confident in HF monitoring, living in a different household enabled them to take a step back from the caregiving role. This is a key element for patient HRQoL as less caregiver strain can have an impact on increasing patient efficacy in HF self-management (416). These changes were most evident in adult-child and friend-friend caregiver dyads and in the younger spousal dyads. Older spousal dyads who were living with the condition over a longer-term did not refer to changes in confidence levels but did identify that they learned new pieces of information due to participating in REACH-HF:

> "She's so much more confident. She can get around so much better…..Erm, so I've stepped back quite a lot………So, erm, as her confidence gets better and I can see it, so my confidence starts saying, "Okay, now get on with it", that goes as well." (Female friend caregiver, 2049, 12 months)

The most significant lifestyle change was maintaining some form of physical activity or returning to physical activity after experiencing a health setback. Patient-caregiver dyads who had a wider goal beyond the intervention were more likely to sustain behaviour change. Goals included planning a holiday, weight loss in preparation for a heart transplant operation, being healthy enough to provide care for their grandchildren and planning to obtain paid employment. These activities were all identified as meaningful to patients and caregivers and provided a focus to engage in HF self-management beyond REACH-HF.

Two patients had difficulty maintaining lifestyle changes that they had initiated during REACH-HF. These patients varied in terms of duration of HF diagnosis. One patient was diagnosed with HF approximately 12 years at the time of the intervention. In contrast, the other patient was diagnosed with HF approximately one year at the time of the intervention. The patient who was living with HF for approximately 12 years was part of a spousal dyad. When queried whether he gained benefit from REACH-HF, he reported:

> "I don't think so, because I, I have got quite a lot that I've picked up, by having a heart attack in 2003." (Male, spousal patient 4061, 12 month)

The spousal caregiver in the above dyad, who was confident in her role as a caregiver pre-REACH-HF agreed with the patient about the benefits of REACH-HF. She identified that even though she tried to encourage and motivate him, changes from REACH-HF were not maintained. This raises a query about the application of REACH-HF and its suitability for sustaining behaviour change in patient-caregiver dyads living with HF over the long-term. This dyad had been living with HF for twelve years:

> "I don't think that he has really taken on board all that was in the programme", "unfortunately he has this idea that he has this condition and it's a bit of a fatalistic attitude, but that nothing he does will make any difference. He doesn't voice it, but I can tell by when people try and

> persuade him that more exercise or diet and things like that, he doesn't really take it on fully." "I've tried over many years, erm, to trying to get him to do things to improve his situation." (Female spousal caregiver, 4061, 12 months)

In contrast, the other dyad reporting difficulty maintaining lifestyle behaviour change as a result of participating in REACH-HF were living with HF over a shorter period. On enrolment, to REACH-HF the patient had been diagnosed with HF for two months. This patient had returned to work full time at 12 months post-intervention. She was the only patient in this sample who was working full time. She was reported feeling uncertain about managing HF and feeling "abandoned" by the facilitator:

> "I think I'm still getting used to it…..If I'm physically feeling okay then I suppose there's no reason for me to think about it and I just get on and do whatever I've got to do. But if I am feeling a little bit off, there's always that in the back of your mind, "Well, why am I feeling off? Is it..?…"Is it the heart? Is it something else? Is it- should I be worried about it? Should I just ignore it?" You know, it's, it's that uncertainty that, that comes with it all the time I suppose."(Female patient, 1130, 12 months)

The caregiver in this dyad, a daughter of the patient, had difficulty providing support and engaging with REACH-HF. This caregiver was also adjusting to the diagnosis and the level of support she was able to offer. She was an only child with a new-born baby and a full-time job. This parent-child dyad demonstrates that coming to terms with a HF diagnosis is a process for both the patient and caregiver. Learning to live with HF requires a lifestyle adjustment and can take a significant amount of time and active involvement from healthcare services over a period of time longer than 12 weeks. The response from dyads 4061 (with a long-term diagnosis of HF) and 1130 (with a new diagnosis) to the REACH-HF intervention implies that there may be an optimal time frame to enrol in REACH-HF for example, longer than two months and less than five years based on the evidence in this secondary analysis.

Younger spousal dyads (45 – 52 years of age) identified that HF is an uncommon condition amongst their age demographic. They emphasised that their experience of living a life with HF was about being united in their approach to managing HF. Living with HF at a younger age prompted them to prioritise family occasions, to make time for each other as a couple and as much as they could live life with HF in the background. They identified supporting each other through ill health and both dyads identified times where the caregiver sought support for their health between the 4 and 12 month interviews. The home visits by the facilitators were the key aspect that younger spousal dyads reported when identifying the benefits from REACH-HF. Both of the patients in the younger spousal dyads experienced a significant deterioration in their health since the 4 month interview. These dyads identified that they had become closer after participating in REACH-HF, they recognised the benefits of having the facilitator visit and using the patient manual as a resource to refer to. However, they clearly stated the significance and importance of the emotional support they offered each other within the dyad. They spoke of the strength and depth of the relationship between them since participating in REACH-HF:

> Interviewer: “Has anything changed in the last 12 months?”
> Caregiver: We’ve got- closer again (Male, spousal caregiver, 1172, 12 months)
>
> “We say because, you know, you don’t- you- you don’t know whether you’re gonna get the chance to say it. We never leave the room, we never leave the house without saying, “I love you.” (Female, spousal patient, 1172, 12 months)
>
> “I think we, we're more stronger as a unit now.” (Female, spousal caregiver, 2020, 12 months)
>
> “We like to spend time on our own, with the kids grown up. Being more away for a weekend together, on our own.” (Male, spousal patient, 2020, 12 months*)*

These examples demonstrate the importance of understanding the context in which HF is taking place, in particular for younger spousal dyads for whom HF is an interruption to their shared expected life course and normative transitions. The availability of a support network for both the patient and caregiver is an important aspect in their ability to manage these transitions. This aligns with the concepts from the Stress Process Model, whereby supportive social settings and systems (i.e. communities, healthcare services, policies) can mediate stress (80, 82). Recognising the priorities of the patient and the caregiver can help inform how HF self-management strategies are approached.

Importantly, caregivers who individualised resources indicated positive changes which were sustained after REACH-HF had finished. Adapting the resources to meet the needs of the patient demonstrated caregivers' understanding of what the patient's key needs were and provided both patient and caregiver with a sense of ownership over the intervention. This suggests that REACH-HF provides the resources for learning about HF self-management and engaging in health behaviour change. However, REACH-HF requires caregivers to tailor the intervention to the needs of the patient to enhance the efficacy of the intervention for their context:

> "Um, so this one pager just sort of allows her on a weekly basis just to have a little look at what steps per minute need be, you know, that exercise to be done, what sort of is a daily at the top of the actual page and what is a weekly…sort of towards the, the end of the page as well. But done it in little sort of, um, little snippets as well, that if there was a-, uh, you know, if she wanted to learn more." (Female, adult-child caregiver, 2016, 12 months)
>
> "And now we've got the resources that, already on hand that we know, that we can use again, time and time as required." (Female, friend caregiver, 2049, 12 months)
>
> "The exercises were lovely…..her improvement that we had when we started them has been maintained."(Female, friend caregiver, 2049, 12 months)

Patients who sustained HF self-management behaviours following participation in REACH-HF were those where the patient and caregiver communicated effectively and openly about HF. For example the patient discussed with the caregiver how they were feeling with regard to their health and the caregiver was able to ask the patient direct questions about their health (parent adult-child dyad, 4015). Additionally, dyads who utilised a whole family approach to participate in REACH-HF sustained self-management behaviour (parent adult-child dyad, 2016) and where caregivers developed a new understanding of HF management behaviours importance of walking and monitoring behaviours, such as, what action to take if they observed swollen ankles (younger spousal dyad 2020, friend-friend dyad 2049).

REACH-HF did not appear to sustain behaviour change for some spousal dyads who were living with HF for a more extended period of time (more than four years). The caregivers in these dyads were well experienced in supporting HF self-management and had well established health behaviours related to living with HF prior to REACH-HF (Participants 4012 and 4061). The caregivers in these dyads identified the benefit of the REACH-HF manual, facilitator and exercise guidance as tools to motivate the patient. However, the patients in these dyads did not view REACH-HF as having any impact on their HF self-management as they did not believe it was of relevance to them. These dyads had well established roles and routines in managing HF and so behaviour change was not sustained (spousal dyad 4012 and spousal dyad 4061):

> "I think initially it was, it was good. I mean MP4012 was doing the exercises and he, I mean he might not've been able to see it but I could see that he was getting stronger." (Female, spousal caregiver, 4012, 12 months)
>
> Interviewer: "Did being part of the programme change the way in which you manage your condition at all? Or the way you think about it even?
> Patient: "Um, ….., no I don't think it has really, I mean, I have been quite interested in, in going along and, and um, doing the different things that, um, but no, I wouldn't have thought it has changed much about thinking about it, no." (Male spousal patient, 4012, 12 months)

It could be suggested that as these spousal dyads were living with HF over a sustained period of time and due to the longevity of their partnership, behaviours and roles were ingrained. A 12 week intervention such as REACH-HF may not have been of sufficient duration to ameliorate entrenched roles and routines or cardiac beliefs.

The other dyad for whom self-management of HF remained difficult was the mother-daughter dyad (Participants 1130). They were living with HF for a short time at enrolment to REACH-HF (2 months) and identified much of that time was spent making sense of the diagnosis. Prior to the follow-up interview at 12 months, this dyad experienced the bereavement of a close family member. The primary objective for the caregiver (daughter) in this dyad was then to provide emotional support to her patient (mother) through the bereavement, thus the self-management strategies from REACH-HF were not a priority for the caregiver. At the 12 month interview the patient identified that she had returned to work full-time which was a success and indicative of an improvement in her health. She identified that she would not make any adjustments to her medication and her GP was her first point of contact if she was not feeling well. This mother-daughter dyad identified that they required additional support to engage with REACH-HF as they were still coming to terms with the diagnosis of HF. This dyad was still at the stage of making sense of the diagnosis and at the 12 month interview it was indicated that they still were striving to achieve a sense of efficacy with regard to HF self-management, which as suggested by Bandura's theory of self-efficacy, can impact one's confidence and beliefs about one's ability (86). Dyads such as this mother and daughter may require a longer intervention in order to support them in coming to terms with the diagnosis and subsequently developing a sense of mastery in HF self-management.

Caregivers engaged with a variety of modes of intervention delivery offered by REACH-HF. This demonstrates the importance of having a selection of intervention delivery modes available to caregivers in order to support them in their role within their specific context. Retired spousal caregivers were more likely to be present in facilitated intervention sessions while younger spousal caregivers (both spousal caregivers were 45 years of age) participated in health promoting behaviour with the patient, for example, engaging in physical activity together. Due to time constraints and demands of other lifestyle factors, adult-child caregivers were most likely to only read the Family and Friends resource and were less likely to engage with the facilitator. This highlights the influence of the patient and caregiver context and the nature of the relationship when engaging in HF self-management. Caregivers who understood the purpose of REACH-HF and used the resources to encourage and promote HF self-management positively influenced patient HRQoL.

6.3.3.2 The nature of the dyadic relationship

The type of relationship between patient and caregiver was a prevalent sub-theme in the follow-up interviews in understanding what role caregivers had in patient HF self-management. The nature of the relationship (i.e. whether spousal, adult-child or friend) informed caregivers’ actions and behaviours before, during and after participating in REACH-HF. Patients’ perspective of the caregiver and whether they had a role and the dynamics of this relationship informed the level of caregiver involvement in HF self-management. Spousal caregivers appeared to transition into the role of caregiver with more ease and acceptance potentially because this was viewed as part of the marital relationship. In contrast, adult-child caregivers and the friend caregiver were able to re-call specifically an incident which indicated they had taken on the caregiver role:

> “we just carry on in our old way, I think, and there's been nothing unusual.”(Female, spousal caregiver, 1098, 4 months)
>
> “many years ago…the doctor didn’t want her to stay on her own at night. Her family sort of came out to see me in the kitchen……the family came out and said, um, “Can we get her into a home?”. I said, “No”; I said, “I’ll stay the night”……”So I just came in and said to the doctor, “No problem; she doesn’t have to go anywhere tonight. I’m staying” (Female, friend caregiver, 2049, 4 months)
>
> “he got very poorly at one point, approximately 12 months ago, and, er, he, I took a phone call from him, and, er, he was showing certain symptoms”…..”the phoning me was sort of a cry for help, because me mum wasn't in a position, because of the dementia, to help, help him out. So he, he settled for me. So I said I'd go over there, and I've accompanied him from that moment on to his appointments, just in case he tried to, to back out of them (Male, adult-child caregiver, 4015, 4 months)

The exception to spouses naturally transitioning into the role of a caregiver were spousal caregivers of patients diagnosed at a younger age (both in their 30s at diagnosis). They described a more significant disruption to family life, living with the diagnosis, rearing children and managing finances and in some situations providing care to parents as well as to their spouse:

> “we’ve just lived through it and muddled through it haven’t we, because, erm, you know, it’s something you expect from somebody much older in a lot of ways. (Male, spousal caregiver, 1172, 4 months)
>
> “it was very hard to, to come to terms with it in the first place, he was so young. Um, he was, what, forty when it happened…..And then I was only, what, thirty two, so I was very young and a young mum. And it was, um, you don’t know anything about the – you don’t know anything about the

> condition and the doctors that tell you about it they don’t know much about it.” (Female, spousal caregiver, 2020, 4 months)

Caregivers were conscious of ensuring that patients took responsibility for their health and were decision-makers. However, in times of ill health, caregivers took greater responsibility in decision-making. Caregivers were less vocal about decision making when patient health was settled. This happened naturally in spousal and friend dyads and did not require deliberate discussion. The passing of time since the health crisis and the ability of caregivers to observe subtle patient cues which demonstrated patients were active in engaging in HF self-management, reassured caregivers that they could take a step back from being the decision-maker:

> *“if I thought we needed an ambulance I’d start suggesting that we needed an ambulance. Then we’d get on to round, “Yes, I do think we are going to have an ambulance”….”But I would like her to say to me, “Yes, I think I would feel happier if I went to hospital.”….”But I would always take the decision if I felt it was the necessary decision at that stage.” (Female friend caregiver, 2049, 4months)*

Taking responsibility for healthcare decision-making was trickier to manage in adult-child caregiver dyads with adult-children uncertain of how much support they needed to continue providing. This was due to the relationship dynamic between adult-child caregivers and their parents, for some it was the change in parent/child roles (i.e. the parent now needs to be cared for by the child) which made this type of conversation difficult. In contrast, for others, it was a continuation of past relationship dynamics whereby they never openly communicated on health issues. REACH-HF did facilitate some adult caregivers in their decision-making regarding the locus of control within dyads, dependent on the symptoms of HF. This was observed by the interviewer and commented on in the field notes:

> “To tell him, erm, what to do, and advise him. Erm, he thinks he's pretty much on the, er, road to recovery, and he, he doesn't need the interference.” (Male, adult-child caregiver, 4015, 4 months)
>
> The sisters have all used the family and friend’s resource and manual and have then had discussions about the best way to support their mother. It helped them decide what support to give and when to give control to their

> mother (Field notes, adult-child-parent dyad, both female, 2016, 12 months)

Another male caregiver (adult-child) expressed initial difficulty with communication due to the change in roles between parent and child. He identified that his father had difficulty accepting assistance and was dependent upon his son to assist with his healthcare needs. Therefore the father (patient) had difficulty listening to his son's (caregiver) advice about his HF self-management. This male adult-child caregiver expressed difficulty communicating with his father about his father's HF self-management. He described difficulty in his role as a caregiver as a result of this:

> "it's all hard"… "Occasionally they, they don't know what to lash out at, so they lash out at the person who's trying to help them out". (Male, adult-child caregiver, 4015, 4 months)

His perspective as an adult-child caregiver is that parents do not listen to their children's advice:

> "it's really difficult to try and tell a parent what to do. I mean, a parent tells you what to do, all your, pretty much all your life."…"So even now, when you're adult, you're an adult, doing a responsible job, they still try and tell you what to do. (Laughter)." (Male, adult-child caregiver, 4015, 4 months)

Female spousal caregivers' predominantly engaged in tasks such as managing diet, cooking, cleaning and encouraging the patient to take their medication; whereas male spousal caregivers were still engaged in a paid work role in addition to the caregiving role. Female patients spoke of the importance of trying to maintain their domestic role within the household. All spousal caregivers appeared to play down their role as caregivers, demonstrating how they view caregiving as part of the marital role:

> "it was a case of making sure that he was, um, as happy as he could be." (Female, spousal caregiver, 2020, 4 months)

> "I think I probably taken over the role of, that perhaps you had in earlier times, haven't I? Where I do a lot of the driving, look after the finances…"Trying to take the worry from you because you do worry more and then I, you know, he does worry more now than you did before." (Female, spousal caregiver, 4061, 4 months)

Adult-child caregivers were less likely to engage in these domestic orientated tasks. Each of the adult-child caregivers balanced caregiving from outside the parental home, engaging in vocational roles, and two adult-child caregivers were raising young families. The friend caregiver did not participate in domestic tasks as this patient had paid caregivers attending to her. This caregiver described her role as providing support with community tasks, medication management and reported she enjoyed spending time with her friend (patient):

> "It's a, it's a delight taking her out. We can laugh about things; we can talk about things." (Female, friend caregiver, 2049, 4 months)
>
> "over the summer has been difficult because I don't see her every day." (Female, adult-child caregiver, 1130, 12 months)

The nature of the relationship between the patient and caregiver informed their approach to caregiving. Differences between spousal, adult-child and friend caregivers have been identified in addition to differences between genders. Patient perceptions of the caregiver role informed how much support patients accepted. The patients in the younger spousal dyads, the friend dyad and the parent adult-child dyads were keen to maintain their independence and were pro-active in engaging in self-management behaviours with varying levels of support from their caregiver dependent on the patients' needs. For example, if there was a acute exacerbation of a health problem and the patient required the caregiver to make healthcare decisions. Whereas patients in spousal dyads appeared more at ease and accepting of care from their spouse, potentially because this was viewed as part of the marital relationship.

6.4 Discussion

This research question asked: "What is the impact of REACH-HF on the nature of caregiving which contributes to improved patient outcomes on the Minnesota Living with HF Questionnaire (MLHFQ)?" The interview topic guide was designed to enable participants and caregivers to explain their experience of living with HF prior to REACH-HF, their understanding of HF and their experience and perceptions of REACH-HF immediately after the intervention (4 months) and at 12 months follow-up. A cross-case analysis approach was utilised for this secondary qualitative analysis. Patient and caregiver interviews, facilitator notes, patient and caregiver demographic data, fidelity scores and field notes informed the construction of themes. Three overarching themes and seven sub-themes demonstrated how caregivers' engagement in REACH-HF influenced patients' HRQoL.

The results suggest that caregivers had a variable level of experience and knowledge in providing HF care pre-REACH-HF. Their experience was informed by interactions with healthcare professionals and learning by living with HF. Developing experiential knowledge in this manner (i.e. by living with HF or through interactions with heath care professionals) may result in gaps in what caregivers know and understand about the managing HF and how to recognise and respond to signs and symptoms of HF (418, 419). However, this was not identified as an issue in this secondary analysis. Caregivers who reported uncertainty about their roles prior to REACH-HF appeared to be those who lacked confidence in activities such as how to recognise and respond to fluid retention, or how much exercise they should be encouraging the patient do participate in. These caregivers identified a general lack of knowledge of HF and how to manage it. This expands on what has previously been reported in the literature whereby, caregiver confidence was identified as an indicator of a caregivers ability to provide HF self-care (187) and may have implications for what caregivers do when contributing to HF self-management (201). As suggested in Bandura's theory of self-efficacy one's belief in oneself impacts on confidence (86). Thus, it is important for healthcare professional or wider family to be aware of caregivers' beliefs of self-efficacy in their role. Supporting caregivers to achieve a sense of mastery in their role is necessary to enhance their effective contributions to HF self-management (201).Clark et al. suggest that caregiver knowledge is important in managing HF, but this alone does not determine successful outcomes in HF self-care (418). Clark et al. put forward the suggestion that contextual factors are the most important element for determining effectiveness in HF self-management (418). The dyads included in this analysis demonstrated that contextual factors mediated caregivers' ability or willingness to contribute to HF self-management in some circumstances, for example adult-child caregivers who were working full time identified difficulties in supporting their parent with self-management behaviours due to the demands on their time.

It is of significance to note, that the specific elements of how contributed to improved patient outcomes varied amongst caregivers. Adult-child caregivers read the resources and through increased knowledge discussed HF self-management strategies with patients. This helped adult-child caregivers in their awareness of how much the patient (their parent) could do. This enabled adult-child caregivers to take a step back or provide greater assistance dependent upon discussions with the patient and what they observed of the patient. Spousal caregivers were most likely to be present in facilitated intervention sessions and via the facilitator engaged in communication about HF, the facilitator was viewed as a support by the spouse for the patient to hear their point of view. This was either in recommendations about swimming where the (patient) spouse adhered to the facilitators suggestions or advice about maintaining a healthy diet which was not maintained by another patient (spouse) which differed between younger and older dyads, at times they also engaged in self-management with the patient, for example partaking in walking together. This research identified that younger spousal caregivers walked together, while older spousal caregivers were more likely to be observing and supporting the patient covertly while younger spousal caregivers participated in the walking programme with the patient. Individualisation of the resources (by the friend caregiver and one of the adult-child caregivers) facilitated the patient to engage in self-management tasks as part of REACH-HF, thus leading to improved patient outcomes. The reason for this variation, as identified in this study and previously identified by Clark et al., was due to the context in which caregiving took place (418). In Strachan et al.'s systematic review of the qualitative literature, the influence of the social situation, financial status and vocational elements were identified as influencing how patients engage in HF self-care (167).

The social supports received by patients was more likely to increase their engagement in self-management, particularly in physical and psychological health outcomes (167). However times where social support negatively impacted patients' were situations where a caregiver assisting too much thus creating a dependency and reducing the patients self-management skills or if social supports were external to the family and required planning, there was an indication that this type of support was tiring for patients (167). Financial hardship was identified as a barrier to self-management whilst vocational elements when perceived by patients as supporting self-management, was identified as an enabler to increasing self-care (167). They report that the interactions between the patient and context are not addressed in HF self-management programmes (167). This secondary qualitative analysis builds on this point by demonstrating the context informed how both patients and caregivers lived with and engaged in HF self-management. For example, the modes of how caregivers engaged with REACH-HF resources were influenced by the time they had to read resources, or their availability to be present for facilitated intervention sessions, as well as the nature of the relationship between the patient and caregiver. There were additional contextual factors that influenced what activities caregivers engaged in to support patients. This included, the duration of the HF diagnosis (patients living longer with HF had a well-established routine in HF self-management and whether it was health promoting or not, it was not ameliorated by a 12 week intervention, whilst newly diagnosed patients, less than one year, were still coming to terms with the diagnosis). The geographic location of the caregiver was also a factor influencing caregiver behaviours and activity (caregivers who lived apart from the patient reported being able to take a step back when they perceived the patient was managing well. Similarly this enhanced the patients' self-efficacy as they were able to observe the caregivers taking a step back). The psychosocial dynamics in which caregiving was taking place was also influential, the demands on the dyad such as financial strain, family worries with grandchildren or unwell spouses and the demands of work. The greater the demands of these other elements the greater they impacted and reduced caregivers ability to participate in HF self-management. The content and multi-modal design of the intervention aimed to address some of these personal, external and environmental factors (28). However, these were considered individually for the patient and caregiver in the design of the intervention. Dyadic related factors, such as the type and quality of the relationship as well as the congruity in their appraisal of symptoms was not transparently addressed and this may be why improved patient HRQoL was not sustained longitudinally in the quantitative multi-variate analysis.

Vellone et al. suggest that caregiver contributions to HF self-management are informed by caregiver related factors such as confidence, capacity to engage in a caregiving role, knowledge of HF, physical and mental health and social support within the context of cultural values (201). Cultural values with regard to the nature of the relationship between patient and caregiver was a key factor influencing how caregivers contributed to HF self-management. Spousal caregiving was interpreted as part of the marital relationship and therefore an expectation of the role (256). However this was not without its challenges and similar to the caregiver literature spousal caregivers in this sample, did experience a change in relationship dynamics and motivating patients was a challenge (256). Younger spousal caregivers (45 years of age in this sample) experienced a multitude of demands on their time and they perceived their role as that of a supporter. Younger spousal caregivers facilitated the patient to maintain roles which were important to them and had been disrupted due to HF such as homemaker and parent (420). The HF caregiver literature identifies younger spousal caregivers as experiencing greater distress and poorer mental health (363, 421). The younger spousal caregivers in this analysis described how engaging in REACH-HF with their partner (patient) facilitated communication, enhanced their relationship and brought them closer. This resulted in responding quicker to a crisis and subsequently avoiding the patient being hospitalised, as well as, the patient adapting their exercise routine to ensure they engaged with healthy self-management behaviour (walking instead or swimming).

The friend caregiver was pragmatic in her approach to REACH-HF. REACH-HF was viewed as a strategy for the patient to engage with in order to support HF self-management, and the caregiver was in the background, providing indirect care (366). The friend caregiver spoke positively about the relationship she had with the patient and emphasises the importance of this friendship. The ability to take this indirect stance and not engage in direct caregiving tasks may have been enhanced by not living with the patient and the reassurance that the patient had healthcare professionals engaging with the patient regularly. It is evident from the HF caregiver literature that caregivers who engage in more direct hours of caregiving perceive great stress and burden in their role (422, 423). The role of the friend caregiver was to positively encourage, support and reinforce the HF self-management strategies discussed between patient and the REACH-HF facilitator which was one element of the intended design of REACH-HF (28). Adult-child caregivers initially had difficulty engaging in a caregiving role with their parent, often due to competing demands on time unlike the friend caregiver, adult-child caregivers can experience enhanced strain and burden due to living away from the patient (424). The male adult-child caregiver identified the challenge in having his voice heard with regard to the HF self-management suggestions he was offering. The female adult-child caregivers did not perceive this issue. Research into adult-child caregiving recognises taking on this role as a challenge for adult children due to the competing demands from their physical and social environment as well as the change in relationship dynamics between patient and caregiver (424, 425). Exploration of the contributions of adult-child caregivers by gender in the qualitative HF caregiver literature is limited (426).

The family approach was utilised successfully by the adult-child caregivers in this sample. The value of social support in HF self-care and its impact on families has been described in the literature (341, 343, 427-429). However, there has been limited examination of how to involve families, and the impact of family involvement in HF interventions. Fivecoat et al. explored the role of social support across time in an observational study (430). Instrumental and emotional support were independently associated with higher levels of self-care confidence, and emotional support was associated with better self-care management (430). Participants completed self-report questionnaires and identified that self-care outcomes increased when social support was involved (430). However, it is necessary to have the appropriate types of family support. Family support is not always useful (431), structures need to be in place for effective family involvement in HF patient self-care. These include family communication, knowledge and understanding in order to effectively contribute to HF self-care (343).

Formally measuring HF self-management provided caregivers with a method of tracking HF progress and instilled confidence and a method of control in HF self-management. This was primarily spoken about with regard to the pedometer and progress tracker. The ability to have data to review progress is an objective measure, which can facilitate empowerment and a perceived sense of control (432). A dyadic intervention study identified that perceiving a sense of control in HF self-care has been found to enhance patients' self-care following a 12-week intervention

(183). However, perceived control over the illness was not maintained at 12 months post-study (183). Caregivers in this sample identified REACH-HF as a mode for helping them to motivate the patient. This included signposting the patient to information they read in the caregiver resource or manual or the facilitator discussing caregiver concerns with the patient (the impact of swimming and the importance of health eating), In order to enhance engagement with REACH-HF resources, some caregivers developed individualised tools to support the patients tracking of HF self-management. One of these included re-creating their version of the progress tracker. However, like the 12 week intervention study conducted by Agren et al. (183), not all caregivers were successful in maintaining patients' motivation to engage with REACH-HF resources over the longer term. This indicates the need for follow-up discussions or one-off intervention sessions to support caregivers in maintaining their contributions to patient self-management during the transitions experienced when living with HF (25, 79).

REACH-HF facilitated communication between many of the patient-caregiver dyads. This was evidenced by caregivers checking patients were engaging in self-care tasks as outlined in the HF manual or completing the physical activity and using the pedometer or exercise DVD. The female caregivers all reported that they felt comfortable with open and honest communication about HF prior to REACH-HF. In the parent-child dyads, REACH-HF facilitated conversations about how to live as a family with HF. This demonstrated a significant change in the male caregiver's contributions to HF self-management. He and his father (patient) moved from being incongruent (disagreement between patient and caregiver) about HF self-care conversations to achieving congruence in their conversations regarding HF self-management. Congruence between the patient and caregiver enhances their engagement in HF self-management. This was demonstrated in the parent adult-child dyad, where two of the adult-child caregivers were supportive of their parent, which enabled the patient to positively engage in HF self-management. Whilst incongruence was observed with one of the spousal dyads where diet was a goal for the caregiver but not for the patient. Communication issues are often present when there is a discrepancy in the dyad about how the patient is managing HF (433). Behaviour change has been identified as being more successful if patients and caregivers work together, and interventions promote concordance between patient and caregivers (177). In REACH-HF, the HF manual was a tool which facilitated caregivers to feel confident in having discussions with the patient about HF.

Caregivers require a multitude of skills to engage in their role (62). Caregivers in REACH-HF had developed skills from the lived experience of the role. These were re-enforced by REACH-HF, enhancing caregivers' understanding of why they were monitoring patients and provided a resource which reassured them about what they were doing and when. Skills in HF self-management evolve and are most likely learned from personal relationships and are retained when they form part of the individual's daily life (434). Caregiver contributions to HF self-management varied between spousal, adult-child-parent and friend-friend caregiver dyads. Patients who had their children or a friend as caregivers were more likely to report change with regard to positive influences on HRQoL. Younger spousal patients identified how they intervention with their caregiver brought them closer whilst older spousal dyads were more likely to continue in their well-established roles and routines, thus there was minimal impact on patient HRQoL in older spousal dyads. This research demonstrates the key role of the context in which caregiving is taking place. This research also highlights the complexity of caregiver contributions to HF self-management and the difficulties in capturing the specific elements of what caregivers do in HF self-management.

6.4.1 Strengths and limitations

Strengths of this secondary analysis include specifically examining the processes and outcomes of REACH-HF from the perspective of what caregivers were doing. Chapter 3 identified that the impact of involving caregivers in HF interventions is rarely examined. This is a burgeoning area of research in the HF caregiver literature. Greater awareness of the impact of caregivers and the context of caregiving can inform how healthcare professionals can work with patients and caregivers, as well as inform the design of future patient-caregiver dyadic HF interventions. Examining dyads (spousal, friend or adult-child) provides greater insight into the impact of REACH-HF for specific dyads. It facilitates an understanding of the needs of these dyads and how they engaged with REACH-HF. This is particularly pertinent for younger spousal dyads due to the limited research conducted with this population in HF. This can inform the future delivery of REACH-HF ensuring differing dyadic needs are met.

The inclusion of male caregivers in this sample is another strength given that there is little research specifically examining the role of male caregivers or indeed, communication between male caregivers and patients in the HF literature (435). The volume of male caregivers is steadily increasing (436), and there is an ongoing debate that they provide a slightly different insight into caregiving compared to female caregivers (436, 437). A synthesis of qualitative male caregiver studies identifies that male caregivers adopt a flexible approach to caregivers and are more likely to adapt to their situation (438). In this sample, some of the male caregivers (particularly the adult-child) had difficulty adopting to the role. Additionally, male caregivers in this sample differed from female caregivers as they identified that they had difficulty communicating with the patient. This awareness can inform future implementation of REACH-HF by promoting and encouraging communication skills amongst male caregivers as both a strategy for promoting engagement in HF self-management but also as an outcome of the REACH-HF intervention. Improved communication enabled living with HF to be normalised within the dyad, strengthening their relationship, and enhancing patient HRQoL.

In order to identify the most appropriate analysis approach for this research question, a number of other options were considered. Guided by the aims of the research question it was identified that the aims were not concerned with: generating theory such as in grounded theory, (439) or ethnographic methodologies such as examining shared behaviours, or beliefs within a cultural group (409). Additionally, the research question was not concerned with the biographies of the participants, such as in narrative methodologies (409). Therefore, these analytical approaches were not appropriate to answer the research question. Interpretive phenomenological analysis (IPA) and thematic analysis were both considered as approaches for analysing this data. However, IPA focuses on an individual’s experience of a particular phenomenon within a given context (440). In contrast, this analysis was concerned with understanding the impact of the REACH-HF intervention across multiple patient-caregiver dyads to identify what the processes of REACH-HF were, which in turn had an impact on caregivers in their caregiving role. Thematic analysis, which is widely used, aims to generate themes from data (441) and is considered applicable to a broad range of research questions and epistemologies (442). However, thematic analysis can lack rigour in the methodological analysis (443), which can be challenging for novice qualitative researchers to conduct transparently. Cross-case analysis facilitates understanding of multiple, similar and differing perspectives (389), and employs a transparent approach to identifying meaningful connections in the data (393). Finally, it has been reported as a suitable approach for understanding the processes leading to change (389).

This study has some important limitations. First, conducting a secondary analysis of qualitative research could be considered a limitation of this study (444).These limitations include not being part of the conceptualisation of the primary research question, not conducting the primary interviews or having access to the audio recordings potentially influencing MN's ability to interpret the data (444). Furthermore, Sherif et al. argue that robust secondary analysis can only every truly be exploratory due to its extension of the primary research question (444). Bishop argues that these limitations can be overcome by proximity to the primary research (445, 446). Indeed these limitations were mediated by having close access to the primary research team (members of the REACH-HF research group acted as supervisors to this researcher) and meeting with members of the PPI group who had a key role in the intervention design and development. These discussions assisted with understanding the original purposes of REACH-HF (370, 378). Documents related to the study protocols and intervention development processes of the REACH-HF intervention were made available for MN to enhance immersion in the data (375, 376). Access to these documents enabled MN to understand the aims, objectives, methodology and context in which the primary research was completed. Implementing these strategies enabled MN to align this study with the original purpose of the research, which is an important element of conducting secondary analysis (373).

What is clearly demonstrated by this research is the importance of the context in which caregiving is taking place and caregivers willingness to contribute to HF self-management which has been reported in other qualitative research (62).

Furthermore, the multi-modal intervention offered by REACH-HF meant that caregivers could engage in the intervention in a mode which best suited their circumstances thus facilitating decision making and contributions to HF self-management (201, 358). This knowledge contributes to the evidence base in relation to the situation specific theory of caregiver contributions to heart failure self-care (201). This qualitative analysis did not examine caregiver outcomes, this may be perceived as a limitation particularly following the discussion in chapter 3 and chapter 4 which identified reporting of caregiver outcomes as a significant limitation in HF research. However caregiver outcomes from the REACH-HF (HFrEF) trial have been reported in one of the primary research studies (327). Therefore, it was identified that further exploration of caregiver outcomes would not contribute additional knowledge to what has already been reported (372).

MN was unable to obtain access to the data set for the REACH-HF HFpEF (Work Package 2) trial. The population living with HFpEF have been identified as, being predominantly female, older, and living with multiple conditions when compared to those living with HFrEF (447). There is little dyadic intervention research in the HFpEF population (30, 448). Therefore, while this secondary analysis outlined the aim as explaining the quantitative findings, it is imperative to note this is only examining what caregivers were doing in relation to patients living with HFrEF. This is a significant limitation and important to acknowledge in the interpretation of these results. Accessing caregivers of patients with HFpEF, potentially a population with greater reliance on caregivers, may have yielded important novel insights into caregiver contributions to patient self-management in an under-researched area. Furthermore, this insight could inform the suggested theoretical model of caregiver contributions in HF self-care and provide important information in a significant area of research which is lacking in HF caregiving (201, 449).

Finally, there is a lack of diversity in the sample for this analysis. When completing the purposive sampling of patients and caregivers for this secondary analysis, availability of interviews from both patient and caregivers at both time points was one of the inclusion criteria. This sample did not contain any patients or caregivers from black and minority ethnic backgrounds. Cultural background influences perspective and values in caregiving (450). The situation specific theory of caregiver contributions to HF self-management suggests that caregiver factors in HF self-management are informed by cultural values (201). Furthermore it has been identified that Caucasian caregivers are less likely to report on positive aspects of caregiving when compared to other caregiver groups (451). Filial obligations, particularly in Eastern cultures may also influence how these caregivers perceive the role (452), with indications in Chinese culture that this obligation increases the stress and burden experienced by caregivers (453). It has been identified that much caregiver research has been conducted from the European and American perspectives (452). Thus, it could be considered that the Westernised design and delivery of REACH-HF may have different areas of priority or self-management needs for caregivers from Eastern cultures. Therefore, this research is unable to comment on caregiver contributions to HF self-management in diverse ethnic communities which is an important limitation of this research.

6.4.2 Implications for clinical practice

This secondary analysis highlights that caregiver’s influence HF self-management. Of importance for clinicians is understanding that caregiver contributions are influenced by the context in which caregiving is taking place. Thus a standard approach is difficult when including caregivers in HF self-management. A similar concept with regard to an individualised approach to caregiver inclusion has previously been identified with regard to caregivers of patients living with dementia(108). Involving caregivers in HF self-management requires an awareness on behalf of clinicians of the relationship type and dynamics between the patient and caregiver (424, 454). However, what this research adds is the identification of the differential caregiver contributions by relationship type. Spousal caregivers were likely to have a more directive role, friend caregivers were in the background indirectly supporting and encouraging, and adult-child caregivers struggled to achieve a balance between being direct and indirect as they were adapting to the change in the parent-child relationship. Furthermore, understanding the external demands on caregivers (i.e. children, grandchildren, employment) as was the situation for adult child caregivers in this sample, can provide an indicator to clinicians of the level of capacity a caregiver may have to engage in supporting HF self-management.

Caregivers began the intervention from different experience and knowledge levels. Determining caregivers' level of knowledge of HF and their understanding of how to manage signs and symptoms of HF is imperative when involving caregivers in HF self-care. As identified by Bahrami et al. caregivers often rely upon lived experience in developing HF knowledge which can be a risky approach in terms of ensuring effective support (419). Providing caregivers with an opportunity to discuss their experience of caregiving, including their duration of living with HF can facilitate clinicians in ascertaining caregivers' level of knowledge in HF self-management. These type of probing questions can also enable clinicians to determine whether caregivers may need additional support or education around HF and how confident caregivers feel in their role, thus their ability to be a co-facilitator in an intervention such as REACH-HF. This information can be gathered through informal discussions between caregivers and clinicians.

Information gathering from caregivers can inform clinicians in how to optimise caregiver involvement in HF self-management interventions. Additionally, engaging caregivers in this type of discussion can facilitate the development of a therapeutic relationship between the caregivers and clinicians (455). Male caregivers in this sample took time to adjust to the experience of having open and honest conversations with the patient about HF self-management. Thus it must be considered that they may need more support in having an open dialogue with clinicians and patients about HF self-management. Previous research reports that male caregivers employ coping strategies and are less distressed in adapting to the caregiving role (349, 456). However, this was not identified for the adult-male child caregiver in this sample. What was identified in this analysis, which is consistent with the literature was the difficulty experienced by male caregivers in verbalising their needs and seeking support (435).

Utilising the wider family outside of the patient and caregiver to support in HF self-management was positively reported by caregivers. Encouraging engagement of wider family in HF self-management can provide additional support for caregivers and patients. Social support can facilitate the maintenance of HRQoL (457). Caregivers utilised the pedometer, progress tracker and chair based exercise DVD to measure progress in HF self-management. Ensuring caregivers have access to resources which assist them with motivating the patient can enhance their contributions to patient HF self-management. Finally, considering the limited long-term sustained changes identified in this research and the wider caregiver literature (301, 305), longer term follow-up intervention sessions are warranted for caregivers and patients. This could include, checking in with caregivers, determining if their HF knowledge remains up to date, and finally, identifying if caregivers need support to re-motivate patients with engaging in HF self-management. This would ensure that patient HRQoL is maintained if HF self-management is stable or it might reinvigorate and re-motivate patients and caregivers to ensure that they are sustaining HF self-management behaviours. This approach could also be particularly important if a patient had an exacerbation or a hospital admission, by supporting patients and caregivers to re-establish a routine in HF self-management.

6.4.3 Implications for research

Longitudinal clinical trials examining caregiver involvement are significantly lacking in HF research (12). Given the trajectory of HF and the long-term health implications of caregiving, post-intervention, longer-term follow-up with patients and caregivers are essential to ensure the ongoing engagement with HF self-management. There is a need for robust longitudinal research examining the ongoing contributions of caregivers (25, 424). This qualitative analysis highlighted how the contextual demands influence how caregivers contribute to HFself-management. There is a lack of consistency in the caregiver literature with regard to adult-child caregivers' experiences of burden and psychological health impacts (193, 458-460). Therefore, this requires further exploration of the experiences of adult-child caregiver contributions to HF self-management. REACH-HF demonstrated that utilising a multi-modal approach was useful as a starting point to engage some adult-child caregivers, however further exploration is required as to whether this involvement can be sustained over time and the implications for their QoL.

The experiences of younger spousal dyads requires further exploration. Receiving a potentially life limiting diagnosis of heart failure at a young age can significantly interrupt one's expected life course. Younger spousal patients and caregivers experience greater psychosocial distress when compared to older spousal dyads (420, 461). As posited in the stress process model if adjustments are not made to adapt to these interruptions through the use of support systems, it can have significant implications for health and wellbeing (80, 82). In comparison to older spousal caregivers, younger spousal caregivers potentially require greater support in adjusting to the transitions of HF and the change of identity and roles within the dyad. This merits further exploration as to how to the needs of younger spousal caregivers are impacted through the act of caregiving, and how to best support the younger dyad in living with HF self-management.

Due to a lack of individuals from ethnically diverse backgrounds in this sample, further research is required on how to firstly, engage this population and secondly, examine their needs and the impact of a trial such as REACH-HF on caregiver contributions to HF self-management with patients and caregivers. Particularly in consideration of cultural values with regard to filial expectations in caregiving (462). It is acknowledged that there is a cohort of caregivers who are considered “hard to reach” (62). However, a starting point may be in assertive community engagement to increase inclusion of stakeholders’ representative of Black, Asian and other minority ethnic groups. Delivering REACH-HF to a diverse population can test the reliability and validity of REACH-HF across a variety of cultures and enhance understanding of how caregivers from differing contexts utilise the multiple components of the REACH-HF intervention such as, the family and friend resource or the patient manual to promote patient HF self-management.

Finally, this research demonstrated the value of conducting secondary analysis in qualitative research. Secondary analysis of qualitative data, as demonstrated in this research study can yield valuable information in understanding the impact of what caregivers were doing within the context of participating in REACH-HF. This should be considered a viable strategy in future qualitative caregiver research.

6.5 Conclusions

This secondary analysis of REACH-HF demonstrated that caregivers make important contributions in supporting patients in their HF self-management, through direct and indirect caregiving tasks. Direct caregiving tasks included going for walks with the patient, discussing HF using the progress tracker or asking questions about the patients' day informed by what they learned in the patient manual or caregiver resources. Indirect caregiving included observing the patients engagement with the chair based exercises, observing for fluid retention, or listening for any changes in breathing. Discreet caregiving tasks were again informed by the REACH-HF patient manual, family and friends resources and the chair based exercise DVD. Patients all recognised the value of having their caregiver involved in the intervention, specifically vocalising the importance of both members of the dyad having access to the same information. However, the specific elements of these caregiver contributions can only be understood by understanding the context within which caregiving is taking place. The mechanisms of REACH-HF which supported caregivers to contribute to patient HF self-management included having a choice of resources which facilitated engagement in REACH-HF, utilising a family approach to caregiving, monitoring HF signs and symptoms by having something to measure and track progress and, providing an outlet to facilitate communication about HF self-managment. Furthermore, identifying the nature of the relationship between the patient and caregiver is important to understand how they might use the REACH-HF resources. The Friends and Family resource was utilised less frequently, and potentially less than anticipated in the development of the intervention. This signifies there is potential for further engagement with caregivers in future iterations of the delivery of the intervention in order to capture whether the Family and Friends resource in its current format is a useful tool for caregivers to use or whether this tool would be used if caregivers were engaged more by facilitators and pro-actively directed to using the Family and Friends resource.

Secondary analysis of this qualitative research was beneficial as it enabled MN to complete further analysis of caregivers' participation in REACH-HF, thus contributing to the caregiver evidence base in HF self-management. As a novice researcher, it was a useful method for enhancing qualitative data analysis skills (371). Furthermore, it was an appropriate approach as it enabled rigorous and transparent analysis (463) resulting in a novel insight into the data set (370) informing future caregiver research and healthcare delivery with patient-caregiver dyads.

CHAPTER 7. Discussion

7.1 Overview of completed research

The overarching aim of this research was to understand the impact of including caregivers in self-management interventions for patients living with common long-term cardiorespiratory illnesses.

The key research questions in this thesis were:

1. What is the impact on patients when caregivers are included in the delivery of self-management interventions?
2. What is the impact on caregivers when they are included in the delivery of self-management interventions?

Cardiorespiratory illnesses are those conditions which affect the heart and lungs and can significantly impede an individual's functioning. Poor cardiorespiratory health has been associated with increased mortality (13). The inclusion of patients with COPD and their caregivers (chapters 3 and 4) and patients with CAD and their caregivers (chapter 3) in the earlier parts of this research facilitated an understanding and comparison of the role of caregivers in the wider context of long-term cardiorespiratory illnesses. Self-management interventions throughout this thesis were considered as interventions involving two or more components which were aimed at developing positive health behaviours for managing long-term illness (280, 281). Examples of this include, exercise and dietary changes or education and medication management, or a combination of all these elements. This research employed a multi-method research approach that combined both quantitative and qualitative research methods. This thesis consists of four linked empirical research studies.

1. A mixed-methods systematic review which identified the experiences of caregivers of patients living with HF, COPD or CAD (chapter 3).
2. A systematic review and meta-analysis of the impact of formally including caregivers in the delivery of self-management interventions on patient outcomes for patients with HF or COPD (chapter 4).

3. A secondary quantitative analysis examining the impact of including caregivers in a home-based self-management intervention (REACH-HF) on patient and caregiver outcomes (chapter 5).
4. A secondary qualitative analysis on the impact of REACH-HF on the nature of caregiving in HF self-care and how this contributed to patient HRQoL (chapter 6).

This discussion chapter presents: (1) an overview of the key findings of each of the empirical chapters (chapters 3, 4, 5, and 6) in relation to the overarching aims and research questions of this thesis, (2) a discussion of the overarching strengths and limitations of the research work undertaken, (3) an overview of the clinical and policy implications of the results, and (4) identification of directions for future research in this field.

7.2 Overview of key findings

7.2.1 What is the impact on patients when caregivers are included in the delivery of self-management interventions? (Chapters 4, 5 and 6)

The systematic review and meta-analysis of RCTs including caregivers in the delivery of self-management interventions for patients with HF or COPD sought to quantify the impact of caregiver inclusion on patient HRQoL (chapter 4). This empirical research sought to compare the magnitude of the impact on patient HRQoL of RCTs that do involve caregivers versus those that do not involve caregivers in the delivery of self-management interventions. The pooled effect of patient HRQoL in RCTs that included caregivers in intervention delivery compared with studies that did not include caregivers were not significantly different ($p = 0.84$). A lack of effect in favour of caregiver inclusion corresponds with what has been identified in the previous reviews examining caregiver inclusion in cancer care, traumatic brain injury, dementia, and elder care (464-467). In accordance with the empirical research study presented in chapter 4, reviews of the literature in cancer caregiving, traumatic brain injury and elder care were limited to an assessment of quantitative evidence (464-466).The interventions included in these reviews were concerned with caregivers only and their subsequent outcomes (464-466). A robust systematic review of caregiving in dementia examined dyadic interventions and determined, while dyadic psychosocial interventions can be effective when specifically targeted at functional domains, such as activities of daily living, determining the overall efficacy of dyadic interventions was difficult due to the heterogeneity of interventions (467). This challenge in synthesising intervention studies due to the variability of intervention components (e.g. duration, dose, and mode of delivery) (464, 465, 467) is a common thread throughout the wider literature and in line with the empirical research study in chapter 4.

Limitations of the meta-analysis are discussed in detail in chapter 4, these included: imperfect matching between trials, inclusion of caregivers may not have been reported, and the included primary studies may not have been as effective as originally hypothesised. Information was not gathered on whether caregivers were key stakeholders in the design of the interventions included in this review. This meta-analysis highlighted how limited the evidence base is with regard to reporting caregiver involvement and the processes of this inclusion in self-management interventions. In order to design interventions and comprehensively understand the influence of caregivers in long-term illness it is important that future studies include caregiver outcomes and consistently report the methodology of how caregivers were included. This is in line with a robust scoping review of contemporary knowledge and research conducted in the field of caregiving (22). Furthermore, the synthesis of caregiver research conducted by Larkin, Henwood and Milne (2019), spanning 16 years (2000-2016) identified that while there is an abundance of research identifying the role of caregivers and the tasks they complete, research examining caregiver involvement rarely acknowledges the influence of the context in which caregiving is taking place, for example the nature of the relationship of the dyad (22).

The relationship between the patient and caregiver is identified as a core element in understanding caregiver contributions to patient self-management of HF in the situation specific theory of caregiver contributions to HF self-care (201). However, assessment of this relationship can be difficult to incorporate in a quantitative synthesis of the literature, such as a meta-analysis. A literature review of respite care in dementia identified that captured qualitative information yielded important insights when trying to determine caregiver experiences of respite care (468). Although little ‘efficacy’ was seen from quantitative measures, interviews with caregivers clearly identified and reported benefits from their experiences of respite care (468). Capturing such subjective experiences through qualitative analysis may also be applicable when examining caregiver inclusion in self-management interventions in long-term cardiorespiratory illnesses.

The identified knowledge gaps and limitations in the systematic review and meta-analysis in chapter 4 informed the research questions in chapter 5 and 6 which focused specifically on patients and caregivers living with HF. This consisted of examining the impact of caregivers on patient outcomes in a self-management intervention, REACH-HF. Caregivers were formally included in the design and delivery of this theoretically informed, evidence-based intervention (28). The univariate analysis of the REACH-HF trial demonstrated that HF patients who participated in the self-management intervention with the involvement of their caregivers had greater improvements in HRQoL outcomes compared with patients without caregivers (chapter 5). Univariate analysis showed a mean difference of 10.6 points (CI 95% = 2.7 to 18.4, p = 0.008) in the MLHFQ total score, in favour of patients with a caregiver compared to those without a caregiver. This interaction in favour of patients with caregivers on MLHFQ total score was also seen at 6 months follow-up (9.6, CI 95% = 1.1 to 18.2, p = 0.026) and for MLHFQ physical and emotional outcomes sub-scores at 4 and 6 months follow-up. The qualitative secondary analysis (which aimed to explain the findings of the quantitative analysis) demonstrated that as a result of REACH-HF, caregivers were enabled to engage in overt and discrete caregiving tasks. This phenomenon has been previously identified in HF caregiving literature as ‘visible and invisible’ caregiving (366). Overt caregiving tasks included: communicating directly about HF self-management, either by using the progress tracker to guide questions that they felt confident to ask the patient, or discussion about how many steps the patient was taking according to their pedometer. In the review conducted by Clark et al. visible caregiving was a daily occurrence and perceived to be time-consuming, it involved decision making on behalf of the patient with regard to understanding when to assist or when to support the patient to maintain independence (366). The process of decision-making in HF is developed through interpretation and feedback from situations and subsequently developing responses to those situations (469). For example, in HF self-management this may involve recognising weight gain due to an increase in fluid retention and adjusting medication to reduce this.

Decision-making is also informed by discrete caregiving tasks. (366). Through observation caregivers recognised how much assistance they need to provide to the patient or whether the patient was engaging in HF self-management tasks. This skill developed through enhanced caregiver knowledge, particularly for those caregivers who did not perceive themselves as skilled in caregiving at baseline. One of the few RCTs which has demonstrated sustained change in HF caregiving examined the influence of improving knowledge in an educational intervention for patient and caregivers (305). At 6 months follow-up patients had greater HRQoL scores compared with the control group due to increased caregiver knowledge (305). Caregivers sustained improved knowledge scores when compared with the control group, however outcomes measures were not collected beyond 6 months follow-up (305). Enhanced caregiver knowledge in REACH-HF, developed due to reading the patient manual, caregiver resources or sitting in on facilitator–led intervention sessions. However, caregiver knowledge was not always sufficient to sustain changes for some patients in this cohort.

These overt and discrete caregiving approaches indicate the importance of the quality of the relationship between the patient and the caregiver. A review of HF literature demonstrated that relationship quality (as perceived by the patient and caregiver) influenced the health status of the patient (429). Congruency within the patient-caregiver dyad which positively influence patient HRQoL was attributed to effective communication between the patient and caregiver, sharing values, having empathy for each other and engaging in enjoyable activities together (429, 470). However, these findings are limited by the lack of longitudinal research as well as the variability of intervention components (429). This does indicate the value in understanding and promoting the positive aspects of caregiving within the dyad in order to enhance or sustain patient HRQoL (471, 472). It was identified within this empirical research that the quality of the relationship between the patient and caregiver influenced how much patients allowed caregivers to be involved in their HF self-management, whether patients heeded caregivers' advice, and whether patients and caregivers jointly participated in self-management tasks (e.g. walking together).

Cross-sectional research examining relationship quality between patients and caregivers in HF has demonstrated that caregiver and patient perceptions of a positive relationship can result in improved confidence in HF management (470). However, these research findings are limited by the high attrition rate of caregivers and the lack of differentiation between dyadic types (i.e. spousal, non-spousal, adult-child) (470). The empirical research presented in this thesis demonstrated the variability of the quality of the relationship amongst differing dyadic types. The influence of the quality of the relationship has been addressed in relation to typologies in HF, these include ‘patient-led’, ‘caregiver-led’, ‘collaborative’ or ‘incongruent’ (473). However, a recently updated review of HF caregiver literature recognises that while patient-caregiver typologies in HF may be important, the value of understanding the nature of the relationship is potentially of greater importance as this relationship precedes the diagnosis (25).

Multivariate analysis in chapter 5 demonstrated that an interaction effect on patient HRQoL in favour of patients with a caregiver was present at 4 months follow-up (9.9, 1.9 to 18.0, $p = 0.015$). This positive effect was not sustained at 6 months follow-up (2.2, -0.5 to 4.9 $p = 0.113$). There is limited evidence of sustained change in patient outcomes in literature assessing the role of caregiver in HF self-management (25, 64). An RCT of patient-partner dyads living with HF, with 24 month follow-up, did not demonstrate any significant differences between the intervention and control group for health, depression or perceived control (301). This study was important as it is one of the few published studies which analysed data at the dyad level in order to account for interdependencies that may occur within the dyadic relationship (301). However, qualitative data was not captured which may have shown differing long-term outcomes in terms of patient and caregiver perceptions of health, depression and control, as seen in the dementia respite study discussed above (301, 468).

There are a number of possible explanations which may account for the limited longer-term improvement in patient HRQoL for those with a caregiver. First, it may be due to the progression of HF. A meta-analysis of the relationship between caregiver wellbeing and patient outcomes identified that increased caregiver strain was associated with poorer patient health (344). Thus, there is potential that patients and caregivers in REACH-HF were experiencing greater strain and poorer health which may have impacted patient HRQoL at 6 months follow-up. For example, deterioration in patient health may have resulted in greater care needs and less improvement in HRQoL. Second, it could be suggested that enhancing patients' self-efficacy in managing HF with REACH-HF indicated they were able to independently engage in HF self-care. Bandura's theory of self-efficacy posits that engagement with self-management tasks and attaining a sense of accomplishment leads to the development of self-efficacy (86). Success and positive experiences via achievements and accomplishments may have increased self-efficacy for patients with HF (86). This may have reduced the difference in longer-term HRQoL between patients with a caregiver and those without. Third, it may have been due to the withdrawal of the presence of the REACH-HF facilitator at 12 weeks. A psychoeducational dyadic study of HF patients and caregivers suggested that ongoing follow-up from a healthcare professional may facilitate sustained change (183). Ongoing professional support has been recognised as a need for caregivers of patients living with stroke and COPD (27, 474).

Analysis of the 12 month follow-up interviews demonstrated that some caregivers had difficulties motivating the patient to sustain engagement in HF self-management strategies. A recently published systematic review examining the impact of autonomy support for individuals living with chronic illness suggests that educating caregivers in the provision of autonomy support can help to sustain behaviour change (475). This concept of support for autonomy suggests that caregivers communicate in a way that is encouraging, respectful of the patient's choice and collaborative as opposed to pressurising or coercive (476). The patient populations included HF, diabetes, COPD, back pain, arthritis, HIV and other unspecified long term illnesses (475). However, the robustness of the findings of this review were limited as the authors included studies which they interpreted as providing autonomy support, as opposed to autonomy support being explicitly identified in the primary trials as a component of the intervention (475).

The challenges caregivers in REACH-HF experienced when trying to motivate patients may further explain why patients with caregivers did not sustain improved patient HRQoL at 6 months follow-up in the multivariate analysis (chapter 5). Dyads who reported difficulty maintaining change identified a combination of factors. These included the duration of diagnosis, the severity of illness, the demands on the caregivers' time, and the concept of the meaningfulness of the task for the patient. These aspects of patients and caregivers perceptions of self-management have been identified in a recent scoping review of systematic reviews which included HF and COPD (477). This synthesis demonstrated the process of engaging in self-management can be influenced by ensuring intervention delivery is individualised and ensuring patients and caregivers perceive the benefits of self-management tasks (477). Patient and caregiver led approaches to self-management can facilitate these processes. There is recognition in the HF literature of the value of collaborative goal setting (478-480). However, this literature is less explicit in identifying the importance of patient-led goal setting which has been identified as a challenging process which often tends to be professional led rather than patient-led (481). A creative approach to goal setting in REACH-HF may have facilitated patients to recognise what was meaningful to them and subsequently supported patients and caregivers to link this to sustained HF self-management. If patients could not identify meaning in why they needed to complete a task (e.g. walking at pace with the pedometer), they were less likely to engage in that task or sustain it beyond REACH-HF. In these situations caregivers had difficulty motivating the patient, the caregiver had to employ more directive strategies to encourage the patient to participate in these activities. In this type of situation caregivers may experience difficulty with providing unconditional positive communication as suggest in the concept of autonomy support (476).

7.2.2 What is the impact on caregivers when they are involved in the delivery of self-management interventions? (Chapters 3, 4, 5)

The mixed-methods systematic review in chapter 3 established that caregiving for patients with cardiorespiratory illnesses were consistent with what is reported in the existing broader caregiver literature (20, 27, 35, 72, 181, 197, 208, 343). Caregiving is complex and can create significant interruptions to a persons expected life course (82). The experiences of patients living with HF was ever-changing, described as an "ebb and flow", they sought knowledge and support throughout all stages of the illness (309). Caregivers of individuals living with other long-term illnesses such as dementia and cancer report similar life changing experiences when providing care to a patient living with these conditions (166, 482). The quantitative analysis in chapter 5 demonstrated that the most consistent patient predictor of caregiver HRQoL was patient illness severity (as classified by NYHA status). Caregivers of patients with higher NYHA severity reported more anxiety at 4 and 6 months follow-up, consistent with previous research (61, 483). A longitudinal observational study by Pressler at al. identified that caregivers of HF patients who were more symptomatic reported higher levels of anxiety and poorer HRQoL (61). A cross-sectional study of caregivers of patients living with Alzheimer’s disease demonstrated that increased patient illness severity was a predictor of poorer caregiver outcomes including increased burden (484). The experience of caregivers of stroke patients demonstrated that when patient health is stable, caregiving was perceived as a positive experience (75). Due to the trajectory of HF and the implications of increasing dependence on caregivers as NYHA status increases, it was expected that caregiver HRQoL in REACH-HF was predicted by patient NYHA status.

This empirical research also demonstrated that increasing duration of HF diagnosis was associated with poorer FAMQoL overall score. MacKenzie and Greenwood (75) reported similar findings in their review of caregiving for patients living with stroke, they identified that caregiver perceptions of caregiving over time became increasingly negative. This may negatively impact caregivers’ QoL and subsequently reduce caregivers’ ability to engage in supportive self-management tasks (e.g. going for a walk with the patient). This is may have also contributed to lack of patient HRQoL gains seen at 6 months follow-up and explains why caregivers verbalised difficulty in motivating patients at 12 month follow-up interviews.

Caregiving of female HF patients was associated with improved QoL (FAMQoL, EQ-5D-5L) and less burden (CBQ Physical, CBQ Social) in REACH-HF. However, a literature review of gender in caregiving suggests that this finding should be interpreted with caution, as the effect of gender on caregiver or patient are inconsistent and need be to be interpreted within the wider context of understanding the nature of the relationship, the cultural dynamics of the dyad, ethnicity, as well as socio-economic status (71). Sub-group analysis demonstrated that caregiver outcomes were not influenced by caregiver gender, a finding which is in line with a meta-analysis of the wider caregiver literature showing small differences experienced by caregivers by gender (485). Larger treatment benefits (REACH-HF vs control) in FAMQoL psychological health, was seen at 6 months follow-up for spousal caregivers than non-spousal caregivers. Larger treatment benefits in emotional burden at 4 months follow-up and depression scores at 6 months follow-up were observed for non-spousal caregivers when compared to spousal caregivers. This finding is similar to a Canadian study conducted with caregivers of patients living with Alzheimer's disease reporting a reduction in adult-child burden at 6 months follow-up when compared to spousal caregivers (486). Analysis of caregivers of patients living with Alzheimer's disease demonstrated that spousal caregivers experience higher burden when patient health deteriorated, and adult-child caregivers reported higher burden when they perceived greater demands on their time (487). In the REACH-HF trial, non-spousal caregivers reported reduced intensity of their caregiving role when patients engaged in self-management tasks. This further underscores the importance of the relationship between the patient and caregiver in determining outcomes for both patient and caregiver HRQoL.

The findings of this research support the logic model presented in chapter 5 of this thesis (see section 5.1.1), i.e. core components of patient and caregivers' behavioural, environmental, and psychological activities all influenced patient's HRQOL (28). Thus impacting how they participated in self-management and ultimately influencing the long term outcomes of patients and caregivers (28). However, an aspect which has not been addressed in the logic model and may be a mediator in dyad engagement in self-management is the concept of the meaningfulness of tasks. The value a person places upon setting goals to achieve lifestyle changes is influenced by how meaningful those goals are (488). For example, the spousal caregiver who identified that the patient needed to exercise had hoped that REACH-HF would assist her in motivating him to do this. However, whilst this patient acknowledged that he knew he should exercise and eat healthily, the prescribed chair-based and walking exercise did not hold meaning for him, given his past experience of exercising competitively. Incorporating the concept of engaging patients and caregivers in self-management tasks which are meaningful to them in their context, can inform a revised logic model for future programmes of research and may be a key component to sustaining behaviour change beyond REACH-HF.

This research in this thesis much aligns with the situation specific theory of caregiver contributions to heart failure self-care (201). This empirical research has demonstrated that caregiver-related factors (demands on their time, their own health), patient-related factors (NYHA status, duration of diagnosis) and dyad-related factors (quality and type of relationship) all informed self-management (200, 201). An example of caregiver self-efficacy being a mediator in this process was the action taken by a spousal caregiver in response to identifying deterioration in the patient's health. The caregiver developed skills and confidence, thus leading to feelings of self-efficacy which positively influenced patient HRQoL by avoiding hospital. This aligns with Chen et al. reporting that caregiver confidence in HF is mediated by knowledge, perceived control, and support (202). The aspect of situation specific theory of caregiver contributions to heart failure self-care model which may require refinement is the concept of caregiver cultural values (200, 201). The developers of the model suggest that caregiver cultural values represent the social, financial, cultural and political values which inform the caregiver values and beliefs (201) However, simply stating this as cultural values may limit the perception of the all-encompassing representation of this aspect of the model. Furthermore, given the identification in this research of the important influence of the dyadic context influencing and informing self-management, it could be suggested that instead of stating how caregivers' cultural values inform their contributions to HF self-care, the dyadic context informs caregiver contributions to HF self-care. For example, if an adult-child is the caregiver for their parent, and they have differing belief systems with regard to cultural norms, values and feelings regarding self-management, this could be a barrier to caregiver contributions in HF self-care. However, if the dyad shares cultural values this may facilitate the caregiving process and outcomes.

7.3 Overarching strengths and limitations

The research undertaken in this thesis provides new and significant contributions to the understanding of caregivers' involvement in self-management interventions for cardiorespiratory illnesses, specifically HF. The strengths and limitations specific to the four research studies are presented within each respective chapter. There were two important overarching strengths and limitations of the research work undertaken and presented in this thesis: (1) a systematic and linked approach to researching the impact of involving caregivers in self-management interventions for long-term cardiorespiratory illnesses, in particular HF, (2) utilising a multi-method research approach. The areas of limitation are summarised below.

(1) Systematic and linked approach

An overarching strength of this thesis was its systematic and comprehensive research approach to meet the overall thesis aim. This thesis was planned with each of the four linked research studies building upon the knowledge ascertained in each previous chapter. The starting point for this research was identifying the complexity of the caregiving role and recognising that the current evidence base with regard to caregiver inclusion in patient self-management of HF is limited (64, 489, 490). Caregivers are recognised as a vital part of HF patients' self-management (12, 363, 415). However, where caregivers are included in trials, there is poor reporting of the modality of caregiver involvement and caregiver outcomes (182). Thus, the findings of both chapter 3 and chapter 4 informed the subsequent analyses of the REACH-HF data.

An updated American Heart Association (AHA) review published in 2020, examining the caregiver literature in HF, identified that while research in HF caregiving has evolved, there remains a multitude of research gaps. These included limitations in high quality multi-centre longitudinal studies, lack of investigation of caregiver experiences, limited attention to dyadic HRQoL outcomes and limited exploration on the influence of the nature of the dyadic relationship (25). This thesis addresses these gaps highlighted in the AHA review by: presenting a comprehensive review of the complexity of caregiving, demonstrating the impact of a HF self-management intervention for dyads on patient and caregiver outcomes via a multi-method longitudinal analysis and providing an insight into the influence of caregiving and the importance of the dyadic relationship following participation in a dyadic self-management intervention for HF.

A further strength of this research is the unique insight identified with regard to the differing dyadic experiences of HF self-management over time. In particular, it demonstrated how different dyads responded in terms of what they had learned from REACH-HF and how they were implementing this 12 months after the intervention.

For example, the younger spousal dyad (2020) using the skills developed to manage a health crisis or the parent-adult child dyad (4061) struggling with HF self-care and adjusting to the HF diagnosis. This longitudinal analysis revealed the transitions experienced by patient-caregiver dyads and how they adapted to changes in signs and symptoms of HF. Longitudinal analysis has been repeatedly cited as lacking in HF caregiver research (12, 172). Thus, this presents a unique insight into the evolving needs of different patient-caregiver dyads.

This secondary analysis was limited to one intervention: REACH-HF applied to HF patients and their caregivers. Therefore, the findings may not be generalisable to other self-management interventions or other long-term conditions. However, there is knowledge that has been identified in this research which aligns with the wider caregiver literature e.g. the importance of understanding the role of the caregiver and their enduring relationship to the patient. The stress process model recognises that the relationship between the patient and caregiver is an important aspect with regard to understanding the background to potential stressors (82). A review of patient-caregiver relationship quality in dementia caregiving synthesised 15 studies and demonstrated that caregiving does impact the quality of the relationship between the patient and caregiver and may have negative implications for the wellbeing of the caregiver (491).

Another limitation in this empirical research was the lack of evidence of consistency of impact of the REACH-HF intervention across caregiver outcomes. There is the possibility that caregiver outcomes for the REACH-HF trial were not aligned with the delivery of the intervention. A systematic review of the selection and use of outcome measures for caregivers of patients with HF, stroke and dementia identified that there is inconsistencies within the caregiver literature of how best to capture caregiver outcomes (361). This review used the Cochrane Database to identify and select trials which met the criteria of this review which may have inadvertently excluded some relevant studies. Of 134 trials included for synthesis, 11 of these were examining HF; depression and QoL were the outcomes most commonly measured (361). Concepts such as coping strategies are identified throughout the caregiver literature as important outcomes of intervention delivery, however, as captured in this systematic review outcome measures were not utilised to capture caregiver coping strategies (361). The REACH-HF logic model posited that behavioural and psychological factors would be targeted by the intervention, these factors were dependent upon patients and caregivers developing knowledge and coping strategies to engage in HF self-management (28). However, caregiver outcomes in this trial did not include assessment of either knowledge or coping strategies.

The overarching aim of this research was to understand the role of caregivers in self-management interventions for patients living with cardiorespiratory illness. However, the primary research conducted for this thesis was limited to the qualitative and quantitative data available from the two linked studies conducted from the REACH-HF research programme of self-management intervention for HF patients and their caregivers. However, the secondary research undertaken in this thesis has a wider scope, including patients with COPD and their caregivers (chapter 3 and 4) and patients with CAD and their caregivers (chapter 3) providing a broader understanding of the role of caregivers in cardiorespiratory illness.

The secondary qualitative analysis was limited to the perspective of HFrEF patients and their caregivers. The quantitative research consisted of the combined data set from the randomised REACH-HF trial and the pilot REACH-HF trial (HFrEF and HFpEF patients and caregivers). In contrast, the secondary analysis of qualitative data consisted of patients and caregivers from the randomised REACH-HF trial only (HFrEF patients and caregivers). The qualitative data from the REACH-HF pilot study (HFpEF patients and caregivers) was not available at the time this study was completed. Therefore, it is important to acknowledge that conclusions about the qualitative findings are representative of HFrEF patients and caregivers only. However, given the primary diagnosis is HF, there are some similarities in physical functioning difficulties (492). Thus, findings of the qualitative evidence may provide a preliminary understanding of the actions that caregivers are engaging in which can influence patient outcomes. This information could be utilised as an information source in future interventions with this population. The population included for analysis throughout the empirical research has predominantly been Caucasian, female caregivers, and male patients. This lack of diversity within this sample limits the generalisability of the findings, especially to patient-caregiver dyads where there may be familial or cultural obligations with regard to caregiving. Qualitative research conducted in the USA with caregivers who identified their ethnicity as South Korean, African American, or Hispanic has shown that while there were similarities in some aspects of caregiving experiences, there was also great variety (493). For example, Hispanic caregivers were mostly male, South Korean caregivers identified inter-generational conflict as a significant issue in their caregiving role, while, food, language, and spirituality were recognised by all caregivers as influencing and informing their knowledge and coping strategies when providing care for someone with dementia (493). This may influence the dynamic of the relationship between the patient and caregiver which has been recognised as being of significance in the delivery of dyadic interventions. Lack of diversity in caregiver research has been well established in the caregiver literature (494). Future patient-caregiver research needs to include representation from Black, Asian and minority ethnic groups to understand their needs in HF self-management. Inviting representatives from these under-served groups to inform the design of dyadic self-management interventions will enhance their applicability and relevance to the wider population.

(2) Utilising a multi-method research approach

Rigorous methods were utilised throughout this research, and theoretical frameworks underpinned each study, as discussed in chapter 2 (80, 82, 86, 94, 201, 495). The systematic reviews and meta-analysis were conducted in accord with PRISMA guidelines and the TiDieR checklist for reporting interventions (209, 291). The secondary analysis of the REACH-HF data utilised a sequential multi-methods approach to analysis (496). There is little research in HF caregiver literature which examines caregiver involvement utilising a combination of quantitative and qualitative research approaches (186, 363). There has been one study which has utilised multiple methods, this was a longitudinal RCT of a psychoeducational intervention for patient-caregiver dyads with an accompanying qualitative analysis of documentation completed by HF nurses delivering the intervention (497). In this RCT, patient and caregiver outcomes were not sustained in the long-term, and the authors suggest the need for long term caregiver involvement. A mixed methods process evaluation may have provided further insight into why outcomes were not sustained long term (63, 301, 497, 498). Thus, this research is significant because it demonstrates the importance of using a multi-method approach to comprehend the complexity of the nature of caregiving following the positive impact of caregivers in a self-management intervention on patient HRQoL outcomes. This sequential approach connected the data by a series of steps. An initial reading of the participant interviews, field notes and facilitator notes informed the quantitative questions formulated; and the findings of the quantitative analysis informed the question posed for the secondary qualitative analysis (496, 499). The qualitative results were interpreted and provided an insight to the quantitative findings (500). To comprehensively appreciate the impact of a dyadic self-care intervention, a multi-methods approach was necessary. This was a time-intensive, iterative process and required an organised, systematic approach from this researcher.

A limitation of this secondary analysis was the lack of integration of qualitative and quantitative data at the stage of interpretation and reporting of the results (501). The purpose of integration is to achieve new insights beyond the results of each study (198, 501). While it could be suggested that there was some limited integration with regards to the methods and discussion, planned-for integration was not undertaken (501). Integration at the point of interpretation may have contributed to enhanced methodological rigour, enriched the credibility of the results and produced a deeper analysis and synthesis of dyads in REACH-HF. Thus further expanding our knowledge of the dyadic experience and outcomes when participating in a self-management intervention (501, 502). A truly integrated and planned-for mixed methods research design could have facilitated comparison across these groups (503). New relationships may have been identified with regards to participation in REACH-HF, in particular indicating why some outcomes were achieved by some dyads and not by others.

The lack of impact of REACH-HF on caregiver outcomes (chapter 5) indicates that REACH-HF did not achieve the anticipated outcomes for caregiver QoL (504) The analysis conducted enabled identification in the data that while some facilitators engaged caregivers as ‘co-facilitators’ in the intervention, whether they addressed caregivers’ needs is less clear and was not part of the scope of the secondary qualitative analysis of this thesis. That the delivery of the intervention i.e. the methodology of caregiver involvement was not as anticipated may be attributable to the fact that the facilitated aspect of the intervention was only for 12 weeks. There was evidence from the analysis of the qualitative interviews in this sample that 12 weeks was not enough time for those dyads who were diagnosed with HF less than one year, and for those living with HF over a longer period (10 years or more), indicating the need for a longer intervention. Additionally, the wider caregiver research in HF (183), traumatic brain injury (505) and cancer care (506) indicates that long-term illnesses requires ongoing professional support both for the patient and caregiver.

A final limitation of this PhD research was the lack of exploration of the positive aspects of caregiving. Identifying positive aspects of caregiving can inform intervention delivery as much as learning from the negative aspects of caregiving. A systematic review of caregiving in dementia research demonstrated that positive perceptions of caregiving were significantly associated with less depressive symptoms, better mental health and improved QoL for caregivers (76). Caregivers who are newer to the role identify more positive experiences than those who are caregiving over a longer period of time (75). Understanding and harnessing these positive emotions in intervention delivery may contribute to sustained outcomes in patient-caregiver self-management interventions.

7.4 Implications for healthcare delivery and policy

The findings of this PhD programme of research have some important implications for healthcare delivery and policy: (1) identifying and understanding the role of the caregiver in the dyad, (2) identify whether there is a need for dyadic facilitation or caregiver facilitation skills, (3) understanding of the context of the patient-caregiver dyad.

1) Identifying and understanding the role of the caregiver

An important first step for healthcare professionals is identifying whether a caregiver is providing support to the patient in their self-management and what the nature of this support is. Having an understanding of the caregivers' knowledge, confidence and coping strategies can inform clinicians about the accuracy of caregivers' knowledge, their confidence to support the patient or engage external healthcare support if required, and their ability to employ coping strategies to maintain their role. Caregivers believe they can better support patients when they have knowledge of HF, additionally, greater caregiver knowledge has been associated with greater patient engagement in self-management (202, 507). Healthcare professionals have an important role in ensuring that this knowledge is appropriate to support self-management. Management of HF may change over time due to the progression of the illness, therefore it is imperative to ensure that where caregivers are present their knowledge remains up to date. It has been suggested that caregivers who are formally involved by healthcare professionals in self-management interventions may require preparation and education on the concepts of self-management and person-centred care as it is a novel experience and a new model of practice for many caregivers (34, 508).

2) Dyadic/Caregiver Facilitation Skills

The findings of this empirical research indicate that caregivers do have an important role in patient self-management in HF and potentially in self-management in COPD. It is important for healthcare professionals to understand how to engage caregivers in intervention delivery either individually or utilising a dyadic approach to intervention delivery. Healthcare services and policymakers should consider self-management interventions from the broader perspective of dyadic-centred care as opposed to the individual or patient only approach (509, 510). That is, integrating family and friends as a core component of the intervention, addressing both the individual and dyadic needs of patients and caregivers (416, 511). This broader perspective of intervention delivery has the potential to increase caregiver confidence (416), reduce caregivers need for vigilance in observing the patient and mediate stressors experienced, such as mental and physical health effects as outlined in chapter 3 (309). A dyadic approach may lead to self-efficacy within the dyad, thus maintaining adherence in HF self-care (340, 344, 512). This may be an alternative approach to healthcare delivery in some healthcare settings. A dyadic-centred care approach may transform how healthcare professionals work with patients and caregivers. Healthcare professionals acknowledge the role of caregivers but can be hesitant to intervene; this has been predominantly reported in primary care settings (513, 514). This hesitation with supporting caregivers is due to time limits, concerns about maintaining boundaries (i.e. treating the patient is the primary objective as opposed to addressing caregiver's health needs), confidentiality, and the therapeutic relationship between the patient and healthcare professional (513, 514). Additionally, emphasis in healthcare training is on the patient and references to caregivers are viewed in terms of how they can enhance the patients' self-care skills (513).

Patient-caregiver dyads utilise support differently; therefore differing approaches to self-management interventions are required (515). This consolidates the benefits of the choice offered by the multi-component REACH-HF intervention. Offering multi-component interventions enabled dyads to select a mode of engaging with the intervention in a manner which suited their needs and their context. Due to the complexity and frequently competing demands of caregiving, a variety of modes of engagement enhance the likelihood of the dyad meaningfully engaging with self-management. This approach to tailoring interventions is recommended in HF self-management to optimise patients self-care skills (516).

Additionally, multi-modal self-management interventions can enhance how patients and caregivers learn and retain information (517). The advantage of multi-modal intervention delivery identified in this research is similar to what was espoused by Schulz et al. in the design and delivery of a caregiver only trial for caregivers of patients living with Alzheimer's Disease (108). Significantly, the findings of this empirical research validated that "not one size fits all" when it comes to HF self-care, thus emphasising the need for multi-component dyad-centred care in self-management interventions.

3) Understanding the context of the patient-caregiver dyad

The empirical research in this thesis has contributed a greater awareness of the personal and external factors of the patient-caregiver dyad, which influences their engagement with self-management interventions in HF. Recognising the personal and external determinants of the dyad can inform healthcare professionals' understanding of the dyad's capacity for engaging in HF self-care and subsequently transform the way healthcare professionals engage with patient-caregiver dyads. Firstly, the type of dyadic relationship informs the type of engagement with self-management interventions (i.e. spousal, younger spousal (<50 years old), adult-child or friend). Examples of this include: spousal caregivers being present for face-to-face appointments with the facilitators, or adult-child caregivers sourcing information online. Relationship quality (270, 518-520), dyadic typologies (12) and dyadic HF self-care (521) have been researched in the HF literature. However explicit comparisons of relationship types (spousal, younger spousal (<50 years old), adult-child or friend) and how the nature of this relationship informs dyadic HF self-care engagement is a gap the literature (25) that has been addressed in this research.

In addition to understanding the interpersonal relationship of the dyad, contextual factors influence how dyads manage illness (20, 146). The family network is cited in the literature as highly influential in HF self-care (170, 522). Kim et al. completed a synthesis of 10 years of caregiver literature in HF, and a primary outcome was the vital role of the wider family in supporting dyadic HF self-care (170). The contextual factors influencing HF self-care have previously been evidenced in the HF literature examining patients only and patients and caregivers (77, 167, 418). However identifying the contextual factors which influence dyadic HF self-care has not been studied from a longitudinal, multi-method perspective as per this thesis. The contextual factors evidenced in this thesis which are essential for healthcare professionals to recognise in order to inform the delivery of self-management interventions include the patient-caregiver dyads' knowledge of HF, duration of HF diagnosis, the physical and mental health of the dyad and the experience of the dyad with sharing HF self-care. Additionally, the implications of being in paid employment or having other dependents and the supports available to the dyad, including the more extensive family network, influence how dyads participate in self-management interventions and engage with healthcare professionals. Understanding the context in which the dyad is living and engaging in self-care provides a solid foundation for determining how to appropriately delivery self-management support.

Awareness of what support is available outside of the patient-caregiver dyad is important. Caregivers who were balancing other roles and commitments with providing care in this context identified more difficulties with the role; these caregivers are documented in the literature as struggling with balancing busy lives and frequently experience financial implications due to caregiving (236, 523). Understanding stressors experienced by the dyad such as the presence of comorbidities, being in full-time work or parenting young children will inform whether dyads will engage with healthcare professionals. These factors will also inform what resources (regarding self-care) they are likely to use and what outcomes they may experience from participating in self-management interventions.

This research places further emphasis on the importance of caregivers completing a carer's needs assessment. There is an onus on healthcare professionals to ensure caregivers are aware of their right to a needs assessment. At present the figures are stark, with only 27% of almost 6,000 caregivers living in England reporting that they were offered and completed a needs assessment in 2019 (3), indicating a limited acknowledgement of the needs of caregivers. This poor uptake of a carer's needs assessment may be due to healthcare professionals not recognising who the caregiver is, or not engaging caregivers in conversations about their needs. Therefore, it is fundamental for healthcare professionals to identify who the caregiver is, recognise the nature of the relationship between the patient and caregiver and understand the personal and external determinants of the dyad at the beginning of the intervention process. This knowledge can serve to optimise the modes of intervention delivery and address the needs of both members of the dyad (524, 525). Best practice guidelines for managing HF and COPD acknowledge the important role of caregivers. Clinical guidelines published by the National Institute for Health and Care Excellence (NICE): "Chronic heart failure in adults: management" (NG106) and, "Chronic obstructive pulmonary disease in over 16s: diagnosis and management" (NG115), emphasise the inclusion of family members or caregivers in discussions about self-management of these illnesses (133). The findings of this PhD research support these guidelines by showing that caregivers of individuals with these conditions do experience significant lifestyle changes and are relied upon by patients to engage in self-management strategies. Greater acknowledgement of the role and potential contributions of caregivers is important to include in guidance. The multicomponent REACH-HF intervention provides a blueprint for the processes of caregiver inclusion and how their theoretically based actions may contribute to improved patient outcomes.

7.5 Directions for future research

The situation-specific theory of caregiver contributions to HF self-care (discussed in chapter 2) presents a theoretical insight into the complexity of caregiver contributions and their impact on HF self-care. This thesis has built on the theoretical evidence base and contributed further knowledge in understanding that caregivers have a role in positively influencing patient outcomes. However, sustaining such positive change in the longer-term was found to be limited. Additionally, it was less clear as to the impact on caregiver outcomes when caregivers are included in self-management intervention delivery. Areas for future research in self-management intervention development for patients with HF or COPD include: (1) facilitation of caregivers in intervention delivery, (2) caregiver outcome measures, (3) patient-caregiver dyads, (4) methodology in caregiver research, (5) longer-term intervention delivery, (6) positive aspects of caregiving, and (7) modes of intervention delivery.

1) Facilitation of caregivers in intervention delivery.
   This is an evolving area of intervention delivery, particularly for individuals living with HF or COPD. There are still gaps with regard to understanding how facilitators can best engage caregivers in intervention delivery. Lorig and Holman have previously suggested that caregivers require preparation prior to being engaged in an intervention (34). They suggest that patients who are living with illness over a longer period of time are well accustomed to the concept of patient-centred care. However for caregivers to be identified as a part of the intervention, and be asked about their needs, is a relatively new

development in healthcare (34). This was reflected in caregivers identifying that their participation in REACH-HF was not for their own needs but for the patient in order for them to achieve their health related goals. Facilitation of caregivers in REACH-HF provided some insights, for example some facilitators contacted caregivers by telephone as a way of exploring their needs, while other facilitators included caregivers as co-facilitators. Understanding how best to support caregivers requires a high level of skill and it was unclear from REACH-HF how robustly caregivers were included. The other consideration is that this is less reported by facilitators. In order to ensure accurate reporting of the facilitation of caregivers, future research could examine methods for successfully engaging caregivers and emphasise the reporting of caregiver inclusion and involvement in research studies.

2) Identification of outcome measures in caregiver research which align with the intervention delivery.
   The National Institute of Health Research (NIHR) Research Design Service released a briefing in 2019 emphasising the priority need for research evaluating caregiver interventions, and the impact of caregiver included interventions on caregiver outcomes (526). An objective of this research was to understand the impact of being involved in self-management interventions on caregiver outcomes. This PhD research demonstrated that caregiving for individuals living with long-term cardiorespiratory illness can have a profound impact on the life of a caregiver. This aligns with what has been identified within the wider caregiver literature. This research also demonstrated that data gathering with regard to caregiver outcomes in self-management interventions is limited (361). Where outcomes have been gathered with regard to the influence on caregivers, findings are inconsistent and as demonstrated in this research, dependent upon the context within which that caregiving is taking place. It is important to ensure that outcome measures selected are aligned with the aims and facilitation of the intervention delivery.

   Additionally, dissemination of research (not just limited to publications), should place an emphasis on reporting caregiver outcomes. Consistently capturing these will establish caregiver outcomes as a key feature of caregiver included studies. Developing the caregiver evidence base in cardiorespiratory illness self-management interventions will lead to greater consistency across the literature in facilitating identification of the predictors of caregiver QoL, thus informing policy development greater understanding of the nuanced influences of caregivers in healthcare self-management interventions. While REACH-HF did include patients and caregivers in the consultation process of the intervention design (28) and a representative of the patient and public involvement (PPI) group was part of the REACH-HF project from design to implementation and evaluation, this representative was not a caregiver. Having a caregiver participating in the group may have produced differing insights to those offered by the PPI representative. Caregiver consultation is required throughout intervention design and delivery to determine how best to capture and interpret caregiver outcomes.

3) Patient-caregiver dyads

This empirical research contributed to understanding the impact of the nature of the relationship between patients and caregivers. Furthermore, the influence of this on patient and caregiver engagement with self-management interventions was established. In particular, this research demonstrated the differing ways older and younger spousal dyads, adult-children and friend caregivers engaged in self-management. This comparative reporting of differing experiences of spousal and non-spousal caregivers has not been robustly researched in HF self-care (521). Overall, testing dyadic interventions remains under-researched in the HF and COPD caregiver literature but is a key area for research (25, 90) particularly as demonstrated in this research due to the identified interdependence of patients and caregivers in HF self-care (416, 512, 520, 527). Thus, further research of interventions involving dyads to build upon what has been learned from this empirical research is required. Robust studies examining patient-caregiver dyads understanding of HF over time, how to address the needs of specific dyads and capturing dyadic outcomes can inform researchers and healthcare professionals in designing and delivering optimal dyadic interventions in long term illnesses (151). Ongoing patient and caregiver engagement throughout the design and delivery of a dyadic intervention is essential. Engaging patients and caregivers throughout the design and delivery of a dyadic intervention for long term illnesses, including HF, can provide valuable learning regarding the design and implementation of the intervention as well as capturing and interpreting outcomes.

4) Methodology in caregiver research
   The importance of examining dyadic interventions utilising a multi-method approach has been demonstrated in this research. Caregiving is not a linear experience and caregiver contributions to the management of cardiorespiratory illnesses changes dependent on patient need (415). Therefore it is difficult to holistically appreciate the complex needs of patient-caregiver dyads if evaluating interventions from one methodological perspective (528). To consolidate our knowledge, testing of future novel dyadic interventions in long term illness requires the integration of qualitative and quantitative methods (529, 530). Integration enables a higher-order interpretation of the complexities of the patient-caregiver dyad and the processes occurring in relation to self-management (501). This approach to intervention implementation can enhance our understanding of the contexts and processes within which dyadic care is taking place and how interventions work best enabling targeted interventions which address the needs of the dyad (400). Robust mixed-methods analysis can add weight to the caregiver evidence base in HF self-management and deliver a powerful message to healthcare professionals, researchers and policymakers about the complexity and processes of patient-caregiver dyads in HF, as well as other long term illness management (500).

5) Longer-term interventions. This empirical research demonstrated that while change may be initially demonstrated by caregiver inclusion in self-management interventions. It was not sustained across many outcome measures. It was indicated that patient illness progression was a predictor of caregiver outcomes. In order to better understand how to sustain change, longer-term follow-up of interventions may be warranted. This may form part of the intervention delivery, for example the initial intervention delivery may be over 12 weeks with a follow-up intervention session delivered at 6 month

intervals for two years. The aspects of long-term illness which may require ongoing support include preparing and supporting patients and caregivers as the illness progresses. For healthcare professionals it provides an opportunity to ensure patient and caregiver knowledge remains accurate and to understand what changes are occurring for the dyad and what coping strategies they are using.

6) Positive elements of caregiving.
   The literature review in chapter 2 discussed the importance of understanding the positive aspects of caregiving in order to understand and validate caregivers' experiences. As this was not specifically examined in the primary research studies in this PhD, this represents a potentially important area for future research. Understanding what caregivers perceive as positive about caregiving for someone with HF or COPD may provide insight as to how to target intervention delivery.

7) Modes of intervention delivery
   Caregivers, in particular those with competing demands for their time, benefitted from a multi-component approach to engaging in the intervention. Multi-component interventions in Alzheimer's research have demonstrated efficacy (531, 532), however, ongoing evaluation of this approach in other HF patient-caregiver dyads as well as other long term illnesses is merited to determine whether the flexibility of this type of intervention can address the needs of patients and particularly caregivers. An online delivery approach may be a mode of engaging adult-child caregivers who were less likely to be present for facilitated intervention sessions. Digital health interventions have been examined in HF self-care with patients and have demonstrated benefits for patients and healthcare professionals (533). However, the inclusion of caregivers has not been researched in digital interventions.

7.6 Overall Conclusions

This PhD research shows that caregivers have a key role in the self-management of patients with long-term cardiorespiratory illnesses, such as HF and COPD. Understanding the caregiver role and the nature of the patient-caregiver relationship can significantly influence how we can better engage patients in self-management of their illness. The context of the patient-caregiver dyad is integral to understanding how to design and deliver self-management interventions. While caregivers experienced some improvement in their burden and quality of life in the REACH-HF trial, these improvements were limited. The multi-component design of self-management interventions, such as REACH-HF, facilitated patients and caregivers to utilise the intervention in a way that suited their context. REACH-HF also facilitated patients and caregivers to communicate about HF self-care, increased their HF knowledge and skills and enabled caregivers to feel supported with the inclusion of the wider family. It appears that non-spousal caregivers may experience greater challenges in the caregiving role when compared to spousal caregivers. That disease severity was the most consistent predictor of poor caregiver outcomes indicates the need for ongoing healthcare support for both patients and caregivers as disease progresses.

The body of quantitative and qualitative research presented in this thesis provides new and important information in this field. The finding that the involvement of caregivers can have a positive impact on improving patient HRQoL illustrates the potential importance of caregiving. Additionally, recognising the value of engaging in self-management tasks that are meaningful to the patient and caregivers may facilitate sustained behaviour change. This PhD research contributes to the understanding of the nature of caregiver contributions in HF self-management and illustrates the nuanced factors and context which influence caregiver outcomes following participation in HF self-management interventions. Understanding the dynamics of the dyad; the intrinsic and extrinsic motivators, as well as the type of relationship between the patient and caregiver, can inform how they engage with HF self-management interventions.

Further research is needed to better understand whether pro-active facilitation of caregivers can enhance caregiver outcomes. Caregiver consultation throughout the design and delivery of dyadic interventions is vital to strengthen our understanding of how we can achieve and sustain improved quality of life outcomes for both patients and caregivers. Finally, this PhD research programme has demonstrated the value of using multiple research methods to understand the complexities of caregiving in a long-term illness. In doing so it has demonstrated that caregiving is a complex experience in cardiorespiratory illnesses. There is scope for caregivers to positively influence patient HRQoL when self-management interventions are designed and delivered in a manner that supports the contextual needs of the patient-caregiver dyad.

Appendices

Appendix 1 Search Strategy

Medline:

MeSH: Caregivers

“Caregivers”.ti,ab OR “care-giver”.ti,ab OR “carer*.ti,ab” OR “informal car*”.ti,ab

AND

MeSH: Quality of life

“Quality of life” OR “outcome measures” OR “caregiver outcomes” OR “care-giver outcomes” OR “time use” OR “time-use” OR “occupations” OR “occupational engagement” OR “self-efficacy” OR “self efficacy” OR “experience” OR “emotion*” OR “psychological health impact” OR “physical health impact” OR “confidence” OR “self-confidence” OR “satisfaction” OR “dissatisfaction” OR “activities of daily living” OR “resilience” OR “social adj2 (interaction or engagement or support) OR “Social adj2 (participation)” OR “caregiver adj2 (support or health professional or medical team or nurse or patient or relationship* or knowledge)” OR “information exchange” OR “coping strategies” OR “leisure activity” OR “conflict” OR “caregiver responsib*” OR care-giver responsib*” OR “caregiver expectation” OR “care-giver expectation” OR “caregiver role” OR “care-giver role” OR “role adjustment” OR “caregiver or care-giver adj2 (attitude to health)”

AND

MeSH: Heart Failure, Heart Diseases, Myocardial Ischaemia, Coronary Artery Disease, Pulmonary Disease, Chronic Obstructive, Pulmonary Heart Disease, Chronic Obstructive Pulmonary Disease, Acute Coronary Syndrome, Cardiovascular Diseases, Coronary Artery Disease, Coronary Artery Bypass, Coronary Disease, Coronary Aneurysm, Stroke, Myocardial Infarction

“Heart Failure”.ti,ab OR “cardiac failure”.ti,ab OR “myocardial failure”.ti,ab OR “left ventricular failure”.ti,ab OR “right ventricular failure”.ti,ab OR “cardiomyopathy”.ti,ab, OR “systolic failure”.ti,ab OR “diastolic failure”.ti,ab OR “Chronic Obstructive Pulmonary Disease”.ti,ab OR “COPD”.ti,ab OR “chronic obstructive lung disease”.ti,ab OR “pulmonary disease”.ti,ab OR “pulmonary disorder”.ti,ab OR “respiratory disease”.ti,ab OR “respiratory disorder”.ti,ab OR “dyspnea”.ti,ab OR “dyspnoea”.ti,ab OR “Stroke”.ti,ab OR “stroke disability”.ti,ab OR “stroke disease”.ti,ab OR “stroke disorder”.ti,ab OR “CVA”.ti,ab OR “cerebrovascular accident”.ti,ab OR “transient ischaemic attack”.ti,ab OR “transient ischemic attack”.ti,ab OR “haemorrhage”.ti,ab OR “hemorrhage”.ti,ab OR “cerebral haemorrhage”.ti,ab OR “cerebral hemorrhage”.ti,ab OR “aneurysm”.ti,ab OR “atrial fibrillation”.ti,ab OR “Coronary Artery Disease”.ti,ab OR “acute coronary syndrome”.ti,ab OR “atherosclerosis”.ti,ab OR “arteriosclerosis”.ti,ab OR “ischaemic heart disease”,ti.ab OR “ischemic heart disease”.ti,ab OR “myocardial infarction”,ti.ab OR “coronary revascularisation”.ti,ab OR “coronary revascularization”.ti,ab OR “angina”.ti,ab OR “CABG”.ti,ab OR “coronary artery bypass graft”.ti,ab OR “stable angina”.ti,ab OR “angina pectoris”.ti,ab

CINAHL:

MeSH: Caregivers, caregiver burden, caregiver supports, caregiver role strain, risk for caregiver role strain, family caregiver status, caregiving endurance potential, caregiver-patient relationship, caregiver well-being, caregiver support, caregiver stressors, caregiver physical health, caregiver performance, caregiver performance: direct care, caregiver performance indirect care, caregiver lifestyle disruption, caregiver emotional health, caregiver strain index, caregiver role strain.

“Caregiver”.ti,ab OR “care-giver”.ti,ab OR “carer*.ti,ab” OR “carer”.ti,ab OR “carers”.ti,ab OR “informal care*”.ti,ab

AND

MeSH: Quality of life

“Quality of life” OR “outcome measures” OR “caregiver outcomes” OR “time use” OR “occupations” OR “occupational engagement” OR “self-efficacy” OR “self efficacy” OR “experience” OR “emotion*” OR “psychological health impact” OR “physical health impact” OR “confidence” OR “self-confidence” OR “satisfaction” OR “dissatisfaction” OR “activities of daily living” OR “resilience” OR “social adj2 (interaction or engagement or support) OR “Social participation” OR “caregiver adj2 (support or health professional or medical team or nurse or patient or relationship* or knowledge)” OR “information exchange” OR “coping strategies” OR “leisure activity” OR “conflict” OR “caregiver responsib*” OR care-giver responsib*” OR “caregiver expectation” OR “care-giver expectation” OR “caregiver role” OR “care-giver role” OR “role adjustment” OR “caregiver or care-giver adj2 (adjustment)” OR “caregiver or care-giver adj2 (acceptance) OR “caregiver or care-giver adj2 (readiness)” OR “caregiver or care-giver adj2 (attitude to health)”

AND

MeSH: Heart Failure, Treatment Failure, Pulmonary Disease, Chronic Obstructive Pulmonary Disease, Chronic Obstructive Pulmonary Disease, Acute Coronary Syndrome, Coronary Arteriosclerosis, Coronary Artery Bypass, Coronary Disease, Coronary Aneurysm, Stroke OR Coronary Artery Disease

“Heart Failure”.ti,ab OR “cardiac failure”.ti,ab OR “myocardial failure”.ti,ab OR “left ventricular failure”.ti,ab OR “right ventricular failure”.ti,ab OR “cardiomyopathy”.ti,ab, OR “systolic failure”.ti,ab OR “diastolic failure”.ti,ab OR “COPD”.ti,ab OR “chronic obstructive lung disease”.ti,ab OR “pulmonary disease”.ti,ab OR “pulmonary disorder”.ti,ab OR “respiratory disease”.ti,ab OR “respiratory disorder”.ti,ab OR “dyspnea”.ti,ab OR “dyspnoea”.ti,ab OR “Stroke”.ti,ab OR “stroke disability”.ti,ab OR “stroke disease”.ti,ab OR “stroke disorder”.ti,ab OR “CVA”.ti,ab OR “cerebrovascular accident”.ti,ab OR “transient ischaemic attack”.ti,ab OR “transient ischemic attack”.ti,ab OR “haemorrhage”.ti,ab OR “hemorrhage”.ti,ab OR “cerebral haemorrhage”.ti,ab OR “cerebral hemorrhage”.ti,ab OR “aneurysm”.ti,ab OR “atrial fibrillation”.ti,ab OR “Coronary Artery Disease”.ti,ab OR “acute coronary syndrome”.ti,ab OR “atherosclerosis”.ti,ab OR “arteriosclerosis”.ti,ab OR “ischaemic heart disease”,ti.ab OR “ischemic heart disease”.ti,ab OR “myocardial infarction”,ti.ab OR “coronary revascularisation”.ti,ab OR “coronary revascularization”.ti,ab OR “angina”.ti,ab OR “CABG”.ti,ab OR “coronary artery bypass graft”.ti,ab OR “stable angina”.ti,ab OR “angina pectoris”.ti,ab

EMBASE:

MeSH: Caregivers

“Caregivers”.ti,ab OR “care-givers”.ti,ab OR “Caregiver”.ti,ab OR “care-giver”.ti,ab OR “carer*.ti,ab” OR “informal car*”.ti,ab

AND

MeSH: Quality of life

“Quality of life” OR “outcome measures” OR “caregiver outcomes” OR “care-giver outcomes” OR “time use” OR “occupations” OR “occupational engagement” OR (“self-efficacy” OR “self efficacy”) OR “experience” OR “emotion*” OR “psychological health impact” OR “physical health impact” OR (“confidence” OR “self-confidence”) OR “satisfaction” OR “dissatisfaction” OR “activities of daily living” OR “resilience” OR “social adj2 (interaction or engagement or support) OR “Social participation” OR “caregiver OR care-giver adj2 (support or health professional or medical team or nurse or patient or relationship* or knowledge)” OR “information exchange” OR “coping strategies” OR “leisure activity” OR “conflict” OR “caregiver responsib*” OR care-giver responsib*” OR “caregiver expectation” OR “care-giver expectation” OR “caregiver role” OR “care-giver role” OR “role adjustment” OR “caregiver or care-giver adj2 (adjustment or acceptance or readiness)” OR “caregiver or care-giver adj2 (attitude to health)”

AND

MeSH: Heart Failure, Chronic Obstructive Pulmonary Disease, Bronchitis, Chronic Obstructive, Disease exacerbation, Pulmonary Disease, Cardiovascular Disease, Stroke, Cerebrovascular Accident, Coronary Artery Disease, Ischemic Heart Disease, Coronary Artery Disease, Acute Coronary Syndrome, Heart Infarction, Coronary Aneurysm, Coronary Artery Aneurysm, Coronary Artery Bypass, Coronary Artery Bypass Graft, Coronary arteriosclerosis, Coronary Artery Atherosclerosis

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PsycInfo:

MeSH: Caregivers

“caregiver”.ti,ab OR “care-giver”.ti,ab OR “carer*.ti,ab” OR “informal car*”.ti,ab

AND

MeSH: Quality of life, Occupations, Well-being, Activities of daily living, Mental Health, Health Behaviour, Emotional Responses, Life satisfaction, Role satisfaction, Resilience, Life Experience, Communication, Strategies, Anxiety, Coping Behaviour, Distress, Recreation, Leisure Time, Participation, Adjustment, Couples

“Quality of life” OR “outcome measures” OR (“caregiver outcomes” OR “care-giver outcomes”) OR (“time-use” OR “time use”) OR “occupations” OR “occupational engagement” OR (“self-efficacy” OR “self efficacy”) OR “experience” OR “emotion*” OR “psychological health impact” OR “physical health impact” OR (“confidence” OR “self-confidence” OR self confidence) OR “satisfaction” OR “dissatisfaction” OR “activities of daily living” OR “resilience” OR “social adj2 (interaction or engagement or support or participation) OR “caregiver OR care-giver adj2 (support or health professional or medical team)” OR “information exchange” OR “coping strategies” OR “leisure activity” OR “conflict” OR “caregiver responsib*” OR care-giver responsib*” OR “caregiver expectation” OR “care-giver expectation” OR “caregiver role” OR “care-giver role” OR “role adjustment” OR “caregiver or care-giver adj2 (adjustment or acceptance or readiness)” OR “caregiver or care-giver adj2 (attitude to health)”

AND

MeSH: Heart Failure, Health Behaviour, Heart Disorders, Cardiovascular Disorders, Self-care skills, Intervention, Treatment Outcomes, Chronic Obstructive Pulmonary Disease, Pulmonary Heart Disease, Stroke, Treatment Outcomes, Intervention, Cerebrovascular Accidents, Coronary Artery Disease, Myocardial Infarctions, Ischemia, Aneurysms

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Web of Science

TI = Title

TS = Topic

TI & TS = “caregiver” OR “care-giver” OR “carer*” OR “informal care*”

AND

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ProQuest: Global Dissertations & Theses/ Applied Social Sciences Index and Abstracts (ASSIA)

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Ethos – British Library

CAREGIVER or CARE-GIVER.ti,ab

Searches initially included Heart Failure, Chronic Obstructive Pulmonary Disease, Stroke and Coronary Artery Disease as “AND” terms, however these yielded no results.

Appendix 2 Narrative Formation

Agren 2010

Profile	Explanation	Study	Emerged from Quant. study	Concept
Modal	This is a narrative description of the group being studied	**Agren, 2010**	Spousal caregiving Female caregivers – older age. Purposive sample of 135 partners of pts hospitalised due to HF. All co-habiting. Pts. HF (NYHA II-IV)	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Mean age – 69, female make up 75% of population in this sample 68% (n = 91) reported low levels of burden, 30% (n = 40) reported medium 2% (n = 3) high levels of burden. (General strain M= 1.88, SD = 0.64, Isolation M = 1.80, SD = 0.77, Disappointment M = 1.72, SD = 0.63, Emotional involvement M = 1.66 SD = 0.63, Environment M = 1.63 , SD =0.56)” “Poorer mental health (p = 0.001) and a lower perceived control (p= 0.001).in the partners and poorer physical health (p= 0.001) of patients predicted higher caregiver burden.”	Mental health - Burden
Comparative	This is a description comparing studies and comparing individuals being studied.		Caregivers reporting more burden when, patient health status is poorer and caregiver mental health poor. Caregivers’ perception of caregiving informs their experience. These were all partners, no adult-child dyad studies. This is consistent with other HF studies identified in this review.	Relationship

			Caregiver mental health and burden is consistently examined but no consistent approach to how it is examined. Patients with NYHA I not included in this study.	
Normative	A comparison of the study individuals with the general population		Burden is higher than general population. Caregivers experiencing poorer mental health than the general population	Impact on caregiver mental health
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Majority low level of burden – indicative of greater perceived level of control. Patient health indicates burden experienced by caregiver. In this study majority reporting low burden 34% of pts diagnosed with NYHA II & 54% NYHA III. This may indicate why 68% of caregivers in this study reported lower burden 14% pts NYHA IV. This indicates that partners subjective experiences play a role in partner experience of burden Cross sectional study	

Al-Rawashdew, 2017

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept**
Modal	This is a narrative description of the group being studied	**Al-Rawashdeh 2017**	Predominantly female, caregivers, mean age 62, Caucasian, patient, HF NYHA I-IV.	
Average	This is a detailed narrative description based on the mean (average) attributes of the		Patients and their spouses had similar levels of sleep disturbance and mental well-being scores were similar between patients and spouses	Spousal sleep Interdependence between caregiver and patient. Greater illness of patient the greater impact on spouse sleep.- Relationship

	individuals/situations being studied		Spouses' sleep disturbance was significantly correlated with their own physical (β = -4.94, p< 0.001) and mental well-being scores (β = -6.62, p< 0.001) patients whose spouse has higher sleep disturbance have poorer mental well-being (β = -2.19, p <0.05)	Spousal subjective well-being impacts sleep Sleep = role in lifestyle change Mental health
Comparative	This is a description comparing studies and comparing individuals being studied.		Spousal caregivers primarily female – consistent with other HF caregiver studies. Patients with NYHA I severity include which provides another insight. Examining sleep disturbance specifically – not specifically studied in other HF caregiver studies. Impact on physical and mental health is examined in caregiver research	
Normative	A comparison of the study individuals with the general population		Interdependence between patient and caregiver. Sleep disturbance more prevalent	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiver and pts impact on each other's lifestyle. Increased patient illness results in caregiver greater sleep disturbance Caregiver wellbeing has an influence on their sleep Cross sectional study	

Badr, 2017

Profile	Explanation	Study	Emerged from Quant. study	Concept
Modal	This is a narrative description of the group being studied	**Badr, 2017**	Sample size of 89 caregivers, mean age 54.8 years of age, predominantly spousal caregivers, caring for COPD pts.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Based on PHQ9 cut-offs, 30% of patients/20% of caregivers had mild depression; 30% of patients/ 8% of caregivers had moderate to severe depression. Depression levels of patients and caregivers were significantly correlated Less frequent patient self-management higher levels of caregiver burden, and being in poorer health were associated with higher levels of depression for both dyad members. Higher levels of depression in a partner were also associated with higher levels of depression for women, regardless of whether women were patients or caregivers	Mental Health Lifestyle Relationship
Comparative	This is a description comparing studies and comparing individuals being studied.		Similar reported in other caregiver literature regarding interdependence between patient and caregivers – in this case depression correlated. Identifying a difference in gender experiences – not commonly reported in other studies.	
Normative	A comparison of the study individuals with the general population		Greater risk of depression for females. Depression correlation between patient and caregiver. Likely greater than in general population	

Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Interdependence between patient and caregiver health. Increased levels of depression amongst caregivers and women at greater risk of depression Burden, physical health and patient self-management influences mental health. Reliance on self-report of caregivers, younger than average age of other COPD caregivers. Strength of this study is that it examines the patient-caregiver dyad. Identifies gender differences in outcomes which is less frequently reported in patient-caregivers COPD studies.	

Bakas, 2006

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept**
Modal	This is a narrative description of the group being studied	**Bakas, 2006**	21 spousal caregivers, primarily white, female. Patients. HF NYHA II-IV, predominantly NYHA III.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Younger caregivers found caregiving tasks more difficult Being an emotional supporter and household tasks were most difficult. Caregiver’s lost out on social roles, financial loss due to caring and deterioration of general health Many caregivers reported that their lives had changed for the worse as a result of providing care (M= 3.7, SD =1.5, 1 worst, 7 best – BCOS scale)) “	Routine disruption Loss of social role - lifestyle Health implications Negative perceptions of caring – caregiver role Mental health

			Future outlook, level of energy, time for social activities, and financial well-being, almost half (47.6%) reported a change for the worse	
Comparative	This is a description comparing studies and comparing individuals being studied.		Smaller sample than other caregiver studies included in review. NYHA II – IV consistent with other studies. Spousal, white caregivers consistent with other caregiver research. Caregivers negative perception of caregiving similar to what has been reported in other studies.	
Normative	A comparison of the study individuals with the general population		Caregivers reporting their lives had changed for the worse. Loss of roles, financial status and socials situation has changed	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		This indicates the negative perceived experiences of caregivers and particularly younger caregivers experiencing greater difficulty. ? Potentially because they have the greater change in their lives & this is an added role to an established lifestyle whereas spousal caregiving potentially an extension of marital role. Pts predominantly NYHA III classification, therefore may require greater support, emotional and practical needs	

Cosette, 1993

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept**
Modal	This is a narrative description of the group being studied	**Cosette, 1993**	Female spousal caregivers	

Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		89 female spouses. Mean age 65. Patient diagnosis COPD COPD Grade III (moderate) – Grade V (severe) on a 5 point scale 40% had used psychotropic drugs more tasks were carried out in the categories of external household management, internal housekeeping, and light emotional support than in the other categories Greater need for emotional support – greater mental health impact on wives	Prevalence of Mental Health needs Caregiving tasks Role
Comparative	This is a description comparing studies and comparing individuals being studied.		Informal social support didn't have any involvement outcome for these spouses	
Normative	A comparison of the study individuals with the general population		Impact on caregiver mental health – specifically focusing on female spouses, most consistent population studied in caregiver research. Focusing specifically on use of psychotropic medication which isn't consistently examined in other studies. Predominantly caregivers report perceived needs/experiences.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Moderate volume of psychotropic drug use primarily associated with depression and the type of caregiving task played a role in mental health impact Female spousal caregivers, it's an extension of the marital role COPD diagnoses were moderate to severe	

Evangelista, 2002

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Evangelista, 2002**	HF patients and their caregivers – living together, relationship to each other not described. Exploring emotional wellbeing of pts and caregivers and whether gender influences this. Sample size 103 dyads	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Caregivers were 70.9% female, predominantly white (80%), mean age 59.4, pts predominantly HF, NYHA III Emotional well-being of caregivers is associated with the emotional well-being of HF patients” Caregivers reported a higher (better) emotional well-being then patients	Mental Health impact of caring. How caregiver and patient impact each other - relationship
Comparative	This is a description comparing studies and comparing individuals being studied.		Caregiver population mean is younger than other studies of HF. Examining well-being of both patients and caregivers which is not consistently examined in caregiver studies – i.e. often patient or caregiver. NYHA III most consistently studied in HF studies.	
Normative	A comparison of the study individuals with the general population		Demonstrates interdependence between caregiver and patient. Greater levels of emotional impact of caring	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiver wellbeing is impact by patient wellbeing. However, caregivers had better overall health than pts. Patients were sicker i.e. predominantly HF NYHA III	

Figuereido, 2013

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Figuereido, 2013**	Family caregivers of pts with COPD – early and advanced. Sample size 158	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Mean age, 58.3, predominantly female. 82.5% in early COPD, 85.7% in advanced COPD Family carers of people with advanced COPD relied significantly more on the three types of coping strategies than those caring for people with early COPD." "Dealing with the consequences of stress was the least used coping method in both groups." Significant correlations were found between self-rated health and problem-solving coping in carers of people with advanced COPD, that is, better physical health perception was associated with an increasing use of problem-solving strategies	Lifestyle Mental health Relationships
Comparative	This is a description comparing studies and comparing individuals being studied.		Correlates with HF and COPD studies where caregivers are predominantly female, slightly younger mean in this group. This is the only study which broke down experience between stage of diagnosis	
Normative	A comparison of the study individuals with the general population		Greater stress levels, influenced by level of tasks engaging with	
Holistic (also called	A description of the overall perception of the investigator		Require greater engagement with coping strategies, increase input from health care teams, support required to	

inferential or summative)			facilitate caregivers to engage in their role	

Figuereido, 2014

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Figuereido, 2014**	Caregivers of pts with early and advanced COPD. Primarily female and spousal 113 caring for relatives with early COPD (mean age 58.3years) and 54 caring for relatives with advanced COPD (mean age 60.5years) Sample size 167	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/situations being studied		Anxiety symptoms were observed in 61.9% of family carers of people with early COPD and in 70.4% of those caring at advanced COPD (p = 0.290) Depression symptoms were significantly more frequent in family carers of people with advanced COPD (p = 0.030) Self-rated physical and mental health were significantly worse in carers of people with advanced COPD when compared to those caring for people with early COPD The overall CADI score was significantly higher in family carers of people with advanced COPD than in carers of people with early COPD	Higher mental health impact on caregivers caring for advanced COPD pts Relationship between patient and caregiver
Comparative	This is a description comparing studies and comparing		Severity of illness influences caregivers coping, wellbeing and volume of task engagement, this has been seen in other studies.	

	individuals being studied.			
Normative	A comparison of the study individuals with the general population		Greater distress, stress, greater engagement with caregiving tasks less social time/leisure time to engage in other self-care tasks	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Worse caregiver health – potentially neglecting own healthcare needs Less time to engage in their own self-care tasks Illness severity had greater negative impact on caregiver.	

Grigorovich, 2017

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Grigorovich, 2017**	Longitudinal study of family caregivers in HF, examining their emotional wellbeing. Utilised an individual growth curve model to track changes and adjust for variables	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Sample size 50, mean age 58, predominantly female and spousal. Caregivers' level of depression symptoms (mean -0.17 ± SE 0.11, p > 0.1) remained stable over the year of follow-up. Caregivers' depression symptoms were significantly associated with more caregiver participation restriction. Positive affect was significantly associated with caregivers' experiencing greater feelings of personal gain and having more social support available.	Loss of social role/routine restriction/disruption – lifestyle change Mental Health impact

Comparative	This is a description comparing studies and comparing individuals being studied.		Mean age is younger sample is smaller, however study is longitudinal. Correlates with other findings re: mental health impacted by lack of support, loss of roles and Pressler's study finding depression maintained over 8 months	
Normative	A comparison of the study individuals with the general population		Greater anxiety and depressive symptoms. Loss of routine, greater role restriction	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		A sense of mastery and support appears to have a greater positive impact on caregivers in their role. Loss of control over routine and lack of self-efficacy are negative impacting caregivers mental health	

Halm, 2006/2007

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Halm, 2006/2007**	American study of spousal caregivers of CABG patients, Multi-centre study. Up to 12 months post CABG. Examining the correlates of caregiver burden Higher burden scores were associated with patient's gender (female) increased personal gain, increased caregiver competence. Lower burden was associated with better health status of the patient (b and higher caregiver mental HRQL Caregivers with higher self-efficacy experienced less depressive symptoms	Relationship Mental Health – burden
Average	This is a detailed narrative description		This sample was 100% spousal, predominantly female, average age	

	based on the mean (average) attributes of the individuals/situations being studied		64.7, primarily Caucasian with a college education. Sample size of 166 caregivers.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Cross sectional sample and reliant on caregiver self-report similar to other caregiver research. Unique as it is examining caregiver experience of CABG and burden. Caregiver burden did not change over time.	
Normative	A comparison of the study individuals with the general population		The impact of spousal relationships and how they inform/influence each other in particular reciprocity of spousal relationships is in line with what is reported here. However influence of patient ill health and caregiver self-efficacy is an overlay not existing in "well population"	Caregiver support
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregivers who identified caregiving as positive and identified benefits and who were more competent may have stretched themselves more in their role, increasing caregiver burden. Caregiver screening is essential to identify spouses at high risk for negative outcomes. Enhancing caregiver mastery can improve their relationship with the patient, minimise depressive symptoms and improve caregiver outcomes - areas for possible intervention	

Hess, 2009

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Hess, 2009**	A convenience sample of family or friend caregivers (18+) who are involved with medication management for adults with HF. The aim was to examine the association between health literacy and self-care in patients, and the association between health literacy and medication administration difficulties in caregivers and to explore whether there are associations between demographic variables and health literacy. Cross sectional study	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Sample size 5, mean age 65, female Caucasian caregivers, 80% high school education. Inclusion criteria were eligibility to read and write English. The study was not powered for the caregiver specific aim, therefore results were individual results for caregiver health literacy and medication administration hassles. 80% adequate health literacy as per S-TOFHLA 20% marginal health literacy as per S-TOFHLA The average FCMAHS score was 27.80 (S.D. = 14.74), with a range of 10-44. The range of possible values for the FCMAHS is 0-100. Higher scores indicate greater medication administration hassles.	Caregiver role (in medication administration)

			*FCMAHS – Family caregiver medication administration hassles scale	
Comparative	This is a description comparing studies and comparing individuals being studied.		Sample is small, no male caregivers included – predominantly female caregivers research in the literature Insufficient evidence in the literature to determine if health literacy and medication administration hassles are associated	
Normative	A comparison of the study individuals with the general population		Study not powered for caregivers, difficult to make comparison to population norms	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregivers with low health literacy may have increased medication administration hassles. However, there was insufficient evidence in the literature to determine if health literacy and medication administration hassles are associated	Caregiver Role

Hooley, 2005

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Hooley, 2005**	Patient and caregiver dyads. Patients with NYHA III OR IV. Convenience sample, six month follow up study. Caregivers primarily female, and, 66% spousal, caregiver ethnicity and education not reported. Examining the relationship between caregiver burden, patient disease severity and depressive symptoms	
Average	This is a detailed narrative description		Average age of caregivers – 61. Primarily female and spousal.	

	based on the mean (average) attributes of the individuals/ situations being studied		Duration/timeframe of caregiving not reported Baseline and follow up outcome measures examining burden, depression and health related quality of life of patients using validated outcome measures. 9/50 (18%) caregivers –High likelihood of clinical depression (BDI-II) Gender was not predictive, male caregivers of female patients had much lower BDI-II scores than female caregivers of male patients (6.8 vs. 23.5; $p<0.05$).” 14/50 - high burden. Relationship between caregiver burden and caregiver depression scores ($r=0.61$; $p<0.0001$), and caregiver burden and patient depression scores ($r=0.28$; $p<0.05$).” Caregivers with higher caregiver burden ($p = 0.002$) and depressive symptomatology ($p=0.002$) were caring for patients likely to suffer death or hospitalization over the following 6 months	Mental health – incl. Burden Relationship between patient and caregiver Caregiver Mental health Relationship
Comparative	This is a description comparing studies and comparing individuals being studied.		Caregivers in this trial consistent with HF literature of studied caregivers. Predominantly caregiver literature examined is cross sectional, this has data collected at baseline and follow up at 6 months- to provide a comparator of progress – this was to examine a change in burden, depression and illness severity over time.	

Normative	A comparison of the study individuals with the general population		Caregiver literature mixed with regard to caregivers experience of burden, correlates include caregiver age (not identified in this study), gender, relationship to patient (not studied here) and patient characteristics including illness severity –indicative in this study of Predominantly caregiver health identified as poorer compared to general population Caregivers starting point for burden not addressed in this study	Relationship
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregivers experience high caregiver burden and depressive symptoms, which are related to patients' QOL, disease burden, and their own caregiver burden. The number of prescribed medications and subsequent 6-month outcomes are associated with these factors	

Hwang, 2011

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Hwang, 2011**	Convenience sample of patient and caregiver dyads, n = 76, predominantly female with a mean age of 53.4. Predominantly spousal, Caucasian, with a high school education. This study is examining the perceived health status of caregivers and identifying factors associated with caregiving. This study is also examining the impact of social support on caregivers. Cross sectional study	

Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Predominantly female caregivers, patients predominantly NYHA II or NYHA III. Majority participating were spousal patients and caregivers, Caucasian and had attended high school. Caregivers relationship to patient, patient NYHA severity, perceived control and social support were associated with lack of family support for caregiver Time since discharge was associated with impact on caregiver health, perceived control and caregiver support.	Relationship Support
Comparative	This is a description comparing studies and comparing individuals being studied.		Non-white caregivers were more positive about their role than white caregivers	
Normative	A comparison of the study individuals with the general population		Caregivers report more social isolation compared to non-caregivers. Constancy of caregiving and vigilance identified in the literature Compared with other caregivers, caregivers of patients with severe heart failure, non-spousal caregivers, and caregivers with low socioeconomic status and no assistance from others in caregiving are more likely to feel burdened in the caregiving role"	Support Role Mental Health Role Relationship Support
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregivers reported that caregiving adversely affected their health. Lower perceived control associated with negative impact of caregiving - Loss of control emerging as a theme in Qual. papers	Role Mental health impact

			Findings suggest the need for interventions to increase caregivers' sense of control and social support.	

Karmilovich, 1994

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Karmilovich, 1994**	Purposive sample of spousal caregivers. N = 41. Patients identified caregivers for participation. Patients with NYHA III or NYHA IV. Cross sectional descriptive survey	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Primarily female caregivers, mean age 56.7. 60% full time employed and 62% 12 years plus education. 73% of patients with NYHA III.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Aims to examine the demands of caregiving and determine caregiver level of stress and the whether there is an association between stress and burden. Determine if there is a relationship between caregiver burden and stress. Assessed physical caregiving demands and role alterations Role Alteration Scale scores higher than physical caregiving scale, indicating greater burden – Burden score Mean – 15.27 (SD 11.3) Positive correlation between the number of helping behaviours and the level of stress	Role / Mental Health impact

			Positive correlation between perceived difficulty performing cg activity and level of stress Females reported more burden than males Burden and stress were not significantly related to level of heart function or ejection fraction	Relationship and role of caregiving Relationship – gender
Normative	A comparison of the study individuals with the general population		Caregiver experiencing higher burden than non-caregivers Caregivers perceiving higher stress particularly when participating in more caregiving duties Illness severity not related to burden – different to other caregiver studies. Gender implication of burden	Knowledge of HF
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiver demands scale tool did not have open ended questions Caregiving seems to be a different experience by gender Demands identified spouse caregivers indicate that burden experienced may relate to emotional burden Perception of illness more important than ejection fraction for this group Caregivers need education about the disease process, daily regimen, expectations for the future, and responsibilities	Role/ Relationship Mental Health

Kneewshaw, 1999

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Kneeshaw, 1999**	Patients post Coronary Artery Bypass Graft. Caregivers of these patients, predominantly NOT spousal. 49	

			caregivers, primarily female. Duration of caregiving not reported. Education/ethnicity not reported. Assessing relationship mutuality and preparedness for caregiving as hospital discharge	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Assessment occurred at three time points – 6 weeks, 3 months, 6 months post discharge Mean age of caregivers – 50.1 Mutuality scale scores indicated that caregivers reported a positive feeling toward whom they would be providing care at the time of hospital discharge There was a significant decrease in the mutuality scale mean scores and at three months Twenty-four caregivers listed at least one area they felt unprepared for with caregiving. The most common concern was fear of the unknown, especially an emergency.	Role Relationship Lifestyle change Support Knowledge
Comparative	This is a description comparing studies and comparing individuals being studied.		Cohort studied similar to other caregivers regarding gender, however primarily not spousal. Generic caregiver literature has examined caregiver preparedness/experience post discharge – primarily report this as overwhelming time, whereas caregivers in this study were positive on discharge and found decrease in this mutuality at 3 months	
Normative	A comparison of the study individuals with the general population		n/a	

Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiving during recovery from surgery more challenging than family members anticipated. Caregivers had concerns about fulfilling the role Caregiving mutuality and preparedness may have been masked in the early weeks post discharge due to community support from visiting nurses, thus caregiving responsibility increased at 3 months.	Knowledge Relationship Support Lifestyle Change Caregiving Role

Loftus, 2004

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Loftus, 2004**	Longitudinal study of caregivers, primarily spousal of HF patients examining the psychological impacts of HF on the patient and caregiver. Convenience sample of 53 caregivers.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Mean age 66.7, 41 female caregivers, ethnicity and education not reported, 42 spousal caregivers. The severity of heart failure and level of patient disability was predictive of caregiver distress Social support was predictor of distress Caregiver mental health was impacted by patient mental health. Relationship quality , duration of caregiving, tasks all contributed to distress – as has been observed in other studies	Relationship Mental Health Mental Health/ Support Relationship Role

Comparative	This is a description comparing studies and comparing individuals being studied.		Relationship quality , duration of caregiving, tasks all contributed to distress – as has been observed in other studies Caregiver mastery and self-esteem positively impacted caregivers – not assessed in other studies in this synthesis.	Role
Normative	A comparison of the study individuals with the general population		Caregivers experiencing higher levels of distress, stress, isolation, lack of support and demands on their time compared with non-caregiving population	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiving is an interpersonal dynamic process. Caregiving depends on the interpersonal relationships and beliefs of patient and caregiver.	Relationship

Lum, 2014

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Lum, 2014**	Caregivers of patients with HF to examine if relationship quality is associated with caregiver benefit or caregiver burden and whether depressive symptoms influence these associations. 19 caregivers, purposively sampled – evenly split between spousal and non-spousal caregivers. Predominantly male caregivers.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/		Cross-sectional study. Average age, 59 years. Male caregivers made up 63% of the study sample. Primarily white caregivers. Patients on average experiencing NYHA II. Caregivers identified by the patient.	Relationship

	situations being studied			
Comparative	This is a description comparing studies and comparing individuals being studied.		Higher relationship quality was associated with less caregiver burden and more caregiver benefit. This is consistent with what has been reported by other caregiver studies. However, context of this not examined. Caregiver characteristics not examined i.e. caregiver mastery which has been identified as having an important role in other studies.	
Normative	A comparison of the study individuals with the general population		Reciprocity in interpersonal relationships is an important factor for influencing and informing individuals lived experience. Caregiver experience of the role are informed by patient-caregiver relationship	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Positive or negative relationship quality can be meaningful for patient-caregiver dyads. Limitations of this study include small sample and cross-sectional study	

Luttik, 2009

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Luttik, 2009**	Multi-centre study. Cross sectional study. QOL in caregiver of people with HF, compared with individuals living with a healthy partner.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/		303 caregivers and 304 individuals of healthy partners/ Average age - 67 (caregiver), 66 (Healthy partner) Primarily Female, Patients - HF – NYHA II - IV	

	situations being studied			
Comparative	This is a description comparing studies and comparing individuals being studied.		Ethnicity and education not reported, more consistently reported in other caregiver studies. Unique study as it is comparing with healthy population.	
Normative	A comparison of the study individuals with the general population		This was a comparator study between caregivers and the general population. An interaction effect was observed between group and gender for general well-being, and for perceived health change A main effect of group was found for the domain of general health perception for caregivers reporting lower general health than partners of healthy persons, regardless of their gender. For general well-being a main effect of gender with female caregivers reporting lower scores compared to males caregivers. Simple effects analyses for the domains of mental health, role limitations because of emotional problems, bodily pain, vitality and social functioning revealed that actual involvement in care was associated with QOL in female partners but not with QOL in males	Relationship
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Limitation: Cross-sectional design, small representation of male partners of people with HF. Further research at different stages of the disease is necessary. Small differences in quality between the two groups.	

			The psychological well-being, of female partners of people with HF, should be assessed carefully Nurses should not be reluctant to involve male partners in the care of women with heart failure.	

Miravittles, 2015

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Miravittles, 2015**	Cross Sectional study of COPD caregivers' burden experienced from the role. Aim to analyse the burden borne by informal caregivers of patients with COPD. Research completed in Spain.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Representative sample extracted from a national survey of 22,795. Average age 56.5, primarily female caregivers. 35% of informal caregivers had health-related problems due to the caregiving provided; 83% had leisure/social-related problems; and among caregivers of working age, 38% recognized having profession-related problems.	Lifestyle change
Comparative	This is a description comparing studies and comparing individuals being studied.		Ethnicity, education and spousal status not reported. Only study which has examined COPD caregivers across a national sample. No information on lung function.	
Normative	A comparison of the study individuals with		Representative sample of the population with caregiver COPD data extracted. The percentage of caregivers	Relationships

	the general population		of COPD patients presenting deterioration in health was quite similar to caregivers of patients with myocardial infarction, mental illness, or cancer.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		The results of this study stress the importance of efforts to improve support for caregivers of patients with COPD. Limitation: Cross-sectional study design.	

Nakken, 2017

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Nakken, 2017**	Spousal caregivers of COPD patients. Investigating the differences between male and female caregivers of patients with COPD.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		188 Dyads, cross-sectional study. Average age - 65.4 female, 65.1 male, Participant gender – 103 female, 85 male Patients: COPD Moderate to Very Severe as per GOLD classification system – Grade II, III, IV	
Comparative	This is a description comparing studies and comparing individuals being studied.		Ethnicity and education not stated. Female caregivers had more symptoms of anxiety and a worse health status than male caregivers, depression, social support and caregiver burden were comparable for male and female partners of patients with COPD Female caregivers perceived male patients to be less care dependent and had more symptoms of depression	Caregiver support Relationships Mental Health Lifestyle

			No differences in caregiver burden between male and female caregivers. Lower levels of social support were associated with higher levels of caregiver strain.	
Normative	A comparison of the study individuals with the general population		Burden higher than general population Caregiver gender differences observed in other studies, significant in this study is the identification of no differences in caregiver burden between male and female caregivers	Mental Health
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Female partners have more symptoms of anxiety, used different coping styles, and have a worse health status. Results need to be interpreted with caution – this study did not use an instrument to diagnose an anxiety or depressive disorder according to DSM V. Excluded non-partner relationships	

Nasström, 2017

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Nasström, 2017**	Purposeful sample of caregivers, aim is to describe the caregivers' perspectives of participating in the care for patients with HF receiving home care	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Sample size – 15. Average age - 77 Primarily female caregivers. Obtained on middle school education. All spousal caregivers.	
Comparative	This is a description comparing studies		Caregivers scored 94% of the max score for received information, 92% of	Relationships Caregiver support

	and comparing individuals being studied.		the max score for participation in care, 83% of the max score for contact and 80% of the max score for overall satisfaction with participation in care Higher degree of overall satisfaction with participation in care was associated with better perceived health measured by the EQ-VAS Receiving more information was associated with better perceived health Caregivers in this sample were participating in the intervention and positive about support received from Healthcare professionals – Less commonly identified in caregiver literature.	Knowledge Mental Health
Normative	A comparison of the study individuals with the general population		Study not comparable with general population.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Key point - receiving sufficient information to be able to manage the HF condition 7% attrition rate.	Knowledge Caregiver support

Park, 2013

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Park, 2013**	Multi-centre, American trial examining spousal caregivers. The purpose of this study was to describe which caregiving tasks are perceived as the most and least demanding and difficult for older adult spousal caregivers of CAB surgery patients	

Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		35 spousal caregivers, average age 60, female 83% and 94% Caucasian. CAB surgery patients who were, on average, 60 years old and 19 days since hospital discharge. Caregivers were not randomised for this trial. Top four demanding and difficult caregiving activities perceived by spousal caregivers of CAB surgery patients were providing transportation, additional household tasks, providing emotional support, and two tied for fourth: monitoring symptoms and additional tasks outside the home.	Caregiver role
Comparative	This is a description comparing studies and comparing individuals being studied.		Caregivers do report not feeling prepared for the role of caregiving. This study looks at work role and how additional responsibilities impact on caregiving role which has been seen in other caregiver studies. This study looks at caregiver perceptions of their tasks engagement. Unique about this study is identification of the different needs of younger v older spousal caregivers, however sample is small, difficult to infer meaning.	Lifestyle change Relationships
Normative	A comparison of the study individuals with the general population		Unable to compare with general population. Comparable with other caregivers' post-surgery experience.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Over 50% of spousal caregivers in this study were employed. The addition of caregiving tasks combined with their usual working roles, adds to the caregivers demands. Intense caregiving demands for the first month after surgery	Caregiver Role

			Uncertainty from this study why younger spouses report more caregiving difficulties than their counterparts	

Yeh, 2012

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Pi-Ming Yeh, 2012**	Multi-centre trial, examining family caregivers. American study. Purposive sample of caregivers examining the influences of older people's ADL dependency, family caregivers' spiritual well-being, quality of relationship, family support, coping and care continuity on the burden of family caregivers of hospitalized older people with HF.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		50 family caregivers, average age 60.33. Primarily female caregivers, and predominantly non-spousal. Primarily high school education. Patients: 50 HF patients.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Most studies in this review have examined spousal caregiving. Total scores of family caregiver burden were not significantly associated with total scores of coping strategies but were significantly associated with the scores of Problem Solving and Coping subscale Higher scores of the older people's ADL dependence, lower scores of quality of relationship and higher scores of lack of family support were found to predict	Caregiver support Mental Health

			significantly greater family caregiver burden	
Normative	A comparison of the study individuals with the general population		Similar across caregiver study regarding the impact of patient-caregiver relationship on perceived caregiver experience of the role. Patient illness severity has been identified across studies as influencing caregivers' perception of the role and the strain/burden experienced. Purposive sample of caregivers – cross sectional; most common in caregiver studies in HF.	Mental health
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		ADL dependence was significantly related to only, lack of family support Important areas of clinical input - availability of family members other than the primary caregiver and the nature of the relationship between the caregiver and the care recipient.	

Pressler, 2013

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Pressler, 2013**	Convenience sample of caregivers. Single centre trial. Aim of study to evaluate changes in caregiver burden, control, depressive symptoms, anxiety, life changes and physical and emotional HRQOL	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/		63 caregivers, average age 59.7, primarily female 76%, 84% Caucasian. Primarily spousal caregivers. Patients: n= 63, HF. Mean age = 69 NYHA I (6%) OR II (24%) = Low NYHA III (52%) OR IV (16%) = High	

	situations being studied		(2% missing data re: NYHA class)	
Comparative	This is a description comparing studies and comparing individuals being studied.		Impact of burden and patient illness severity is seen repeatedly across studies in this review. Strength of this trial is that it is longitudinal. Uniquely observed in this study is that caregiver perception of the role and time spent on tasks improve over time, additionally, depressive symptoms decreased over time. Contradictory to what was identified in other caregiver studies which report long term caregiving increasingly negatively impacts caregivers' physical and mental health – of note these caregivers had poor baseline levels for physical and emotional HRQoL. Caregivers of patients with high HF symptoms spent more time on caregiving tasks at 4month follow up, perceived greater difficulty with caregiving tasks and reported higher bassline anxiety and poorer physical HRQOL at baseline and 4 month follow up Primary time use of caregivers per week – household tasks, providing emotional support, ,managing dietary needs and transportation	Mental health Lifestyle change Caregiver role Relationships
Normative	A comparison of the study individuals with the general population		Comparable to other caregiver studies as opposed to general population.	
Holistic (also called	A description of the overall perception of the investigator		Family caregivers improved perceptions of the time and difficulty of caregiving	

inferential or summative)			over 8 months. Caregivers had fewer depressive symptoms over time. Caregivers of patients with more HF-related symptoms had poorer perceptions of the caregiving experience. Caregivers need to be routinely assessed for burden and depressive symptoms	

Riegner, 1996

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Riegner, 1996**	Patients and caregivers living with COPD. Aim to understand quality of life associated with role strain, perceived social support and humour in the life experience of patients and caregivers. Multi-centre research from an unpublished thesis.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		83 Dyads, all co-habiting, with predominantly high school education. Average age 63.2. Gender, female (60.2%). Predominately Caucasian. Patients - COPD (not specified). Convenience sample, cross-sectional study.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Low Caregiver/ Spouse role strain for the couple was significantly associated. Younger age of the patient was related to making a contribution for quality of life. The social support satisfaction for the couple made a significant contribution to their quality of life	Relationships Caregiver support

			Role Strain was significantly associated with quality of life For caregivers; the social support satisfaction made a significant contribution to quality of life. Patient – caregiver relationship quality is repeatedly identified across HF and COPD caregiver literature as influencing perceived experience of caregiving role.	
Normative	A comparison of the study individuals with the general population		Interpersonal relationships – informing functioning within the dyad.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Low role strain and high social support satisfaction were significantly related to greater quality of life for all. Older caregivers with a large social support network and high satisfaction also enjoyed better quality of life.	Caregiver support Caregiver role Relationships

Saunders, 2008/2009

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Saunders, 2008/2009/2010**	Caregivers of HF patients aim is to examine the: interrelationships of the domains of caregiver burden, caregiver depression, levels of caregiver-perceived patient disease severity, and caregiver HRQOL and identify elements within the caregiving environment that are associated with caregiver burden. Cross-sectional multi-centre study.	
Average	This is a detailed narrative description based on the mean		50 caregivers, average age - 58.1, 84% female. Primarily non-spousal caregivers.	

	(average) attributes of the individuals/ situations being studied		Patients: 79 HF pts. Ejection fraction- 20%-64% range, average HYHA II – III.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Average age, younger than other caregiver populations in this review. Consistent regarding female caregivers, and different regarding non-spousal caregivers being predominant caregivers. Reported ejection fraction, not frequently reported in other studies. Purposive sample. CG burden is associated with lower CG HRQOL Lower caregiver HRQL was associated with increased levels of caregiver perceived patient disease severity – Similar to what has been identified in other studies in this review 76%) reported having health problems in the previous 12 months" Overall, scores for the burden domains ranked from highest to lowest: schedule, finances, family, and health. Caregiver age and caregiver depressive symptoms explained variance in perceived caregiver health burden Increasing caregiver depressive symptoms, higher caregiver hours and more patient comorbidities explained significant variations in perceived lack of family support in caregiving.	Mental Health Support Relationships
Normative	A comparison of the study individuals with		Similar to what has been identified in other caregiver literature – caregiving burden and patient disease severity	

	the general population		were associated, the more perceived caregiving tasks and increased burden impact on caregiver HRQoL	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		higher caregiver burden is significantly associated with caregiver older age, being Caucasian, caring for additional person(s), having multiple health problems, and/or feeling depressed, more patient comorbidities and lack of a respite caregiver Caregiver health needs to assessed in order to provide nurse-focused care for the caregiver, separately from the patient	

Saunders 2010

Profile	Explanation	Study	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Saunders, 2010**	Secondary analysis. Multi-centre study of HF caregivers to compare employed and unemployed caregivers on important caregiver outcomes, depression, and well-being, while assessing for relevant caregiver and patient characteristics in the process.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		41 caregivers - 22 unemployed,19employed Average age59(UNEMP), 52(EMP) Primarily female and spousal caregivers. Patients: Primary diagnosis of HF, a minimum age of 40. This study was not powered for caregiver inclusion, small sample and reliant on self-report data of caregivers.	

Comparative	This is a description comparing studies and comparing individuals being studied.		Caregiver depression was not significantly different between the employed and unemployed caregiver groups Employed caregivers perceived higher well-being in all domains except for the psychological/spiritual domain well-being and family 95% of those employed were satisfied with having a job. This has not been examined in the other caregiver studies in this review.	Mental Health
Normative	A comparison of the study individuals with the general population		Unique studying examining specifically employed caregivers, correlates with wider vocational rehabilitation literature whereby engaging in a worker role increases self-esteem, and has positive impacts on physical and mental health	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Employed caregivers were younger and more often older children of patients and more likely to be sharing the HF caregiver role with another family member Implications for nurses to assist unemployed caregivers in vocational rehabilitation	Caregiver Role Relationships

Schwarz, 2003

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Schwarz, 2003**	Examining perceived stress of caregiving in HF caregivers. Single centre, American trial.	
Average	This is a detailed narrative description		Cross sectional, convenience sample of 75 caregivers. Average age 63.	

	based on the mean (average) attributes of the individuals/ situations being studied		Primarily female caregivers, 88% White, obtained at least a high school education (79%). Primarily spousal caregivers. Patients: HF patients over 65 (HF type not specified)	
Comparative	This is a description comparing studies and comparing individuals being studied.		The effects model with salivary cortisol was not significant. Baseline depressive symptoms were low, unlike Presslers study where baseline emotional and physical HRQoL were moderately poor. Stress was the only significant variable Informal social support did not moderate the negative effects of stress on depressive symptoms. Unique finding – identifying that social support did not moderate depressive symptoms – this association has not been made in other studies	Mental Health Lifestyle Caregiver Role
Normative	A comparison of the study individuals with the general population		Caregivers experiencing persistent levels of stress did not have higher cortisol levels than persons who perceived less stress. Salivary cortisol levels were not elevated in persons with perceived stress.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Variables that may have affected stress and depressive symptoms: age of caregivers, length of time in caregiving, and the patients' cognitive and functional abilities. The majority of patients needed minimal assistance with activities of daily living	

Scott, 2000

Profile	**Explanation**	**Study**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Scott, 2000**	Purposive sample of family caregivers of an American multi-centre trial. Cross sectional study. Aim of the study to examine the perceived HRQOL of caregivers for individuals with end-stage HF.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		18 family carers – primarily spousal , two non-spousal Average age 63 Gender - 89%F, 11%M Patients: 20 end stage HF patients, 47-82 years. All in receipt of inotropic infusions	
Comparative	This is a description comparing studies and comparing individuals being studied.		Caregiver mastery and self-esteem were examined by Vellone et al. Similar to this they identified that caregiver self-esteem/mastery enhanced their contributions to patient care. However this study is unique as it has identified that as caregiver esteem increased, patient HRQoL decreased. The participants reported being the least prepared for the stress associated with caregiving Majority of caregivers felt positive about their role. 56% of caregivers reported a strong desire to perform the role Caregivers had to eliminate things from their schedule or interrupt their current activities to provide car. 39% of the caregivers reported constant fatigue.	Lifestyle change Caregiver role Caregiver support

			Caregivers were dissatisfied with lifestyle changes and the stress associated with caregiving Statistically significant effect was noted when HRQOL was regressed on caregiver mental health and caregiver esteem	
Normative	A comparison of the study individuals with the general population		Bandura describes self-efficacy and mastery as having positive impact on how people perceive and complete tasks. Caregivers in this study align with the beliefs of Banduras theory of self-efficacy. Mental well-being scores of 72% of the caregivers in this study were below the normative values established for the general population. 89% of caregivers had mental health scores less than the established age norm	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Caregiver esteem was identified as a significant predictor of the recipients' HRQOL. As caregiver esteem increased, the care recipients' HRQOL decreased When caregivers perceived that they were unprepared for the role, they experienced more adverse effects Caregiver undertook the role for family obligation but derived satisfaction and fulfilment from helping others. This can mediate the negative impact of caregiving on caregiver mental health The caregiving role can have positive impact on caregiver lifestyle. Caregiver perceptions of HRQOL are enhanced when viewing and experiencing positive elements of caregiving. Caregiving	Caregiver Role Lifestyle change Mental Health

			experience is more meaningful than burdensome Caregivers must be prepared for the psychological implications of end of life care	

Takata, 2008

Profile	Explanation	Study examples	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Takata, 2008**	Convenience sample of 45 family caregivers	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Average age 68 **,** 82.2% F, 7.8% M Primarily spousal caregivers COPD patients on long term oxygen therapy. Caregivers' ethnicity and education not reported. This is a cross sectional study of a small, convenience sample of caregivers. Zarit burden scale was used to determine caregiver burden.	
Comparative	This is a description comparing studies and comparing individuals being studied.		Heavily burdened caregivers were providing care for a longer period of time). They more likely to attend training class for caregivers. Caregivers experiencing less burden wanted access to training classes Heavily burdened caregivers want to use social services such as 53.3% or caregivers were depressed. Examination of burden is common in this caregiver literature, this study is unique as it examines the differences between heavier and lower burden and whether there are differing needs according to this. The impact of time on	Caregiver role Caregiver lifestyle Knowledge

			caregiving in this study increased caregiving burden- due to the trajectory of COPD. Presslers study identified the impact of caregiving on emotional health plateaued over time. The patient population in this study were very unwell.	
Normative	A comparison of the study individuals with the general population		Greater burden amongst caregivers than the general population. This study also differentiates between caregivers who perceived heavy and low burden	Mental Health - Burden
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Heavily burdened caregivers spend more time on physical care and they are less likely to be able to go out 8 hours or more a day… Heavily burdened caregivers of COPD patients have greater difficulty accessing social services Supports for the caregivers of COPD patients should be provided	

Vellone, 2015

Profile	**Explanation**	**Study examples**	**Emerged from Quant. study**	**Concept identified**
Modal	This is a narrative description of the group being studied	**Vellone, 2015**	Convenience sample of 515 patient-caregiver dyads. Examining caregiver contributions to HF self-care. Primarily non-spousal and middle school education	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		Non-spousal caregivers, Italian, convenience sample. Cross sectional study. Multi-centre design. Caregiver primarily had middle school education. Average age 56.6 years of age. Patients primarily NYHA II & III	

Comparative	This is a description comparing studies and comparing individuals being studied.		Primarily non-spousal sample is unique and lower education obtained on average than in other studies. Caregivers confident to follow advice but lack of understanding of what they were doing and why – this is reported by other caregivers. This is an Italian based study. Unique as it examined both patient and caregiver. It is a cross sectional which is similar to other studies, large sample of 515 caregivers. Important as it examined the self-efficacy of caregivers and caregiver confidence – explicit links with theoretical underpinnings in caregiving and HF literature. Not as explicit in other caregiving studies	Knowledge Mental health Relationship between patient and caregiver
Normative	A comparison of the study individuals with the general population		Comparison with general caregiving population – caregiver self-efficacy has been examined but not in HF or COPD caregiving.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		Large sample size examining patient and caregiver dyads. Examining caregiver perceived tasks. Unique study as it identified caregiver self-efficacy has a significant part in self-care maintenance and management and it is not just dependent on socio-demographic and clinical characteristics. This has not been explored in other studies.	

Woolfe, 2007

Profile	Explanation	Study examples	Emerged from Quant. study	Concept identified
Modal	This is a narrative description of the group being studied	**Woolfe, 2007**	This is a group of adult caregivers providing care for people with COPD. No patient details are reported. It is a convenience sample of caregivers from a single health centre in Australia.	
Average	This is a detailed narrative description based on the mean (average) attributes of the individuals/ situations being studied		This is examining the needs of caregivers for adults with COPD. The sample size is 63, average age, ethnicity, education are all not reported. Spouses make up 80.6% of the caregivers in this sample. There are no details reported about the patients' type of COPD.	
Comparative	This is a description comparing studies and comparing individuals being studied.		This study does not report a lot of information that is reported in other caregiver studies e.g. age, ethnicity, and education of caregivers and severity of COPD. It is similar to many other caregiver studies as it is primarily spousal caregivers it is examining. This was a survey, caregiver experiences were examined from a snapshot in time which is similar to caregiver research in COPD.	
Normative	A comparison of the study individuals with the general population		Needs identified by caregivers include information, psychological support and personal support – however these needs were not being met by other persons in the caregivers life - these needs are similar to other caregiver research. With regard to the well adult population - these needs are similar but not as exacerbated as they are for caregivers.	Need for information - knowledge Impact on mental health Caregiver lifestyle Caregiver support

			Caregivers felt trapped, stressed, and fearful and needed time to sleep and time away from home. Caregiver’s identified their role as stressful and this being acknowledged by family and the patient would have been helpful. This is similar with general population – support from family and friends enhance resilience. Healthcare support was identified as being highly important and was being met – caregiver studies are mixed with regard to the support caregivers perceive they receive.	
Holistic (also called inferential or summative)	A description of the overall perception of the investigator		This study is poor in methodological rigour – convenience sample, poor reporting of caregiver and patient details, 63% response rate for survey. It does provide an overview of caregiver needs which are in line with other caregiver studies. Caregiving role has an impact on caregiver mental health, they require support both formal and informal in their role. There are mixed experiences with how supported caregivers feel.	

Appendix 3 Concept mapping across all papers

Caregiver experience - Concepts/Mapping Table – Qualitative Papers

MENTAL HEALTH = 1 **ROLE = 2** **LIFESTYLE CHANGE = 3**
SUPPORT = 4 **KNOWLEDGE/INFORMATION = 5**
RELATIONSHIPS = 6
Concepts only in Qualitative Papers: **EXPERT BY EXPERIENCE = 7** **VIGILANCE = 8**
TIME = 9 **SHARED CARE = 10**

	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Andersen (2015) (**HF**)	✓		✓	✓	✓					✓
Baker (2010) **(HF)**	✓	✓	✓	✓		✓		✓		✓
Bove (2016) **(COPD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Burke (2014) **(HF)**	✓	✓	✓	✓	✓	✓	✓	✓		✓
Clark (2008) **(HF)**		✓	✓	✓	✓	✓	✓	✓	✓	✓
Figueiredo (2015) (**COPD**)	✓	✓	✓	✓	✓	✓	✓	✓	✓	
• Halm (2016) **(CAD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
• Halm (2017) **(CAD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Hynes (2012) **(COPD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Imes (2011) **(HF)**	✓	✓	✓	✓	✓	✓		✓	✓	✓
Kitko (2010) **(HF)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Liljeroos (2014) **(HF)**	✓		✓	✓	✓	✓		✓	✓	✓
Lindqvist (2013) **(COPD)**	✓	✓	✓	✓	✓	✓		✓	✓	✓
Luttik (2007) **(HF)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Marcuccilli (2011) **(HF)**	✓		✓	✓		✓	✓	✓	✓	✓
Marcuccilli (2014) **(HF)**	✓	✓	✓	✓	✓	✓		✓	✓	
Pattenden (2007) **(HF)**	✓	✓	✓	✓		✓		✓		
Rolley (2010) **(CAD)**	✓	✓	✓	✓	✓	✓		✓		
Spence (2008) **(COPD)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Strom (2015) **(HF)**	✓	✓	✓	✓		✓	✓	✓		✓
Wallin (2013)	✓	✓	✓	✓	✓	✓			✓	

(CAD)										
Wingham (2015) **(HF)**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Heart Failure	**12**	**10**	**13**	**13**	**9**	**12**	**7**	**12**	**8**	**11**
COPD	**5**	**5**	**5**	**5**	**5**	**5**	**4**	**5**	**5**	**4**
CAD	**3**	**3**	**3**	**4**	**3**	**3**	**1**	**2**	**2**	**1**
Total	**20**	**18**	**21**	**21**	**17**	**20**	**12**	**19**	**15**	**16**

• = same study

Caregiver experience - Concepts/Mapping – Quantitative Papers

MENTAL HEALTH IMPACT = 1
ROLE = 2
LIFESTYLE CHANGE = 3
SUPPORT = 4
KNOWLEDGE/INFORMATION = 5
RELATIONSHIPS = 6

	1	**2**	**3**	**4**	**5**	**6**
Agren (2010) **(HF)**	✓					✓
Al-Rawashdeh (2017) **(HF)**	✓		✓			✓
Badr (2017) **(COPD)**	✓		✓			✓
Bakas (2006) **(HF)**	✓	✓	✓			
Chung (2016) **(HF)**	✓	✓	✓			
Cossette (1993) **(COPD)**	✓	✓		✓		
Evangelista (2002) **(HF)**	✓					✓
Figueiredo (2013) **(COPD)**	✓		✓			✓
Figueiredo (2014) **(COPD)**	✓					✓
Grigorovich (2017) **(HF)**	✓		✓	✓		
•Halm (2006) **(CAD)**	✓			✓		✓
•Halm (2007) **(CAD)**	✓			✓		✓
Hess (2009) **(HF)**		✓				
Hooley (2005) **(HF)**	✓					✓
Hwang (2011) **(HF)**	✓	✓		✓		✓
Karmilovich (1994) **(HF)**	✓	✓			✓	✓

Kneeshaw (1999) **(CAD)**		✓	✓	✓	✓	✓
Loftus (2004) **(HF)**	✓	✓		✓		✓
Lum (2014) **(HF)**						✓
Luttik (2009) **(HF)**						✓
Miravitlles (2015) **(COPD)**			✓			✓
Nakken (2017) **(COPD)**	✓		✓	✓		✓
Park (2013) **(CAD)**		✓	✓			✓
Pi-Ming Yeh (2012) **(HF)**	✓			✓		
Pressler (2013) **(HF)**	✓	✓	✓			✓
Riegner (1996) **(COPD)**		✓		✓		✓
•Saunders (2008) **(HF)**	✓			✓		✓
•Saunders (2009) **(HF)**	✓			✓		✓
Saunders (2010) **(HF)**	✓	✓				✓
Schwarz (2003) **(HF)**	✓			✓		
Scott (2000) **(HF)**	✓	✓	✓	✓		
Takata (2008) **(COPD)**	✓	✓	✓	✓	✓	
Vellone (2015) **(HF)**	✓				✓	✓
Woolfe (2007) **(COPD)**	✓		✓	✓	✓	
Heart Failure	**15**	**9**	**6**	**7**	**2**	**13**
COPD	**5**	**3**	**6**	**5**	**2**	**6**
CAD	**4**	**2**	**2**	**3**	**1**	**3**
Mixed Method Study	**1**					
Total	**25**	**14**	**14**	**15**	**5**	**22**

•= same study: counted as one

Caregiver experience - Concepts/Mapping – Mixed Method Papers

MENTAL HEALTH IMPACT = 1 **ROLE = 2** **LIFESTYLE CHANGE = 3**
SUPPORT = 4 **KNOWLEDGE/INFORMATION = 5**
RELATIONSHIPS = 6

	1	**2**	**3**	**4**	**5**	**6**
Näsström (2017) **(HF)**	✓			✓	✓	✓
TOTAL	**1**			**1**	**1**	1

Appendix 4 Outline of study results

First Author/Year	Diagnosis	Outcome Measure	Result/Findings
Ågren (2010)	HF (NYHA II-IV)	Caregiver Burden Scale Short Form (SF)-36 Beck Depression Inventory Control Attitude Scale Knowledge Questionnaire Charlson Co-morbidity Index	68% of partners = low level burden 30% of partners = medium burden 2% of partners = high burden Regression analysis showed poor mental health (p=0.001) and lower perceived control (p=0.001) in partners and poor patient physical health (p=0.001) predicts higher caregiver burden
Al-Rawashdeh (2017)	HF (NYHA I-IV)	Beck Depression Inventory Minnesota Living with HF (Modified for caregivers) Patient Health Questionnaire Short-Form 12 Health Survey	Patients whose spouse has higher sleep disturbance have poorer mental well-being (β = -2.19, p <0.05) Caregiver sleep disturbance significantly correlated with their own physical (β = -4.94, p<0.001) and mental well-being scores (β = -6.62, p< 0.001)
Andersen (2015)	HF	n/a	1) Involvement, willingness to assume responsibility and desire for knowledge 2) Unclear Responsibility and Insufficient Flow of information 3) Available and Competent Supporters
Badr (2017)	COPD	Patient Health Questionnaire COPD Severity Index Activities of Daily Living scale Lubben Social Network Scale Zarit Burden Interview Checklist created for this study of co-morbidities	30% of patients and 20% of caregivers = mild depression 30% of patients and 8% of caregivers = moderate to severe depression. Depression levels of patients and caregivers were significantly correlated (r=0.28, P= 0.01)

Bakas (2006)	HF (NYHA II-IV)	Control Attitudes Scale Oberst Caregiving Burden Scale Bakas Caregiving Outcomes Scale Medical Outcomes Study General Health	Caregivers reported their lives had changed for the worse due to providing care (M= 3.7, SD =1.5, 1 = worst, 7 = best Performing household tasks and managing patient behaviours were most difficult, and the caregiver’s emotional and financial well-being, time for social activities, and general health had deteriorated (ρ -0.46, $p < 0.05$).
Baker (2010)	HF (LVAD in situ)	n/a	1) Commitment
Bove (2016)	COPD (GOLD C&D)	n/a	1) Undefined and unpredictable responsibility
Burke (2014)	HF (NYHA II-IV)	n/a	1) Health Manager/Care Plan Enforcer 2) Advocate for Improved Quality of Life 3) Expert in the Lived Experience of HF 4) Expressions of Role Conflict and Role Strain
Chung (2016)	HF (NYHA II-IV)	Beck Depression Inventory-II Zarit Burden Interview Oberst Caregiving Burden Scale Bakas Caregiving Outcome Scale Medical Outcome Study	42% reported severe burden Caregivers of patients with depressive symptoms had a higher level of burden (25±13 vs 13.5±12 on the ZBI; $p<0.001$), Caregivers reported worse mental quality of life (46±10 vs 51±10 -12v2; $p=0.026$) than those of patients without depressive symptoms

Clark (2008)	HF (NYHA II – IV)	n/a	1) The sharing of caring 2) The basis of care: formal and informal forms of knowledge about CHF 3) The activities of informal care: visible and invisible
Cossette (1993)	COPD (GOLD III-V)	The SCL-90 scale The subjective Stress Scale Caregiving tasks index The family/friend support index	Nearly 40% of wives used psychotropic drugs Difficult emotional support significantly predicted somatization (β= 0.26, p ≤ 0.05), depression (β= 0.34, p ≤ 0.01), obsession compulsion (β= 0.43, ≤ 0.01), Anxiety (β= 0.26, p ≤ 0.05), and hostility (β= 0.37, p ≤ 0.01)
Evangelista (2002)	HF (NYHA I – IV)	SF-12 (Mental Component Summary Scale)	Caregiver emotional wellbeing associated with patients emotional wellbeing Caregivers' mental health score: Adjusted R2 = 0 .536, F = 40.299, p = .000 Caregivers reported higher mental wellbeing than patients (P < .001, p = 0.018 (patients), p = 0.118).
Figueiredo (2013)	COPD (GOLD I-IV)	Carers Assessment of Managing Index (Portuguese version) International Classification of Functioning Disability and Health	Better physical health perception was associated with an increasing use of problem-solving strategies: (rs = -0.313; p = 0.029)
Figueiredo (2014)	COPD (GOLD I-IV)	International Classification of Functioning Disability and Health Hospital Anxiety and Depression Scale (Portuguese version) Carers' Assessment of Difficulties Index	61.9% = caregivers of early COPD patients observed to be anxious 70.4% = caregivers of advanced COPD patients observed to be anxious Depression significantly more frequent in

		(Portuguese version)	caregivers of advanced COPD patients (p = 0.030) Self-rated physical (p = 0.035) and mental health (p = 0.011) worse in caregivers of advanced COPD patients
Figueiredo (2015)	COPD (Mod – Severe)	n/a	1) Meaning 2) Challenges and constraints 3) Fears and concerns about the future 4) Needs 5) Positive aspects
Grigorovich (2017)	HF (NYHA II-IV)	Center for Epidemiological Studies-Depression (CES-D) Positive Affect Scale Caregiver Impact Scale Caregiver Assistance Scale Pearlin Mastery Scale Medical Outcomes Study Social Support Survey, Personal Gain Scale Brain Impairment Behaviour, MLWHFQ	Caregivers depression remained stable over1 year (mean -0.17 ± SE 0.11, p > 0.1). Caregiver's depression associated with participation restriction (p< 0.05) Caregivers positive affect remained stable over 1year (0.10 ± 0.10, p > 0.1) Positive affect associated (p<0.05) with caregivers feelings of personal gain and social support
*Halm et al. (2006)	CAD	Caregiving Burden Scale Bakas Caregiving Outcomes Scale Karnofsky Performance Scale gain Caregiver Competence Scale State-Trait Anxiety Inventory CES-D Mutuality Scale Expressive Support Scale	Higher burden scores were associated with patient's gender (female) ,(β = .21, p = .02), increased personal (β = .29, p = .004), increased caregiver SF-12 (spouse proxy ratings) competence (β = .20, p = .05). Lower burden was associated with better health status of the patient (β=-.22, p = .02), higher caregiver mental HRQL (β = -.38, p = .01). Caregiver burden was not significantly different at 3, 6, or 12 months post-surgery

*Halm et al. (2007)	CAD	(as above Halm, 2006)	Controlling for caregiver and patient characteristics, caregivers who perceived less mastery (β = 0.45, p = .001) had higher depressive symptoms
*Halm (2016)	CAD	n/a	1) Knowing what I am supposed to be doing 2) Managing multiple medications 3) Assisting with mobility 4) Dealing with unmonitorable symptoms 5) Managing poor appetite 6) Keeping spirits up 7) Navigating memory loss & confusion 8) Surviving moodiness 9) Dealing with financial matters
*Halm (2017)	CAD	n/a	1) Caregiving work – comfort, monitoring, support & functional
Hess (2009)	HF	Short-Form Test of Functional Health Literacy Self- Care Index of Heart Failure Family Caregiver Medication Administration Hassles (FCMAHS)	Analyses are the individual results for caregiver health literacy and medication administration hassles as the study was insufficiently powered. 80% of caregivers had adequate health literacy Average FCMAHS score was 27.80 (S.D. = 14.74), with a range of 10-44. Higher scores (out of 100) indicate greater medication administration hassle.
Hooley (2005)	HF	Minnesota Living with Heart Failure Questionnaire (MLHFQ) Beck Depression Inventory II Zarit Caregiver Burden Interview	18% of caregivers had high likelihood of clinically significant depression Correlation between: caregiver burden and caregiver depression scores (r=0.61; p<0.0001), and caregiver burden and patient depression scores (r=0.28; p<0.05)
Hwang (2011)	HF	Dutch Objective Burden Inventory	Lack of family support for caregivers correlated with

	(NYHA I – IV)	(English version) Medical Outcome Study Social Support Survey Control Attitudes Scale-Revised Caregiver Reaction Assessment Short Form 36 Health Survey Charlson Co-morbidity Index	patient's NYHA class, caregivers' relationship to the patient, p=0.003), caregivers' perceived control p<.001) and social support (p <.001) impact of caregiving on caregivers' health was associated with time since the patient's last hospital discharge, (p= .008 caregivers' perceived control, (p = .03) and social support (p <.001)
Hynes (2012)	COPD (NYHA III or IV)	n/a	1) Then and Now 2) Awareness of the disease and constant state of anxiety 3) The Caring Role 4) Perceived illness effects: striving for normalisation and symptom burden 5) Support 6) Contact with healthcare services
Imes (2011)	HF (NYHA III-IV)	n/a	1) My experience of HF in My Loved One 2) Experience with Healthcare providers 3) Patient's experience of HF as Perceived by the Partner
Karmilovich (1994)	HF (NYHA III OR IV)	Caregiver Demands Scale (physical demands/role alteration) Brief Symptom Inventory	Significant positive correlation between the number of helping behaviours and the level of stress (r = 0.32, p=0.04). Positive correlation between perceived difficulty performing caring activity and level of stress (r = 0.43, p=0.01). Burden score Mean = 15.27 (SD 11.3)
Kitko (2010)	HF	n/a	1) The work of providing care 2) Work of living with the illness

			3) The Work of navigating the system 4) The work of maintaining self 5) The work of managing the household 6) The work of vigilance 7) The work of normalcy
Kneeshaw (1999)	CAD	Mutuality Scale Preparedness for Caregiving Scale Recovery Inventory of the OARS activities of daily living	Significant decrease between the mutuality scale means at hospital discharge and at 3 months (p < .05) Preparedness for caring - most common concern caregivers was fear of the unknown, especially an emergency
Liljeroos (2014)	HF	n/a	1) Dyads perceive a need for continuous guidance throughout difference phases of the illness trajectory 2) Dyads perceive a need to share burden and support with each other and other dyads
Lindqvist (2013)	COPD (Mild to severe)	n/a	(1) Unchanged life situation where no support was needed (2) Socially restricted life and changed roles where support is needed (3) Changes in health where support is needed (4) Changes in the couple's relationship and their need for support.
Loftus (2004)	HF (NYHA II-IV)	Self-reported health status questionnaire State-Trait Anxiety Inventory Pearlin scale of Mastery Rosenberg Self-Esteem Scale Social Support Scale	Severity of heart failure and level of patient disability predictive of caregiver distress (personal cost, ANCOVA, F=3.94, p<. 05; depression, ANCOVA, F=7.15, p<.05) independent of caregiver neuroticism Satisfaction with social support was a better predictor of distress than a global measure of social support

		Dyadic Adjustment Scale Caregiver Distress Scale Sense of Competence Questionnaire Centre for Epidemiological Studies depression Scale	
Lum (2014)	HF (NYHA II-IV)	Zarit Burden Inventory Benefit Finding Scale burden Patient Health Questionnaire	Higher relationship quality associated with less caregiver & more caregiver benefit - (r = -0.54, 95% CI: [-0.81, -0.10], P = 0.02)
Luttik (2007)	HF	n/a	1) Changes in life 2) Anxiety 3) Changes in relationship 4) Sexuality 5) Coping/Support
Luttik (2009)	HF (NYHA II-IV)	Medical Outcome Study General Health Survey (RAND-36) Objective Burden Inventory Interaction Cantril's Ladder	Partners of people with CHF reported lower general health than partners of healthy persons (F (1,598) = 4.066, P < 0.05) effect between group (partners of people with CHF vs. individuals living with a healthy partner) and gender for general well-being, F(1,581) = 4.526, P < 0.05, and for perceived health change, F(1,604) = 4.283, P < 0.05
Marcuccilli (2011)	HF –LVAD in situ	n/a	1) Caregiving – a "24/7" Responsibility 2) Coping Strategies 3) Caregiving satisfaction
Marcuccilli (2014)	HF-LVAD	n/a	1) Advanced Heart Failure is a Life Changing Event 2) Self-doubt about LVAD Caregiving Improved with Time 3) Lifestyle Adjustments come with Time 4) Persistent Worry and Stress

			5) Caregiving is not a Burden – it's part of life
Miravitlles (2015)	COPD	Survey on Disabilities, Personal Autonomy, and Dependency Situations (National Institute of Statistics in Spain)	35% of caregivers had health problems 83% of caregivers had social/leisure problems 38% of those of working age had profession related problems
Nakken (2017)	COPD	Charlson comorbidity index Dutch relationship questionnaire Care dependency scale Utrecht Coping List Hospital Anxiety and Depression Scale EuroQol-5 Family Appraisal of Caregiving Medical Outcome Study Social Support	Depression levels (P=0.261) social support (P=0.222 to 0.897) and caregiver burden (P=0.410 to 0.720) were comparable for male and female caregivers Female caregivers had more symptoms of anxiety (P<0.0001) and worse health status (P=0.001) Lower levels of social support were associated with higher levels of caregiver strain No differences in caregiver burden between gender (P=0.401 to 0.724)
Näsström (2017)	HF	Charlson comorbidity index The Patient Health Questionnaire Relatives' perception of quality of care Dutch Objective Burden Inventory EuroQol	1) Adapting to the caring needs and illness trajectory 2) Coping with caregiving demands 3) Interacting with healthcare providers 4) Need for knowledge to comprehend the health situation More information was associated with better perceived health
Park (2013)	CAD	Caregiving Burden Scale	Subscale scores of caregiving demand and caregiving difficulty were 31.1 and 22.9 Demanding caregiving activities perceived by caregivers were: providing transportation, additional household

			tasks, providing emotional support, and two tied for fourth: monitoring symptoms and additional tasks outside the home
Pattenden (2007)	HF	n/a	1) Symptoms, multiple medications, co-morbidities 2) Confusion, anxiety and depression 3) Adapting life to heart failure 4) Changing roles for carers
Pi-Ming Yeh (2012)	HF	JAREL Spiritual Well-being Scale Carers Assessments of Managing Index Care Continuity Scale Caregiver Reaction Assessment Caregivers Esteem Subscale Lack of Family Support Subscale	People expressed medium levels of ADL dependency (Mean = 9.56, SD = 3.93) Higher scores of the older people's ADL dependence (β = 0.47, P < 0.001), lower scores of quality of relationship (β = -0.39, P < 0.01) and higher scores of lack of family support (β = 0.41, P < 0.001) were found to predict significantly greater family caregiver burden
Pressler (2013)	HF	Oberst Caregiving Burden Scale Control Attitudes Scale Patient Health Questionniare-8 Inventory months. Anxiety Subscale Bakas Caregiving Outcomes Scale Medical Outcomes Study Short Form-12 Comorbidity Index Family Assessment Device	Caregivers perception of life changed - (NYHA I-IV) neutral on average and improved from baseline to 4 (P=0.054) and 8 (P= 0.003) Poor physical and emotional HRQOL at baseline Caregivers of patients with high HF symptoms spent more time on caregiving tasks at 4months (P = 0.001) & 8 months (P=0.003), perceived greater difficulty with caregiving tasks (baseline P=0.031 & 4mo. P <0.001) and reported higher bassline anxiety (P=0.019) and poorer physical HRQOL at baseline (P < 0.001) and 4 mo. (P=0.008)

Riegner (1996)	COPD	Caregiver Strain Index Social Support Questionnaire – Short Form Situational Humor Response Questionnaire Coping Humor Scale Situation Survey	Role Strain significantly associated with quality of life (β = 0.15, F=11.5, p <.001) For caregivers; social support satisfaction made a significant contribution to quality of life with β= Life 0.26, F=22.90, p.<.0001, and R^2 of .26
Rolley (2010)	CAD	n/a	1) A gendered approach to health, illness and caring 2) Shock, disbelief and the process of adjustment following PCI 3) Challenges and changes of the carer-patient relationship 4) The needs of the carer: support and information
*Saunders (2009)	HF	CES-D 10 Caregiver Reaction Assessment Quality of Life Index finances	Caregiver burden is associated with lower CG HRQOL; increased burden in support (r=–0.50, p < .01.), (r=–0.52 p < .01), schedule (r=–0.62, p < .01) and health (r=–.71, p < .01) = decreased HRQOL
*Saunders (2008)	HF	(as above Saunders, 2009)	76% of caregivers had health problems in past month Highest to lowest burden ranked: schedule (M = 3.20, SD = 1.09), finances (M = 2.39, SD = 1.18), family (M = 2.38, SD = 1.10), and health (M = 2.21, SD = .98).
Saunders (2010)	HF	Centre for Epidemiological Studies Short Depression Scale Quality of Life Index (QLI)	Caregiver depression not difference between employed and unemployed caregivers (t= 1.0, p < 0.05) Employed caregivers perceived higher well-being except for psychological/spiritual domain, well-being (t =-2.9, p<0.01), health/function (t =-2.3, p<0.05), socioeconomic (t = -2.7, p<0.05), family (t =-3.4, P<0.01)
Schwarz (2003)	HF	Perceived Stress Scale	The effects model with salivary cortisol was not

		Center for Epidemiological Stress Studies Depression Scale Inventory of Socially Supportive Behaviours Scale Clinical Assays Gamma Coat	significant (F=1.9, p=.15) as measured by the PSS, was the only significant variable (t=5.80, p=.000) No significant associations between salivary Cortisol cortisol and the PSS (F=1.059, p=.384)
Scott (2000)	HF	Caregiver Preparedness Scale MLHFQ Caregiver Reaction Assessment Mental Health Inventory-5 Quality of Life Index	Caregivers reported being least prepared for stress associated with role (M = 2.11) 89% of caregiver scores for mental health were The less than age norm 55% of the caregivers have to eliminate things from their schedule/interrupt current activities to provide care. 39% of the caregivers reported constant fatigue
Spence (2008)	COPD (Adv.)	n/a	1) Impact of family caregiving 2) Unmet Support Needs 3) Carers' perceptions of patients
Strom (2015)	HF	n/a	1) Being on the alert 2) Being a forced volunteer
Takata (2008)	COPD	Zarit Burden Interview (Japanese version) Barthel Index	53.3% of caregivers were depressed Caregivers providing longer term care were more burdened HB caregivers want to use social services such as Nursing Home 90.9% v 34.8% (p<0.05)
Vellone (2015)	HF (NYHA I-IV)	Caregiver Contribution to Self-care of heart failure Index	54.2% of caregivers were unable to recognize the signs and symptoms of a heart failure exacerbation quickly or very quickly
Wallin (2013)	CAD	n/a	1) Difficulties managing a changed life situation

			2) Feeling like I come second 3) Feeling new hope for the future
Woolfe (2007)	COPD	Family Caregiver Needs Survey	Information is the most important need for caregivers, (M= 6.37, SD = 0.8) Important but poorly met needs = information (27.7), psychological (26.5) and personal (25.3)
Wingham (2015)	HF	n/a	1) Providing support 2) Transition to becoming a caregiver 3) Engaging help

HF = Heart Failure, COPD = Chronic Obstructive Pulmonary Disease, LVAD = Left Ventricular Assist Device, LVAD DT = Left Ventricular Assist Device Destination Therapy, CAD = Coronary Artery Disease, n/a = not applicable, PCI = Percutaneous coronary intervention, MLWHFQ = Minnesota Living with Heart Failure Questionnaire * = same study

Appendix 5 Search Strategy

Vertical Use: “OR”	**Population (Diagnosis)**	**Intervention**	**Deign**
	Heart OR Cardiac OR Myocardial AND failure.ti,ab	(Self-management AND (education OR information OR advice OR rehabilitation* OR program* OR health OR design))	Randomized AND controlled AND trial OR randomised AND controlled AND trial
	Left OR Right ventricular AND failure.ti,ab	((rehabilitati* or educat*) AND (literature or audiovisual or av or audio visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or podcast* or email* or e-mail*))	Controlled AND clinical AND trial
	Heart OR Cardiac OR Myocardial AND incompetence*	((educat* or intervent*) AND (communit* or nurs* OR health OR rehabilitation))	
	Cardiac OR Myocardial AND insufficiency	Evidence-based AND intervention	
	Systolic OR Diastolic AND failure	(education AND (service* OR group* OR program* OR session))	
	Chronic Obstructive Pulmonary Disease.ti,ab	Self-management AND (intervention OR therap*)	
	Dysp*	(health AND (management OR behaviour*))	
	airway* OR airflow* AND disease OR disorder	Group AND intervention	
	respiratory AND disease OR disorder	(Palliative care) AND intervention	
	chronic airflow obstruction		
	Pulmonary OR respiratory AND disease*.ti,ab		
	MeSH: Heart Failure (MAJOR CONCEPT), Chronic Obstructive Pulmonary Disease (Major Concept)	MeSH: Health Education (MAJOR CONCEPT) Self-management Rehabilitation (Major concept)	

Appendix 6 Matched Sampling Strategy

		Author (* = same study)	Year	Intervention	Dx	Country	Exercise
1	**Patient only**	Aguado et al.	2010	Education	HF	Spain	No
	Caregiver & Pt.	Agren et al *	2015	Psychoeducation	HF	Sweden	No
		Agren et al *	2015	Psychoeducation outcomes on partners	HF	Sweden	No
2	**Patient only**	Agvall, B. et al	2013	Education	HF	Sweden	No
	Caregiver & Pt.	Agren et al *	2012	Psychoeducation	HF	Sweden	No
		Liljeroos, Maria*	2017	Psychoeducation	HF	Sweden	No
		Liljeroos, M.*	2015	Ed/psychosocial	HF		No
3	**Patient only**	Bekelman, D. B.	2015	Team approach to disease managment	HF	USA	No
	Caregiver & Pt.	Naylor et al.	2004	Education - APN coordination	HF	USA	No
4	**Patient only**	Altenburg, W. A.	2015	Physical activity	COPD	Netherlands	Yes
	Caregiver & Pt.	Marques, A.	2015	Exercise, psychosocial support and education	COPD	Portugal	Yes
5	**Patient only**	Gary, R*	2007	Exercise and education	HF	USA	Yes
		Gary, R.*	2004/2006	Exercise and education	HF	USA	Yes
	Caregiver & Pt.	Azad et al.	2008	Ed and exercise	HF	Canada	Yes
6	**Patient only**	Doughty, R. N.	2002	Integrated care	HF	New Zealand	No
	Caregiver & Pt.	Deek, H.	2017	Educational intervention	HF	Lebanon	No
7	**Patient only**	Bocchi, E. A.	2008	Repeated education disease management	HF	Brazil	No
	Caregiver & Pt.	Hasanpour-Dehkordi, Ali	2016	Education	HF	Iran	No
8	**Patient only**	Bischoff, Erik W. M. A.	2012	Self-management programme	COPD	Netherlands	No
	Caregiver & Pt.	Jonsdottir, H.	2015	Education, smoking cessation, group self-management	COPD	Iceland	No

9	**Patient only**	Billington, J.	2015	Nurse led education	COPD	UK	No
	Caregiver & Pt.	Farquhar, Morag C.	2016	Education/Support	COPD (80%)	UK	No
10	**Patient only**	Kalter-Leibovici, O.	2017	Disease Management Programme	HF	Israel	No
	Caregiver & Pt.	Srisuk, Nittaya	2017	Relaxation response, education	HF	Thailand	No
11	**Patient only**	Clark, Angela P.	2015	Education/support at home	HF	USA	No
	Caregiver & Pt.	Martensson, J.	2005	Education and Management	HF	Sweden	No
12	**Patient only**	Andryukhin, A.	2010	Nurse education/disease management	HF	Russia	Yes
	Caregiver & Pt.	Witham, M	2012	Ed and exercise	HF	Scotland	Yes
13	**Patient only**	Rich, M. W.	1995	Multidisciplinary Intervention	HF	USA	No
	Caregiver & Pt.	Cline, C. M. J.	1998	Education post discharge	HF	Sweden	No

Appendix 7 Summary of included studies

First Author	Year	Country /Severity	Diagnosis Group (n)	Control Group (n)	Intervention	Sample (Gender %F/Mean Age)	HRQoL Outcome Measure
+Aguado	2010	Spain	HF NYHA II-IV LVEF < 45%	Usual care. No education. Outpatient follow up. (64)	Education on self-management, activities habits and prevention (42)	106 IV: 23.8F / 77.8 C: 34.4F / 77.4	MLHFQ SF-36
±●Agren ±●Agren	2015 2015	Sweden	Post-operative HF	Standard care by members of a cardiac surgery care team. (17)	Patients and partners received psycho-educational support 2-4 weeks after discharge (25 Dyads)	42 Dyads IV: 12F(pt)/69(pt); 67(cg) C: 6F(pt) /70(pt) 66(cg)	SF-36
+Agvall	2013	Sweden	HF NYHA I-III EF < 50%	One initial visit to the GP as per local guidelines, follow-up was once a year (81)	Heart failure management programme for HF patients in primary care centres (79)	160 IV: 27F/75 C: 36F/75	SF-36
±●Agren ±●Liljeroos ±●Liljeroos	2012 2017 2015	Sweden	HF NYHA II -IV	Traditional inpatient care outpatient appointment as required. Partners not routinely included (71)	Integrated dyad care program with education and psychosocial support (84)	155 Dyads IV: 31F(pt)/69(pt); 67(cg) C: 19F(pt)/73(pt); 69(cg)	SF-36
+Bekelman	2015	USA	HF NYHA I-IV EF <50%	Received care from their regular health professionals and regular telehealth nurses Received information sheets describing self-care for HF & weighing scale (197)	3 Components Team review of medical records Telemonitoring Self-care education programme including medication, diet, depression &signs &symptoms of decompensation (187)	392 IV: 5F/67.3 C: 2F/67.9	KCCQ
±Naylor	2004	USA	HF Systolic & Diastolic	Routine Care Site-specific heart failure– pt management/discharge planning /referrals as required 58% received referrals for skilled nursing/physical therapy (121)	Discharge planning and 3 month home follow up (118)	239 76F/57%	MLHFQ

+Altenburg	2015	Netherlands	COPD GOLD I-IV FEV1 (%pred): 60 (40-75)	Usual Care PR group received 9 weeks exercise training (77)	12- weeks’ customized lifestyle physical activity counselling programme 3 groups, PR, PC, SC (78)	144 34F/62	SF-36 Clinical COPD Questionnaire Chronic Respiratory Questionnaire
±Marques	2015	Portugal	COPD FEV 1(% pred): IV: 67(±22.4) C: 74.3(±21.7)	12 weeks of PR, psychosocial support and exercise for pt. No involvement of family (28)	12 weeks of PR composed of exercise training and psychosocial support and education. Family participated in psychosocial and education sessions (28)	56 Dyads IV:18.2F(pt)/ 68.8(pt); 62(cg C: 50F(pt)/ 65.9(pt), 55(cg)	SGRQ
+Andryukhin	2010	Russia	HF NYHA I -III Preserved EF	Usual care as per national guidelines (41)	Educational programme 4 weekly group sessions targeting lifestyle modifications & risk factors (44)	85 IV: 72.7F/66.5 C: 65.8F/68	MLHFQ
±Azad	2008	Canada	HF NYHA I-IV	Optimal medical care (45)	Interdisciplinary self-management including exercise, diet, daily activities, support and HF education (46)	91 IV:n/sF/74.2 C: n/sF/75/8	MLHFQ SF-36
+Doughty	2002	New Zealand	HF NYHA III-IV LVEF % IV: 30.6 C: 33.8	Care of GP & additional follow up if recommended by medical team (97)	One to one education with nurse 6 weekly visits with GP or HF clinic Group education. Self-management of HF (100)	197 IV: 36F/72.5 C: 44F/73.5	MLHFQ
±Deek	2017	Lebanon	HF EF Mean 36 NYHA II/III 95%	Usual Care No education session (130)	Pts and cg received one comprehensive family-centred educational session on self-care and symptoms management (126)	256 IV:47F/65 C: 43F/68)	SF12-V2
+Bocchi	2008	Brazil	HF EF <45%: C:=80% IV: = 81.6%	Standard follow-up medical visits – catered to patients’ needs (117)	Disease Management Programme; consisting of a long-term repetitive multidisciplinary education	350 IV: 29F/50 C:36F/52)	MLHFQ

					program and telephone monitoring	90	SF-36
±Hassanpour-Dehkordi	2016	Iran	HF NYHA III: IV:72% C:76% EF OF 35%-45% IV: 75% C: 77%	n/s (45)	Family training and support at home (45)	IV: 40F/60.8 C: 38F/59.1)	
+Bischoff	2012	Netherlands	COPD FEV1(% pred.): Self-mgt. group: 66.3 Routine monitoring: 62.9 (14.4) C: 67.0 (18.0)	As per guidelines in general practices in Netherlands (55)	Self-mgt group: Modules & written action plan. Education on self-mgt. & early recognition of symptoms (55) Routine monitoring: routine visits to GP office including evaluation of symptoms (55)	165 Self-mgt: 33F/65.5 Routine Monitoring: 24F/65.8 C: 49F/63.5	SGRQ
±Jonsdottir	2015	Iceland	COPD GOLD I-IV FEV1(% pred): IV: 54 C: 61	Traditional healthcare i.e. visits to primary health centre, physician or lung specialist (52)	Patient/family education & discussion Smoking cessation Peer education Self-mgt. of COPD (48)	119 IV: 29F/59.4 C: 25F/58.6	SGRQ
+Billington	2015	UK	COPD Mild & Moderate FEV1 (% pred) IV: 55.78 C: 58.23	2 page self-mgt. plan Guidelines on symptoms Medications in emergency (38)	Telephone education Use of written action plan Medication advice & support (35)	73 IV: 49F/72 C: 55F/72	CAT
±Farquhar	2016	UK	COPD GOLD I-IV	Wait list control (43)	Manage symptoms of breathlessness psychological, social and physical approach (44)	87 IV: 36F(pt)/72.3(pt);62.5(cg) C: 42F(pt)/72.2(pt); 62(cg)	Chronic Respiratory Q. EQ-5D
+Kalter-Leibovici	2017	Israel	HF (all types) NYHA I-IV	Usual care Referred to primary care with treatment plan by Cardiologist (678)	Regular contact with nurses for self-care education monitoring signs & symptoms medication mgt. & HF clinic follow up (682)	1,360 IV: 31F/70.8 C: 24F/70.7	SF-36
±Srisuk	2017	Thailand	HF NYHA I-IV	Usual care Standard medical	HF education manual & DVD Counselling	100 Dyads IV: 56F(pt)/65(pt);39(cg)	MLHFQ SF-12

				& nursing care (50)	Telephone follow up (50)	C: 50F(pt)/59(pt);43(cg)	
+Clark	2015	USA	HF NYHA I-III	Received notebook on information on health & health promotion (25)	Building self-efficacy using education & skill building Encouraged to contact nurses for support (25)	50 IV: 64F/62.4 C: 40F/62.4	KCCQ
±Mårtennson	2005	Sweden	HF NYHA II-IV	Team based care Home visits included (75)	HF education via telephone & home visits (78)	153 46F/79	SF-36 MLHFQ
+●Gary +●Gary +●Gary	2007 2006 2004	USA USA USA	HF NYHA II-III LVEF ≥45%	12 week education group not educated on exercise self-mgt. topics for HF Weekly home visits Received patient manual (10)	In addition to control group 12 week walking intervention (13)	23 100F/68	MLHFQ
±Witham	2012	Scotland	HF NYHA II-III	Received booklet with general healthcare advice (54)	Exercise classes clinic & home Cognitive behavioural techniques utilised Received same booklet as control group (53)	107 IV: 34F(pt)/80(pt);65(cg) C: 31F(pt)/79(pt); 70(cg)	MLHFQ EQ-5D
+Rich	1995	USA	HF	Standard care as per physician treatment (140)	Intensive HF education Individualised dietary plan Medication advice Telephone & home follow up (142)	282 IV: 68F/80 C: 59F/78	Chronic HF Questionnaire
±Cline	1998	Sweden	HF	Outpatient clinic follow up. Treating Physician evaluated & treated as appropriate (110)	Education on pharmacological & non-pharmacological mgt. at home In hospital presentations on signs & symptoms Use of diary to record information Follow up by nurse via telephone and home visit Doctor appointments also offered at 1 & 4 months (80)	190 IV: 45F/76 C: 45F/75	Quality of life in HF MLHFQ NHP

Studies are grouped with their matched pairing, + = patient only, ± = patient and caregiver, ●= Same study, LVEF=Left Ventricular Ejection Fraction, IV = Intervention group, C = Control group, MLHFQ = Minnesota Living with Heart Failure Questionnaire, SF-36 = Short Form 36, pt=patient, cg=caregiver, EF = Ejection Fraction, KCCQ = Kansas City Cardiomyopathy Questionnaire, GOLD = Global Initiative for Chronic Obstructive Lung Disease, FEV1=forced expiration volume in 1 s, PR = Pulmonary Rehabilitation, PC = Primary Care, SC=Secondary

Care, SF12-V2 = Short Form-12Version 2, SGRQ = St. George's Respiratory Questionnaire, NYHA = New York Heart Association, n/s = not stated, ICICE = Improving Chronic Illness Care Evaluation, HFSS = Heart Failure Symptom Scale, , SF-12 = Short Form 12, Self-mgt. = self-management, CAT = COPD Assessment Tool, NHP = Nottingham Health Profile

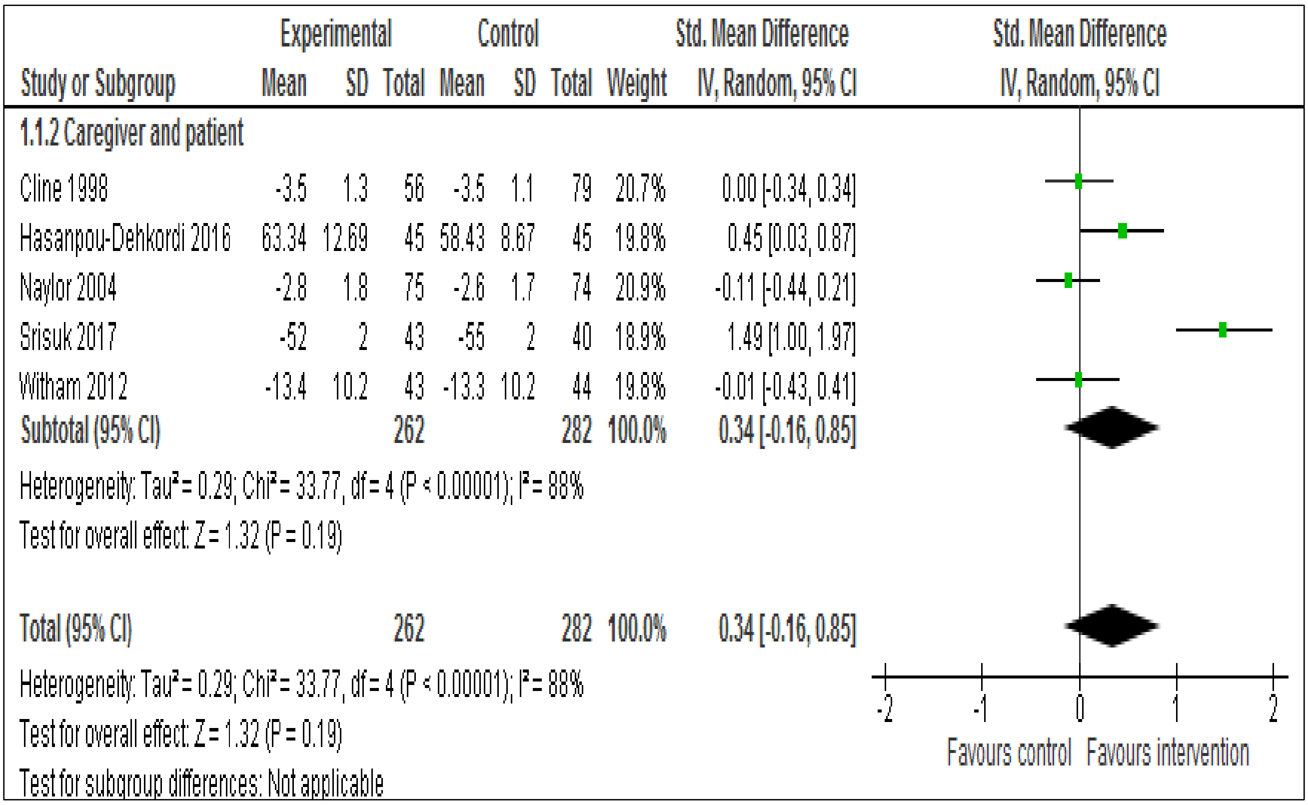
Appendix 8 Risk of bias assessment

Author	Random Sequence generation	Allocation concealment	Blinding of participants/ personnel	Blinding of outcome assessment	Incomplete data reporting	Selective reporting	Groups balanced at baseline	Did groups receive same treatment
Aguado 2010	Low Risk	Unclear Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
Agren 2015	Low Risk	Unclear Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
Agvall 2013	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Agren 2012 Liljeroos 2015/2017	Low Risk	Unclear Risk	High Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Low Risk
Bekelman 2015	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Naylor 2004	Low Risk	Low Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk
Altenburg 2015	Low Risk	Low Risk	High Risk	High Risk	High Risk	High Risk	Low Risk	High Risk
Marques 2015	Low Risk	Low Risk	Unclear Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk

Andryuhkin 2010	Unclear Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk
Azad 2008	Low Risk	Low Risk	High Risk	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Doughty 2002	Low Risk	Unclear Risk	Unclear Risk	High Risk	High Risk	Low Risk	Low Risk	Low Risk
Deek 2017	Low Risk	Low Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk
Bocchi 2008	Low Risk	Low Risk	High Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk
Hasanpour-Dehkordi 2016	Unclear Risk	Unclear Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk	Unclear Risk
Bischoff 2012	Low Risk	Low Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk	High Risk
Jonsdottir 2015	Low Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk
Billington 2015	Low Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Farquhar 2016	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	High Risk	Low Risk	Low Risk
Kalter-Leibovici 2017	Low Risk	Low Risk	High Risk	High Risk	Low Risk	Unclear Risk	Low Risk	Low Risk
Srisuk 2017	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk

Clark 2015	Unclear Risk	Unclear Risk	High Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Mårtensson 2005	Low Risk	Unclear Risk	High Risk	Unclear Risk	High Risk	High Risk	Low Risk	Low Risk
Gary 2006/2007	Unclear Risk	Unclear Risk	High Risk	Unclear Risk	High Risk	Unclear Risk	Low Risk	Low Risk
Witham 2012	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Rich 1995	Low Risk	Low Risk	High Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Cline	Low Risk	Unclear Risk	High Risk	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk

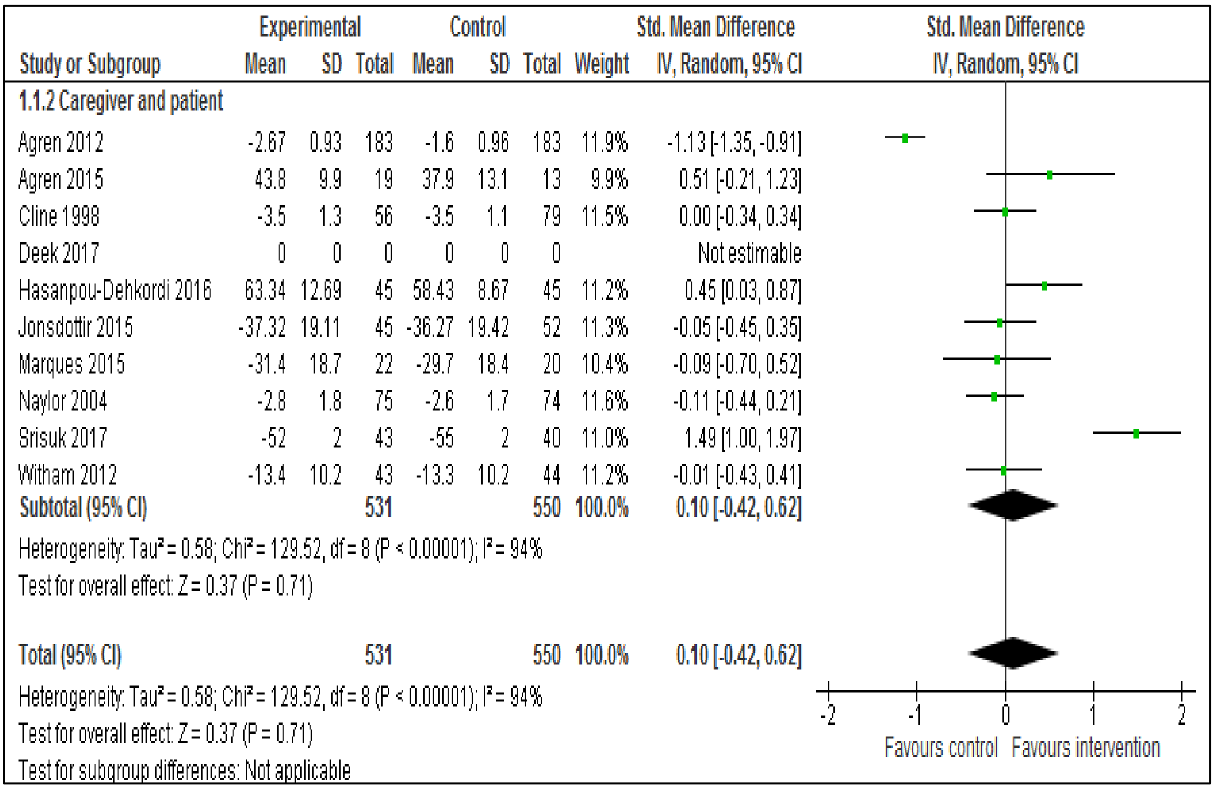
Appendix 9 Sensitivity Analysis Caregiver included studies with HF only



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.1.2 Caregiver and patient								
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	20.7%	0.00 [-0.34, 0.34]
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	19.8%	0.45 [0.03, 0.87]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	20.9%	-0.11 [-0.44, 0.21]
Srisuk 2017	-52	2	43	-55	2	40	18.9%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	19.8%	-0.01 [-0.43, 0.41]
Subtotal (95% CI)			**262**			**282**	**100.0%**	**0.34 [-0.16, 0.85]**
Heterogeneity: Tau² = 0.29; Chi² = 33.77, df = 4 (P < 0.00001); I² = 88%								
Test for overall effect: Z = 1.32 (P = 0.19)								
Total (95% CI)			**262**			**282**	**100.0%**	**0.34 [-0.16, 0.85]**
Heterogeneity: Tau² = 0.29; Chi² = 33.77, df = 4 (P < 0.00001); I² = 88%								
Test for overall effect: Z = 1.32 (P = 0.19)								
Test for subgroup differences: Not applicable								

Appendix 10 Caregiver studies with Physical Component Scale (PCS) and Mental Component Scale (MCS) of SF-36

Caregiver studies with Physical Component Scale (PCS) of SF-36 included



	Experimental			Control				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
1.1.2 Caregiver and patient								
Agren 2012	-2.67	0.93	183	-1.6	0.96	183	11.9%	-1.13 [-1.35, -0.91]
Agren 2015	43.8	9.9	19	37.9	13.1	13	9.9%	0.51 [-0.21, 1.23]
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	11.5%	0.00 [-0.34, 0.34]
Deek 2017	0	0	0	0	0	0		Not estimable
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	11.2%	0.45 [0.03, 0.87]
Jonsdottir 2015	-37.32	19.11	45	-36.27	19.42	52	11.3%	-0.05 [-0.45, 0.35]
Marques 2015	-31.4	18.7	22	-29.7	18.4	20	10.4%	-0.09 [-0.70, 0.52]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	11.6%	-0.11 [-0.44, 0.21]
Srisuk 2017	-52	2	43	-55	2	40	11.0%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	11.2%	-0.01 [-0.43, 0.41]
Subtotal (95% CI)			**531**			**550**	**100.0%**	**0.10 [-0.42, 0.62]**
Total (95% CI)			**531**			**550**	**100.0%**	**0.10 [-0.42, 0.62]**

Subtotal: Heterogeneity: Tau^2 = 0.58; Chi^2 = 129.52, df = 8 (P < 0.00001); I^2 = 94%

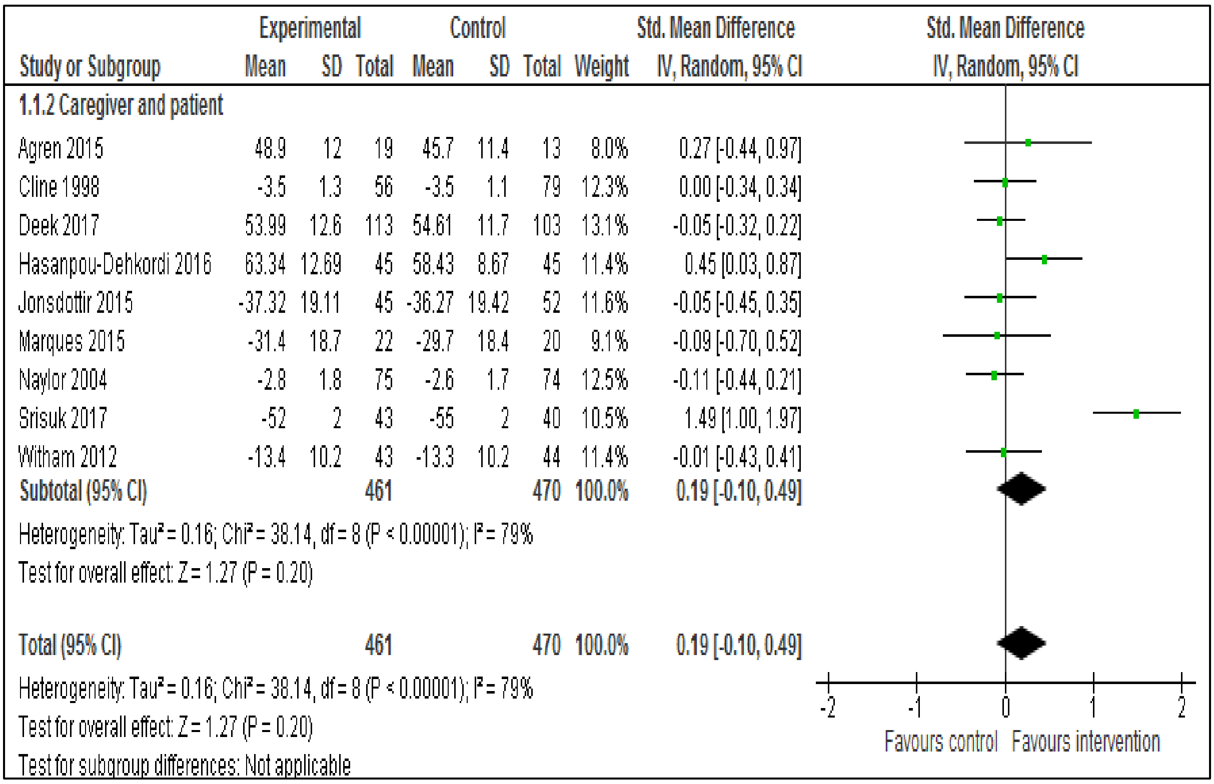
Test for overall effect: Z = 0.37 (P = 0.71)

Total: Heterogeneity: Tau^2 = 0.58; Chi^2 = 129.52, df = 8 (P < 0.00001); I^2 = 94%

Test for overall effect: Z = 0.37 (P = 0.71)

Test for subgroup differences: Not applicable

Caregiver studies with Mental Component Scale (MCS) of SF-36 included



	Experimental			Control				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
1.1.2 Caregiver and patient								
Agren 2015	48.9	12	19	45.7	11.4	13	8.0%	0.27 [-0.44, 0.97]
Cline 1998	-3.5	1.3	56	-3.5	1.1	79	12.3%	0.00 [-0.34, 0.34]
Deek 2017	53.99	12.6	113	54.61	11.7	103	13.1%	-0.05 [-0.32, 0.22]
Hasanpou-Dehkordi 2016	63.34	12.69	45	58.43	8.67	45	11.4%	0.45 [0.03, 0.87]
Jonsdottir 2015	-37.32	19.11	45	-36.27	19.42	52	11.6%	-0.05 [-0.45, 0.35]
Marques 2015	-31.4	18.7	22	-29.7	18.4	20	9.1%	-0.09 [-0.70, 0.52]
Naylor 2004	-2.8	1.8	75	-2.6	1.7	74	12.5%	-0.11 [-0.44, 0.21]
Srisuk 2017	-52	2	43	-55	2	40	10.5%	1.49 [1.00, 1.97]
Witham 2012	-13.4	10.2	43	-13.3	10.2	44	11.4%	-0.01 [-0.43, 0.41]
Subtotal (95% CI)			**461**			**470**	**100.0%**	**0.19 [-0.10, 0.49]**
Total (95% CI)			**461**			**470**	**100.0%**	**0.19 [-0.10, 0.49]**

Subtotal: Heterogeneity: Tau^2 = 0.16; Chi^2 = 38.14, df = 8 (P < 0.00001); I^2 = 79%

Test for overall effect: Z = 1.27 (P = 0.20)

Total: Heterogeneity: Tau^2 = 0.16; Chi^2 = 38.14, df = 8 (P < 0.00001); I^2 = 79%

Test for overall effect: Z = 1.27 (P = 0.20)

Test for subgroup differences: Not applicable

Appendix 11 Vote Counting

Author Year	Time point	Outcome Measure	Outcome Mean (SD) Unless otherwise specified “C” – Intervention with pt. & cg. V “Non-C” Control group with pt. & cg. “P” – Intervention with pt. only V “Non-P” Control group with pt. only	Categorisation of effect	Comments
Aguado 2010	Baseline	MLHFQ	51.2 (27.7) v 48.6 (25.8), p=0.77	P = Non-P	
	24 months	MLHFQ	11.9 (10.5) v 18.3 (16.2), p=0.19	P = Non-P	
	Baseline	SF-36 Physical health	35 (8) v 40 (11), p = 0.14	P = Non-P	Between group p values calculated using STATA 15.0
	24 months	SF-36 Physical health	50 (5) v 44 (3), p = 0.00	P > Non-P	
	Baseline	SF-36 Mental health	37 (12) v 36 (13), p = 0.81	P = Non-P	
	24 months	SF-36 Mental health	52 (7) v 44 (6), p=0.00	P > Non-P	

Statistical Test: Logistic regression comparison of means for paired data, statistical significance *p* < 0.05

Author Year	Time point	Outcome Measure	Outcome	Categorisation of effect	Comments
Agren 2012	Baseline	SF-36 PCS	33.6 (6.8) v 31.8 (8.8), p = 0.46	C = Non-C	
	3 months	SF-36 PCS	39.7 (11.2) v 36.7 (14.4), p = 0.45	C = Non-C	Between group p values calculated using STATA 15.0
	12 months	SF-36 PCS	43.8 (9.9) v 37.9 (13.1), p=0.15	C = Non-C	
	Baseline	SF-36 MCS	40.2 (12.7) v 43.4 (14.0), p =0.44	C = Non-C	
	3 months	SF-36 MCS	50.6 (12.7) v 51.7 (11.1) , p= 0.77	C = Non-C	
	12 months	SF-36 MCS	48.9 (12.0) v 45.7 (11.4), p = 0.45	C = Non-C	

Baseline	SF-36-PF	48.8 (23.3) v 44.2 (27.8), p = 0.56	C = Non-C
3 months	SF-36-PF	65.8 (28.0) v 61.1 (26.2), p = 0.58	C = Non-C
12 months	SF-36-PF	76.0 (19.9) v 57.4 (31.2), p = 0.04	C > Non-C
Baseline	SF-36-RP	8.0 (23.6) v 6.6 (18.4), p = 0.83	C = Non-C
3 months	SF-36-RP	32.9 (41.7) v 35.7 (41.3), p = 0.83	C = Non-C
12 months	SF-36-RP	46.0 (45.1) v 32.7 (41.3), p = 0.4	C = Non-C
Baseline	SF-36-BP	56.7 (23.9) v 54.3 (24.8), p = 0.75	C = Non-C
3 months	SF-36-BP	73.9 (24.6) v 63.8 (35.4), p = 0.28	C = Non-C
12 months	SF-36-BP	77.3 (25.2) v 70.3 (31.7), p = 0.49	C = Non-C
Baseline	SF-36-GH	57.6 (17.6) v 58.7 (21.1), p = 0.85	C = Non-C
3 months	SF-36-GH	66.9 (19.0) v 60.1 (24.7), p = 0.31	C = Non-C
12 months	SF-36-GH	66.0 (20.1) v 56.3 (26.1), p=0.24	C = Non-C
Baseline	SF-36-VT	40.8 (22.6) v 42.1 (22 .8), p = 0.85	C = Non-C
3 months	SF-36-VT	60.0 (21.9) v 58.6 (24.0), p = 0.84	C = Non-C
12 months	SF-36-VT	63.2 (22.1) v 51.5 (22.8), p = 0.15	C = Non-C
Baseline	SF-36-SF	55.0 (27.9) v 65.8 (30.9), p = 0.24	C = Non-C
3 months	SF-36-SF	86.2 (17.6) v 84.8 (23.6), p = 0.82	C = Non-C
12 months	SF-36-SF	85.5 (19.2) v 75.0 (27.5), p = 0.21	C = Non-C

	Baseline	SF-36-RE	36.0 (44.0) v 36.8 (44.3), p = 0.95	C = Non-C	
	3 months	SF-36-RE	66.7 (47.1) v 69.0 (42.3), p = 0.87	C = Non-C	
	12 months	SF-36-RE	63.2 (42.9) v 60.3 (40.6), p = 0.84	C = Non-C	
	Baseline	SF-36-MH	67.8 (22.3) v 71.2 (23.0), p = 0.63	C = Non-C	
	3 months	SF-36-MH	80.8 (20.1) v 82.0 (16.3), p = 0.83	C = Non-C	
	12 months	SF-36-MH	82.3 (20.3) v 70.2 (18.8), p = 0.09	C = Non-C	

Statistical test: Student *t* test, statistical significance *p* < 0.05

Agvall 2013	SF-36			
	Physical Functioning (PF)	2 (23) v -2 (23), p = 0.27	P = Non-P	Mean difference between baseline and 12 months
	Role Physical (RP)	7 (95) v 2 (95), p=0.51	P = Non-P	SD calculated from p value
	Bodily Pain (BP)	-2(31) v 0 (31), p = 0.41	P = Non-P	
	General Health (GH)	-1(33), v -1(33), p =0.7	P = Non-P	
	Vitality (VT)	0(68), v -2(68), p=0.71	P = Non-P	
	Social Role Functioning (SF)	3 (63), v -5(63), p = 0.11	P = Non-P	
	Role Emotional (RE)	4(93), v -10 (93), p = 0.06	P = Non-P	
	Mental Health (MH)	3(65), v -2 (65), p=0.33	P = Non-P	

Statistical test: Student's unpaired and paired two-sided t-test, statistical significance *p* < 0.05

Liljeroos 2015

Baseline	SF-36-PCS	33.6(8.7) v 31.8(10), p = 0.23	C = Non-C	p values calculated using STATA 15.0

	Baseline	SF-36-MCS	39.9 (12.8) v 42.2 (12.6), p = 0.26	C = Non-C	
	Difference in score between baseline and 3 months	SF-36-PCS	-0.5 (7.6) v -0.5 (6.4), p = 0.99	C = Non-C	
		SF-36 MCS	0.3 (8.8) v -3.1 (12.5), p = 0.1	C = Non-C	
	Difference in score between baseline and 12 months	SF-36 PCS	-1.9 (9.8) v -0.5 (7.9), p =0.39	C = Non-C	
		SF-36-MCS	-4.55 (11.2) v -3.1(10.4), p = 0.88	C = Non-C	
	Baseline – 24 months	SF-36 PCS	-2.67 (0.93) v -1.6 (0.96), p = 0.415	C = Non-C	Mean difference from baseline to 24 months
	Baseline – 24 months	SF -36 MCS	3.49 (1.1) v 2.56 (1.2), p = 0.601	C = Non-C	
	Baseline – 24 months	SF-36 PF	-4.28 (2.26) v -1.48 (1.88), p = 0.325	C = Non-C	
	Baseline – 24 months	SF -36 RP	-3.5 (4.57) v -1.68 (4.12), p = 0.777	C = Non-C	
	Baseline – 24 months	SF-36 BP	-3.33 (2.91) v -0.77 (3.04), p= 0.586	C = Non-C	
	Baseline – 24 months	SF-36 GH	-0.18 (2.07) v -2.58 (1.85), p = 0.428	C = Non-C	
	Baseline – 24 months	SF-36-VT	5.23 (2.18) v 2.89 (2.19), p = 0.473	C = Non-C	
	Baseline – 24 months	SF-36-SF	1.4 (2.36) v 4.58 (2.48), p = 0.371	C = Non-C	
	Baseline – 24 months	SF-36-RE	7.66 (4.32) v 5.05 (4.15), p = 0.677	C = Non-C	
	Baseline – 24 months	SF-36-MH	3.3 (1.89) v 2.87 (1.89), p = 0.888	C = Non-C	

Statistical test: Multiple linear regression analyses (robust variance estimates), statistical significance $p < 0.05$

Bekelman 2015	Baseline	KCCQ	37.9 (13.3) v 36.9(14.6), p = 0.48	P = Non-P	p values calculated using STATA 15.0
	3 months	KCCQ	43.8(10.4) v 43.7(10.6), p = 0.92	P = Non-P	

	6 months	KCCQ	47.2(11.1) v 46.9 (11.3), p = 0.8	P = Non-P	
	12 months	KCCQ	54.2 (16) v 53.6(16.4), p = 0.73	P = Non-P	

Statistical test: Paired t test and likelihood-based random-effects model, statistical significance $p < 0.05$

Naylor 2004	Baseline	MLHFQ Total	2.4 (0.7) v 2.3 (0.7), p = 0.27	C = Non-C	
		MLHFQ Emotional	3.3 (1.3) v 3.3 (1.2), p = 1	C < Non-C	p values calculated using STATA 15.0
		MLHFQ Physical	2.8 (0.9) v 2.8 (0.9), p = 1	C < Non-C	
	2 weeks	MLHFQ Total	3 (1.2) v 2.7 (1.2), p = 0.06	C = Non-C	
		MLHFQ Emotional	3.6 (1.3) v 3.3 (1.4), p = 0.09	C = Non-C	
		MLHFQ Physical	3.5 (1.2) v 3 (1.2), p = 0	C > Non-C	
	6 weeks	MLHFQ Total	3.1 (1.3) v 2.9 (1.4), p = 0.28	C = Non-C	
		MLHFQ Emotional	3.5 (1.5) v 3.3 (1.6), p = 0.35	C = Non-C	
		MLHFQ Physical	3.6 (1.4) v 3.3 (1.5), p = 0.15	C = Non-C	

12 weeks	MLHFQ Total	3.2 (1.5) v 2.7 (1.5), p = 0.02	C > Non-C
	MLHFQ Emotional	3.6 (1.6) v 3.2 (1.7), p = 0.09	C = Non-C
	MLHFQ Physical	3.6 (1.4) v 3.1 (1.6), p = 0.02	C > Non-C
26 weeks	MLHFQ Total	2.9 (1.6) v 2.6 (1.5), p = 0.19	C = Non-C
	MLHFQ Emotional	3.2 (1.7) v 3.1 (1.8), p = 0.7	C = Non-C
	MLHFQ Physical	3.3 (1.6) v 3 (1.7), p = 0.22	C = Non-C
52 weeks	MLHFQ Total	2.8 (1.8) v 2.6 (1.7), p = 0.48	C = Non-C
	MLHFQ Emotional	3.1 (1.9) v 3 (1.9), p = 0.74	C = Non-C
	MLHFQ Physical	3.1 (1.9) v 2.9 (1.9), p = 0.52	C = Non-C

Statistical test: Intention-to-treat principle, statistical significance $p < 0.05$

Altenburg 2015		**<u>Median (IQR)</u>** **All intervention groups**		
Baseline	CRQ	109 (87-119) v 102(86 -118), p = 0.31	P = Non-P	p value calculated using STATA 15 after imputing mean and SD
3 months	CRQ	112 (91-122) v 114 (96-126), p = 0.79	P = Non-P	

15 months	CRQ	113 (89-129) v 114 (94-129), p = 0.92	P = Non-P
Baseline	CCQ	1.35 (0.70-2.28) v 1.4 (0.85 – 2.20), p = 0.87	P = Non-P
3 months	CCQ	1.20 (0.70 – 1.83) v 1 (0.50 – 1.80), p = 0.5	P = Non-P
15 months	CCQ	1.3 (0.50 – 2.10) v 1.1 (0.60 – 2.00), p = 0.62	P = Non-P
		Control Primary Care v Intervention Primary Care	
Baseline	CRQ	116 (103-125) v 118 (102 – 134), p = 0.85	P = Non-P
3 months	CRQ	121 (112 – 131) v 131 (118 – 135), p = 0.2	P = Non-P
15 months	CRQ	121 (116-131) v 125 (116 – 135), p = 0.59	P = Non-P
Baseline	CCQ	0.7 (0.40 – 1.20) v 0.8 (0.20 – 1.30), p = 0.79	P = Non-P
3 months	CCQ	0.7 (0.50 – 0.93) v 0.4 (0.20 – 0.95), p = 0.26	P = Non-P
15 months	CCQ	0.5 (0.40 – 1.30) v 0.5 (0.30 – 0.75), p = 1	P < Non-P
		Control Secondary Care v Secondary Care Intervention	
Baseline	CRQ	114 (88 – 124) v 107 (102 – 122), p = 0.54	P = Non-P
3 months	CRQ	106 (78 – 117) v 111 (94 – 121), p = 0.72	P = Non-P
15 months	CRQ	117 (98 – 130) v 112 (105 – 123), p = 0.65	P = Non-P
Baseline	CCQ	1.2 (0.80 – 1.70) v 1.4 (0.90 -2.10), p = 0.63	P = Non-P
3 months	CCQ	1.4 (0.80 – 1.80) v 1.5 (0.85 – 1.95), p = 0.81	P = Non-P
15 months	CCQ	1.3 (0.90 – 2.08) v 1.2 (0.70 – 1.80), p = 0.83	P = Non-P
		Control Pulmonary Rehab Group v Pulmonary Rehab Intervention Group	

	Baseline	CRQ	90 (77 – 109) v 86 (77 – 98), p = 0.66	P = Non-P	
	3 months	CRQ	100 (89 – 117) v 101 (92 – 116), p = 0.93	P = Non-P	
	15 months	CRQ	80 (70-98) v 77 (62 – 93), p = 0.85	P = Non-P	
	Baseline	CCQ	2.3 (1.45 – 2.90) v 2.15 (1.28 -3.23), p = 0.76	P = Non-P	
	3 months	CCQ	1.8 (1.00 – 2.40) v 1.75 (0.98 – 2.30), p = 0.92	P = Non-P	
	15 months	CCQ	2.3 (1.60 – 2.90) v 3.1 (2.15 – 3.55), p = 0.25	P = Non-P	

Statistical test: Spearman’s correlations, statistical significance *p* < 0.05

Marques 2015	Baseline	SGRQ Total	37.9 (18.2) V 38.3 (17.9), p = 0.94	C = Non-C	p value calculated SGRQ using STATA 15
		Symptoms	51 (22.5) v 51.9 (17.8), p = 0.88	C = Non-C	
		SGRQ Activities	53.2 (21.9) v 51.7 (23.2), p = 0.85	C = Non-C	
		SGRQ Impact	23.7 (19.5) v 25.1 (19.2), p = 0.81	C = Non-C	
	Post Intervention	SGRQ Total	31.4 (18.7) v 29.7 (18.4), p = 0.76	C = Non-C	
		SGRQ Symptoms	40.3 (19.4) v 37 (22.6), p = 0.61	C = Non-C	
		SGRQ Activities	43.1 (23.8) v 40.8 (26.3), p = 0.76	C = Non-C	

		SGRQ Impact	18.9 (16.1) v 2- (16.3), p = 0.82	C = Non-C	

Statistical test: Mann-Whitney U tests, statistical significance *p* < 0.05

Gary 2007	Week 1	MLHFQ	38 (26) v 24 (16), p = 0.14	P = Non-P	p value calculated using STATA 15
	Week 15	MLHFQ	20 (16) v 25 (18), p = 0.48	P = Non-P	

Statistical test: Independent t tests, statistical significance *p* < 0.05

Azad 2008	Baseline	MLHFQ	**Mean (Range)** 28.66 (0-69) v 23.99 (3-51), p =0.158	C = Non-C	
	Post intervention	MLHFQ	N/R, p = -.47	C = Non-C	
		MOS SF-36	N/R	N/R	

Statistical test: Student’s t-test, statistical significance *p* < 0.05

Doughty 2002	Baseline Total	MLHFQ	50.4 (25.7) v 44.7 (25.3), p = 0.12	P = Non-P	
	12 months	MLHFQ Total	29.5 (22.4) v 28.8 (23.2), p = 0.85	P = Non-P	
	Baseline	MLHFQ Physical	26.6 (12.1) v 24.7 (12.6), p = 0.29	P = Non-P	p value calculated using STATA 15
	12 moths	MLHFQ Physical	14.3 (10.8) v 16.4 (13.4), p = 0.31	P = Non-P	

	Baseline	MLHFQ Emotional	10.8 (7.9) v 9.3 (7.8), p = 0.18	P = Non-P	
	12 months	MLHFQ Emotional	7 (6.9) v 5.3 (5.7), p = 0.12	P = Non-P	

Statistical test: Student’s t-test, statistical significance $p < 0.05$

Deek 2016	Baseline	SF-12 PCS	35(7) v 35 (7), p =0.97	C = Non-C	
	Baseline	SF-12 MCS	46(12) v 48 (12), p = 0.46	C = Non-C	
	30 Days	SF-12 PCS	37.2 (4.7) v 37.4 (4.7), p = 0.77	C = Non-C	
	30 Days	SF-12 MCS	53.9 (12.6) v 54.6 (11.7), p =0.25	C = Non-C	

Statistical test: Student’s t-test, statistical significance $p < 0.05$

Bocchi 2008	Baseline	MLHFQ	57 (15) v 50 (15), p = 0.00	P > Non-P	Baseline score estimated from Figure 4 p value calculated from STATA 15
	12 months	MLHFQ	29 (20) v 39 (22), p = 0.00	P > Non-P	
	36 months	MLHFQ	26 (19) v 29 (18), p = 0.15	P = Non-P	
	60 months	MLHFQ	32 (19) v 48 (32), p = 0.00	P > Non-P	

Statistical test: Two-way analysis of variance with repeated measures on time, statistical significance $p < 0.05$

Hasanpour 2016	Baseline	SF-36	61.01 (14.9) v 62.34 (11.25), p > 0.05	C = Non-C	p values calculated using

3 months	SF-36	63.34 (12.69) v 58.43 (8.67), p < 0.05	C > Non-C	STATA 15
Baseline	SF-36 Physical performance	53.2 (8.87) v 52.2 (7.85), p = 0.57	C = Non-C	
3 months	SF-36 Physical performance	56.12 (10.19) v 49.92 (7.24), p = 0.001	C > Non-C	
Baseline	SF-36 Activity limitation – emotional problem	66.9 (12.39) v 68.84 (10.3), p = 0.42	C = Non-C	
3 months	SF-36 Activity limitation – emotional problem	57.12 (10.14) v 75.26 (9.26), p = 0	C > Non-C	
Baseline	SF-36 Activity limitation – physical problem	56.32 (10.23) v 54.9 (7.71), p 0.45	C = Non-C	
3 months	SF-36 Activity limitation – physical problem	52.1 (10.25) v 62.32 (6.2), p = 0	C > Non-C	
Baseline	SF-36 Fatigue	54.98 (12.62) v 55.43 (11.67), p = 0.86	C = Non-C	
3 months	SF-36 Fatigue	51.78 (16.29) v 60.76 (10.28), p = 0.002	C > Non-C	
Baseline	SF-36 Mental Health	61.12 (16.83) v 62.9 (15.68), p = 0.58	C = Non-C	
3 months	SF-36 Mental Health	66.56 (15.12) v 61.9 (12.2), p = 0.11	C = Non-C	
Baseline	SF-36 Social Performance	65.92 (15.71) v 67.82 (15.68), p = 0.35	C = Non-C	

3 months	SF-36 Social Performance	71.89 (16.96) v 67.13 (12.28), p = 0.13	C= Non-C	
Baseline	SF-36 Physical pain	70.1 (18.47) v 71.28 (13.55), p = 0.73	C = Non-C	
3 months	SF-36 Physical pain	66.12 (16.13) v 78.12 (15.5), p = 0	C > Non-C	
Baseline	SF-36 General health	74.62 (16.24) v 72.33 (15.5), p =0.49	C = Non-C	
3 months	SF-36 General health	76.12 (16.13) v 68.12 (15.5), p =0.01	C > Non-C	

Statistical test: Independent and paired t-test., statistical significance *p* < 0.05

Bischoff 2012

Baseline	SGRQ	5.1 (0.94) v 5.26 (0.81), p = 0.34	P = Non-P	p values calculated using STATA 15
6 months	SGRQ	5.38 (1.79) v 5.45 (1.85), p = 0.84	P = Non-P	
12 months	SGRQ	5.3 (2.29) v 5.3 (2.14), p = 1	P < Non-P	
18 months	SGRQ	5.18 (2.18) v 5.5 (1.77), p = 0.39	P = Non-P	
24 months	SGRQ	5.09 (1.89) v 5.44 (1.57), p = 0.33	P = Non-P	

Statistical test: Generalised estimating equations logistic regression model with compound symmetry to estimate differences in clinically important improvements, statistical significance *p* < 0.05

Jonsdottir 2015

Baseline	SGRQ	35.93 (20.37) v 34.55 (17.81), p = 0.71	C = Non-C	Baseline p value calculated using STATA 15
Post Intervention	SGRQ	37.32 (19.11) v 36.27 (19.42), p = 0.75	C = Non-C	

Statistical test: Independent group t-test and the Chi-squared test, statistical significance *p* < 0.05

Billington 2014

Baseline	CAT	15.56 (6.8) v 13.94 (7.44), p = 0.34	P = Non-P	Baseline p value calculated using STATA 15
12 weeks	CAT	12.44 (6.46) v 13.46 (8.04), p = 0.053* *Adjusted p value. Unadjusted p = 0.021	P = Non-P P > Non-P	

Statistical test: Paired t-tests, statistical significance $p < 0.05$

Farquhar 2016

T1	CRQ Dyspnea	3.11 (0.91) v 3.06 (0.92), p = 0.8	C = Non-C	p value calculated using STATA 15
T2	CRQ Dyspnea	3.35 (0.81) v 3.27 (0.93), p = 0.68	C = Non-C	
T3	CRQ Dyspnea	3.59 (0.99) v 3.41 (0.99), p = 0.42	C = Non-C	
T4	CRQ Dyspnea	N/A v 3.6 (1.08). Intervention group completed at this time point. Follow up at T5		
T5	CRQ Dyspnea	3.86 (1.03) v 3.67 (1.16), p = 0.47	C = Non-C	
T1	CRQ fatigue	3.15 (0.96) v 2.75 (1.18), p = 0.08	C = Non-C	
T2	CRQ fatigue	3.44 (1.01) v 2.9 (1.11), p = 0.02	C > Non-C	
T3	CRQ fatigue	3.27 (0.98) v 3.04 (1.22), p = 0.34	C = Non-C	
T4	CRQ fatigue	N/A v 3.05 (1.16). Intervention group completed at this time point. Follow up at T5		
T5	CRQ fatigue	3.73 (0.88) v 3.15 (1.09), p = 0.01	C > Non-C	
T1	CRQ emotional	3.95 (1.05) v 3.78 (1.18), p = 0.48	C = Non-C	
T2	CRQ emotional	4.3 (1.11) v 4.06 (1.06), p = 0.32	C = Non-C	
T3	CRQ emotional	4.42 (1.18) v 4.24 (1.06), p = 0.48	C = Non-C	
T4	CRQ emotional	N/A v 4.3 (1.3). Intervention group completed at this time point. Follow up at T5		

T5	CRQ emotional	4.35 (1.11) v 4.49 (1.05), p = 0.58	C = Non-C
T1	CRQ mastery	3.87 (1.28) v 3.9 (1.33), p = 0.91	C = Non-C
T2	CRQ mastery	4.43 (1.29) v 4.02 (1.25), p = 0.15	C = Non-C
T3	CRQ mastery	4.49 (1.35) v 4.23 (1.16), p = 0.36	C = Non-C
T4	CRQ mastery	N/A v 4.42 (1.29). Intervention group completed at this time point. Follow up at T5	
T5	CRQ mastery	4.71 (1.1) v 4.69 (1.13), p = 0.94	C = Non-C
2 wks.	EQ-5D	0.49 (N/R) v 0.55 (NR), p = N/R	N/R
4 wks.	EQ-5D	0.58 (N/R) v 0.58 (NR), p = N/R	N/R
6 wks	EQ-5D	0.59 (N/R) v 0.54 (N/R), p = N/R	N/R

Statistical test: Intention-to-treat analyses using a linear regression model, statistical significance *p* < 0.05

Kalter-Leibovici 2017	Baseline	SF36 Physical	**Median (IQR)** 38 (27 - 53) v 41 (30 - 54), p = 0.1	P = Non-P	p value calculated using
		SF36 Mental	46 (37 - 58) v 48 (38 - 58), p = 0.13	P = Non-P	STATA 15
	6 months	SF36 Physical	45 (32 - 61) v 45 (32 - 62), p = 1	P < Non-P	
		SF36 Mental	51 (40 - 63) v 48 (38 - 62), p = 0.11	P = Non-P	
	12 months	SF36 Physical	46 (33 - 63) v 46 (32 - 61), p = 1	P < Non-P	

	SF36 Mental	52 (40 - 64) v 50 (39 - 62), p = 0.31	P = Non-P
18 months	SF36 Physical	47 (32 - 64) v 47 (33 - 61), p = 1	P < Non-P
	SF36 Mental	51 (40 - 64) v 52 (40 - 64), p = 0.64	P = Non-P
24 months	SF36 Physical	46 (32 - 63) v 44 (32 - 61), p = 0.49	P = Non-P
	SF36 Mental	53 (41 - 65) v 50 (39 - 64), p = 0.21	P = Non-P
30 months	SF36 Physical	43 (31 - 64) v 46 (31 - 64), p = 0.42	P = Non-P
	SF36 Mental	50 (40 - 63) v 49 (40 - 64), p = 0.71	P = Non-P
36 months	SF36 Physical	46 (33 - 65) v 46 (32 - 65), p = 1	P < Non-P
	SF36 Mental	56 (43 - 65) v 52 (41 - 67), p = 0.21	P = Non-P
42 months	SF36 Physical	47 (32 - 65) v 48 (31 - 67), p = 0.85	P = Non-P
	SF36 Mental	53 (42 - 65) v 53 (41 - 67), p = 1	P < Non-P

48 months	SF36 Physical	48 (28 - 67) v 52 (37 - 65), p = 0.58	P = Non-P
	SF36 Mental	52 (38 - 66) v 55 (44 - 66), p = 0.52	P = Non-P
54 months	SF36 Physical	46 (31 - 74) v 45 (40 - 68), p = 0.94	P = Non-P
	SF36 Mental	55 (46 - 69) v 54 (45 - 67), p = 0.91	P = Non-P

Statistical test: Dichotomously categorized to represent a minimal clinically important difference from baseline, (≥2.5 points increase), non-liner mixed models with random intercept to demonstrate treatment OR.

Srisuk 2016

Baseline	MLHFQ	50.2 (2.5) v 53 (2.5) **Mean difference (CI)** -2.8 (-7.8, 2.1), p = 0.255	C = Non-C
3 months	MLHFQ	50.3 (2.2) v 53 (2.2) **Mean difference (CI)** -2.7 (-7.1, 1.6), p = 0.221	C = Non-C
6 months	MLHFQ	52 (2) v 55 (2) **Mean difference (CI)** -3.0 (-7.1, 1.0), p = 0.139	C = Non-C
Baseline	MLHFQ Emotional	11.8 (0.9) v 12 (0.9) **Mean difference (CI)** -1.2 (-2.9, 0.5), p = 0.173	C = Non-C
3 months	MLHFQ Emotional	11.5 (0.7) v 13.2 (0.7) **Mean difference (CI)** -1.7 (-3.0, - 0.3), p = 0.014	C > Non-C

	6 months	MLHFQ	12.1 (0.6) v 13.6 (0.6) **Mean difference (CI)** -1.5 (-2.8, -0.3), p = 0.015		C > Non-C	
	Baseline	MLHFQ Physical	19.8 (1.1) V 19.9 (1.1) **Mean difference (CI)** -0.1 (-2.2, 2.0), p = 0.925		C = Non-C	
	3 months	MLHFQ Physical	52.1 (1.5) v 49.3 (1.5) **Mean difference (CI)** 0.0 (-2.0, 2.0), p = 0.991		C = Non-C	
	6 months	MLHFQ	19.6 (0.9) v 20 (0.9) **Mean difference (CI)** -0.4 (-2.2, 1.4), p = 0.683		C = Non-C	

Statistical test: T-test and effect size, between group difference over time analysed using a linear mixed effects model, statistical significance *p* < 0.05

Clark 2015	Time 1	KCCQ Physical Limitations	54.10 (27.22) v 62.23 (28.25)			
	Time 2	KCCQ Physical Limitations	59.1 (28.2) v 61.78 (27.28)			
	Time 3	KCCQ Physical Limitations	61.28 (26.93) v 60 (27.18)			
	Time 4	KCCQ Physical Limitations	58.6 (27.4) v 64.58 (25.27)	p = 0.367	P = Non-P	P value = time x group
	Time 1	KCCQ Total symptom score	60.92 (27.53) v 64.42 (24.37)			
	Time 2	KCCQ Total symptom score	71.88 (21.38) v 65.38 (25.23)			

Time 3	KCCQ Total symptom score	70.58 (23.27) v 66.33 (26.95)		
Time 4	KCCQ Total symptom score	64.08 (24.31) v 63.96 (26.98)	p = 0.427	P = Non-P
Time 1	KCCQ Self-efficacy subscale	73 (24.12) v 81 (17.35)		
Time 2	KCCQ Self-efficacy subscale	94.5 (8.9) v 88.5 (13.46)		
Time 3	KCCQ Self-efficacy subscale	92 (12.44) v 87.5 (13.5)		
Time 4	KCCQ Self-efficacy subscale	93 (11.46) v 86.5 (16.5)	p = 0.028	P > Non-P
Time 1	KCCQ QoL subscale	53.82 (28.34) v 63.67 (26.99)		
Time 2	KCCQ QoL subscale	71.53 (21.27) v 63.67 (25.1)		
Time 3	KCCQ QoL subscale	68.4 (24.69) v 65.33 (28.63)		
Time 4	KCCQ QoL subscale	69.79 (23.67) v 55.67 (31.71)	p = 0.018	P > Non-P
Time 1	KCCQ Social limitation subscale	59.15 (29.03) v 65.34 (25.87)		
Time 2	KCCQ			

	Social limitation subscale	69.93 (27.29) v 60.89 (24.83)		
Time 3	KCCQ Social limitation subscale	66.67 (28.5) v 56.16 (26.84)		
Time 4	KCCQ Social limitation subscale	61.78 (26.26) v 57.77 (28.33)	p = 0.072	P = Non-P
Time 1	KCCQ Overall summary scores	55.38 (23.98) v 63.08 (22.9)		
Time 2	KCCQ Social limitation subscale	67.23 (20.69) v 61.82 (21.13)		
Time 3	KCCQ Social limitation subscale	65.77 (21.6) v 61.53 (24.16)		
Time 4	KCCQ Social limitation subscale	62.61 (21.8) v 60.43 (24.12)	p = 0.035	P > Non-P

Statistical test: Repeated measures analysis of variance (ANOVA), statistical significance $p < 0.05$

Martensson

2005	Between group differences Baseline to 3 months	SF36 Physical Component scale	-3 (NR), p = NR	
		SF36 Physical functioning	-5.5 (NR), p = NR	
		SF36 Role – physical	-22 (1.44), p = 0.008	C > Non-C
		SF36 Bodily pain	-5 (NR), p = NR	

	SF36 General health	-5.1 (NR), p= NR	
	SF36 Mental component scale	-5 (NR), p = NR	
	SF36 Vitality	-6.7 (3.46), p = 0.051	C = Non-C
	SF36 Social functioning	-10 (2.275), p = 0.056	C = Non-C
	SF36 Role – emotional	-21.3 (NR), p = NR	
	SF36 Mental health	-0.5 (NR), p = NR	
Between group differences Baseline to 12 months	SF36 Physical Component scale	-1.5 (NR), p = NR	
	SF36 Physical functioning	-6.5 (NR), p = NR	
	SF36 Role physical	-5.4 (NR), p = NR	
	SF36 Bodily pain	-2.5 (NR), p = NR	
	SF36 General health	-2.6 (NR), p = NR	
	SF36 Mental component scale	-2.5 (NR), p = NR	

	SF36 Vitality	-3 (NR), p = NR	
	SF36 Social functioning	-7.5 (NR), p = NR	
	SF36 Role emotional	-14.5 (NR), p = NR	
	SF36 Mental health	-1.6 (NR), p = NR	
Within group differences Baseline to 3 months	MLHFQ Physical health	-2.3 (NR) v -0.3 (NR), p = NR	
	MLHFQ Emotional scale	-0.9 (NR) v 0.2 (NR), p = NR	
	MLHFQ Total	-3.2 (NR) v 1.5 (NR), p =NR	
Within group Difference Baseline to 12 months	MLHFQ Physical health	-0.1 (NR) v 0.5 (NR), p = NR	
	MLHFQ Emotional scale	-0.1 (NR) v 0.1 (NR), p = NR	
	MLHFQ Total	-2.1 (NR) v 2.9 (NR), p = NR	

Statistical test: Student's t test, Wilcoxon matched pairs text for within group comparison, statistical significance *p* < 0.05

Andryukhin 2010 Baseline	MLHFQ Total	**Median (IQR)** 54.5 (44-59) v 58 (49-65), p = 0.44	P = Non-P

	Baseline	MLHFQ Physical	22.5 (18-25) v 23 (20-27), p = 0.8	P = Non-P	p value calculated using STATA after imputing mean & SD
	Baseline	MLHFQ Emotional	7 (7-11) v 11 (9-14), p = 0	P > Non-P	
	6 months	MLHFQ Total	44.5 (15-47) v 61 (55 -70), p = 0	P > Non-P	
	6 months	MLHFQ Physical	18 (15 -21) v 26 (21-28), p = 0	P > Non-P	
	6 months	MLHFQ Emotional	6 (5-9) v 13 (10 – 15), p = 0	P > Non-P	

Statistical test: Mann Whitney *U* test, statistical significance $p < 0.05$

Witham 2015	Baseline	EQ-5D	**Median (IQR)** 0.73 (0.23) v 0.76 (0.24)		
	Week 8	EQ-5D	NR		
	Week 24	EQ-5D	NR		
	Baseline	MLHFQ	15 (22) v 8 (12)		
	Week 8	MLHFQ	NR		
	Week 24	MLHFQ	**Mean (SD)** 13.4 (10.2) v 13.3(10.2), p = 0.96	C = Non-C	0.96 calculated using STATA 15
	Change between Baseline to 8 weeks	EQ-5D	**Mean difference (CI)** 0.08 (-0.02 to 0.17), p = 0.11	C = Non-C	

Baseline to 24 weeks	EQ-5D	0.07 (-0.03 to 0.16), p = 0.15	C = Non-C	
Change between Baseline to 8 weeks	MLHFQ	1.4 (-1.9 to 4.7), p = 0.41	C = Non-C	
	MLHFQ	0.1 (-4.4 to 4.6), p = 0.95	C = Non-C	
Statistical test: Intention to treat analysis, ANOVA analysis to compare change in scores, statistical significance $p < 0.05$				
Rich 1995				
Baseline	Chronic HF Questionnaire	72.1 (15.6) v 74.4 (16.3), p = 0.42	P = Non-P	
90 days	Chronic HF Questionnaire	94.3 (21.3) v 85.7 (19), p = 0.01	P > Non-P	p value calculated using STATA 15
Baseline	Chronic HF Questionnaire Dyspnea subscale	9 (7.9) v 8.1 (7.7), p = 0.51	P = Non-P	
90 days	Chronic HF Questionnaire Dyspnea subscale	15.8 (12.8) v 11.9 (10), p = 0.06	P = Non-P	
Baseline	Chronic HF Questionnaire Fatigue	12.9 (5.3) v 14.1 (5.6), p = 0.21	P = Non-P	
90 days	Chronic HF Questionnaire Fatigue	18.3 (6.3) v 16.8 (5.5), p = 0.15	P = Non-P	
Baseline	Chronic HF Questionnaire Emotional function	31.9 (8.5) v 33.3 (8.1), p = 0.34	P = Non-P	
90 days	Chronic HF Questionnaire Emotional function	37.4 (7.8) v 35.2 (8.4), p = 0.13	P = Non-P	
Baseline	Chronic HF Questionnaire Environmental mastery	18.3 (5.8) v 18.9 (4.8), p = 0.53	P = Non-P	
90 days	Chronic HF Questionnaire			

		Environmental mastery	22.7 (4.9) v 21.7 (4.6), p = 0.24	P = Non-P	

Statistical test: Student’s t-test (normally distributed data) Wilcoxon rank-sum test (non-normal distributed data), statistical significance $p < 0.05$

Cline 1998	Baseline	Quality of life in HF	4.5 (1) v 4.2 (1.1), p = 0.005	C > Non-C	
	One year	Quality of life in HF	3.5 (1.3) v 3.5 (1.1), p = 1	C < Non-C	p value calculated using STATA 15
	Baseline	Nottingham Health profile	30.1 (21.6) v 26.9 (21.2), p = 0.309	C = Non-C	
	One year	Nottingham Health profile	25.3 (22.2) v 23.4 (22.2), p = 0.62	C = Non-C	
	Baseline	MLHFQ	4.3 (1.5) v 3.7 (1.6), p = 0.009	C > Non-C	
	One year	MLHFQ	3.3 (1.4) v 3.2 (1.6), p = 0.7	C = Non-C	

Statistical test: Two tailed t test (normally distributed data), Mann-Whitney *U* test (non-normal distributed data) statistical significance $p < 0.05$

Categorisation of effect:
C = Non-C: Patient and caregiver intervention group is equal to patient and caregiver control group = 115 (85%)
C > Non-C: Patient and caregiver intervention group statistically superior = 18 (13%)
C < Non-C: Patient and caregiver control group statistically superior = 3 (2%)

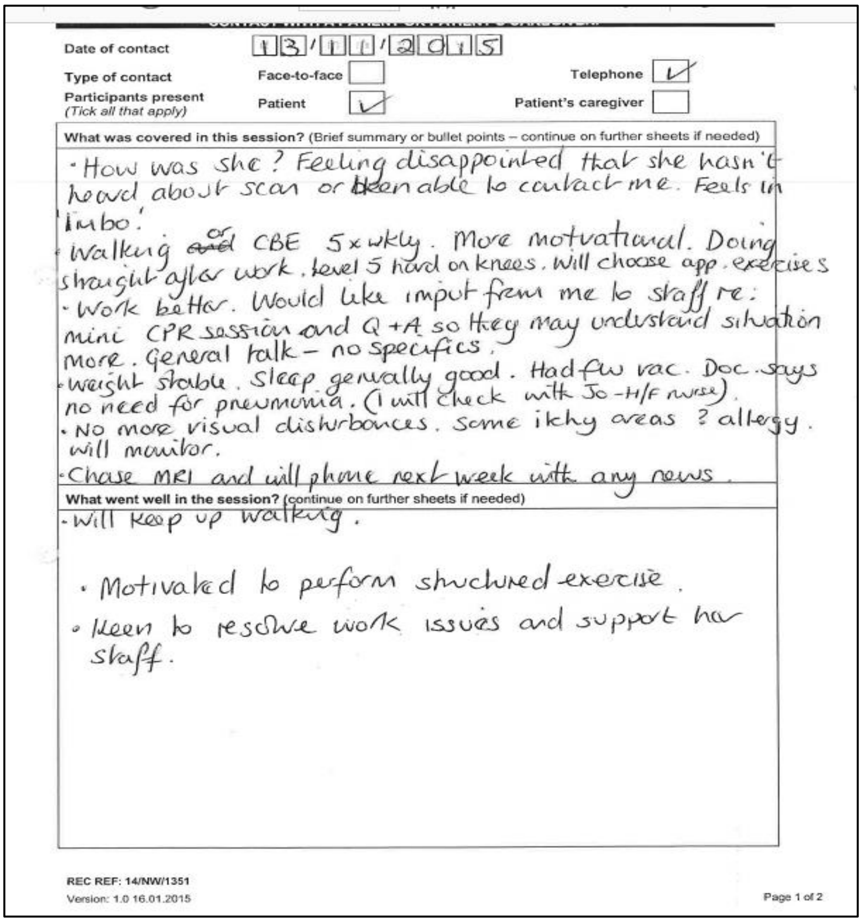
P = Non-P: Patient intervention group is equal to patient control group = 83 (80%)
P > Non-P: Patient intervention group statistically superior = 13 (13%)
P < Non-P: Patient control group statistically superior = 7 (7%)

Abbreviations:
Pt. – patient
Cg. – caregiver
SD – Standard Deviation

I - intervention
C – Control
MLHHFQ – Minnesota Living with Heart Failure Questionnaire
SF-36 – Short Form 36
SF-PCS – Short Form Physical Component Scale
SF-MCS – Short Form Mental Component Scale
SF-36 -PF – Short Form Physical Functioning
SF-36-RP – Short Form 36 Role Physical
SF-36-BP – Short Form 36 Bodily Pain
SF-36-GH – Short Form 36 General Health
SF-36-VT – Short Form 36 Vitality
SF-36-SF – Short Form 36 Social Functioning
SF-36-REShort Form 36 Role Emotional
SF-36-MH – Short Form 36 Mental Health
KCCQ – Kansas City Cardiomyopathy Questionnaire
CRQ – Chronic Respiratory Questionnaire
CCQ – Clinical COPD Questionnaire (COPD – Chronic Obstructive Pulmonary Disease)
SGRQ – St. Georges Respiratory Questionnaire
N/R – Not reported
MOS SF-3F – Medical Outcomes Study Short Form 36
SF-12 PCS – Short Form 12 Physical Component Scale
SF-12 MCS - Short Form 12 Mental Component Scale
CAT – COPD Assessment Test
T1 – Time 1, T2 – Time 2, T3 – Time 3, T4 – Time 4
N/A – Not applicable
Wks – weeks
EQ-5D – EuroQol measure
HF – Heart Failure

Appendix 12 Facilitator Contact Sheet

Example:



Date of contact 13/11/2015

Type of contact Face-to-face ☐ Telephone ☑

Participants present *(Tick all that apply)* Patient ☑ Patient's caregiver ☐

What was covered in this session? (Brief summary or bullet points – continue on further sheets if needed)

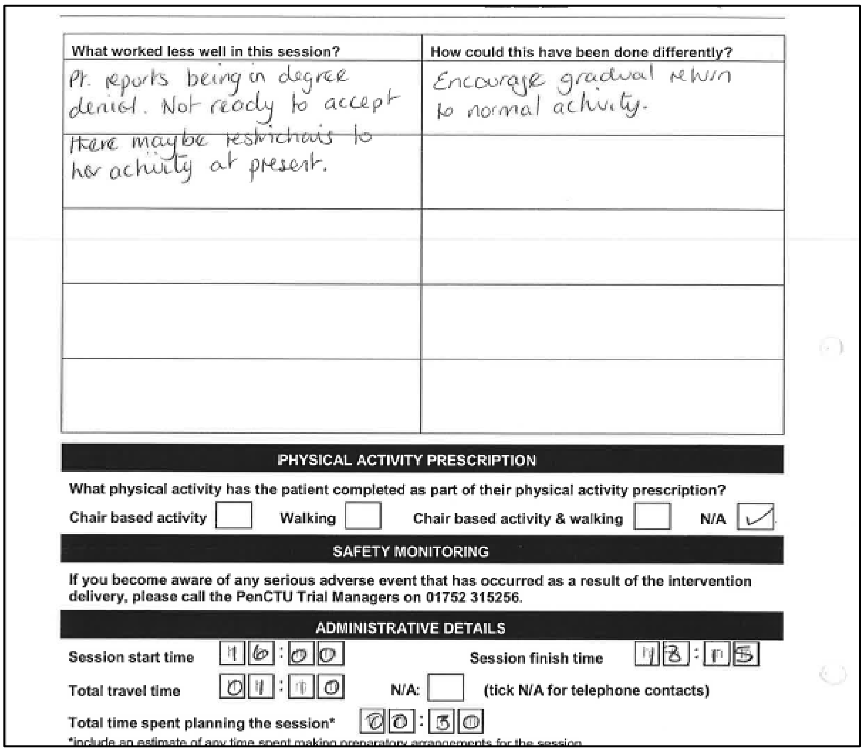
- How was she? Feeling disappointed that she hasn't heard about scan or been able to contact me. Feels in limbo!
- Walking ~~and~~ or CBE 5x wkly. More motivational. Doing straight after work. Level 5 hard on knees. Will choose app. exercises
- Work better. Would like input from me to staff re: mini CPR session and Q+A so they may understand situation more. General talk – no specifics.
- Weight stable. Sleep generally good. Had flu vac. Doc. says no need for pneumonia. (I will check with Jo – H/F nurse).
- No more visual disturbances. Some itchy areas ? allergy. Will monitor.
- Chase MRI and will phone next week with any news.

What went well in the session? (continue on further sheets if needed)

- Will keep up walking.
- Motivated to perform structured exercise.
- Keen to resolve work issues and support her staff.

REC REF: 14/NW/1351
Version: 1.0 16.01.2015

Page 1 of 2



What worked less well in this session?	How could this have been done differently?
Pt. reports being in degree denial. Not ready to accept	Encourage gradual return to normal activity.
there maybe restrictions to her activity at present.	

PHYSICAL ACTIVITY PRESCRIPTION

What physical activity has the patient completed as part of their physical activity prescription?

Chair based activity ☐ Walking ☐ Chair based activity & walking ☐ N/A ☑

SAFETY MONITORING

If you become aware of any serious adverse event that has occurred as a result of the intervention delivery, please call the PenCTU Trial Managers on 01752 315256.

ADMINISTRATIVE DETAILS

Session start time 16:00 Session finish time 18:15

Total travel time 01:10 N/A: ☐ (tick N/A for telephone contacts)

Total time spent planning the session* 00:30

*include an estimate of any time spent making preparatory arrangements for the session

Appendix 13 Data Sharing Work Instructions for REACH-HF research team and PhD students

Data Sharing Work Instructions
For REACH-HF research team and our PhD students

Introduction

Patients and caregivers have consented to the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) randomised controlled trial and associated Process Evaluation. RCHT through the RD&I department is the sponsor of the research.

Data has been collected and analysed to address the primary research question. The relevant sections of the data are held at the Peninsula Clinical Trials unit held by Plymouth University, and with the University of Exeter Medical School process evaluation team. This is in line with the expectations of the funder the National Institute of Health Research (NIHR), contracts between RCHT and these organisations, and the research governance framework.

While research addresses the research questions and problems posed, the data commonly indicates that there are other questions that could be addressed. The funding body now expects that the research teams make anonymised data available where possible, for other questions rather than funding new data collection, particularly as conducting research is expensive. There is an ethical argument that we should not be asking patients and caregivers to take part in research unnecessarily.

We wish to put in place some work instructions for members of the REACH-HF team including our PhD students who want to access the data collected during the study, these instructions will safeguard and manage the data. There will be a separate discussion about data being made available to research teams outside of the group.

Instructions

1. A protocol for the research proposal must be sent to the Co-chief investigators – Professor Rod Taylor and Associate Professor Hayes Dalal
2. The Co-Chief Investigators with Dr Jennifer Wingham will review the proposal to determine if the REACH-HF data set will be able to address the research question and that the methodology is appropriate.
3. This proposal should confirm that the project is being submitted for ethics review
4. Relevant sections of anonymised REACH-HF data will be shared if the proposal is accepted. Pseudo-anonymised data will not be shared from the 25th May 2018.
5. Data will be shared through encrypted memory sticks or through use of the secure NHS email system following the Information Governance policy.
6. This data must be stored only on encrypted password protected laptops or secure servers provided by the employing institution
7. There will no return to patients and caregivers to collect new data

8. No additional clinical data from trust clinical databases will be provided to address the research question
9. A final report and any publications of the project must be shared with the REACH-HF co-Chief Investigators and the Sponsor.
10. The data should be archived according to local policy and any relevant regulations.

Appendix 14 Univariate regression analysis - The predictors of health-related quality of life for caregivers of HF patients in REACH-HF

Variables	Unstandardized beta coefficient (95% CI)	P-value
HADS – Anxiety N=117		
Patient Factors		
NYHA	1.9 (0.9 to 2.9)	< 0.0001
HFpEF or HFrEF	-3.8 (-5.6 to -2.1)	< 0.0001
Age	-0.0 (-0.1 to 0.1)	0.612
Gender		
Main activity: Unemployed Unpaid Occupation (student/housework/volunteer) Retired (Age/ill health)	 **4.9 (0.9 to 9.0)** 4.3 (-3.4 to 12.2) **2.7 (0.4 to 5.1)**	 **0.017** 0.273 **0.024**
Continued education	-0.1 (-1.6 to 1.3)	0.845
Degree	0.1 (-1.4 to 1.7)	0.851
No. of Comorbidities	**1.0 (0.2 to 1.8)**	**0.014**
Years of HF Diagnosis	0.0 (-0.1 to 0.2)	0.605
Live alone	0.7 (-1.4 to 2.8)	0.503
Caregiver age	-0.0 (-0.1 to 0.0)	0.505
Caregiver gender	0.6 (-1.1 to 2.3)	0.484
Caregiver continued education	0.2 (-1.2 to 1.6)	0.799
Caregiver main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 -1.1 (-4.7 to 2.6) **4.7 (0.1 to 9.2)** -0.7 (-2.3 to 0.9)	 0.568 **0.045** 0.387
Caregiver degree	0.2 (-1.3 to 1.8)	0.753
HADS – DEPRESSION N = 102		
Patient Factors		
NYHA	0.9 (-0.4 to 2.2)	0.169
Trial	1.7 (-0.5 to 3.9)	0.127
Patient Age	-0.0 (-0.1 to 0.0)	0.521
Patient Gender	-1.5 (-3.5 to 0.4)	0.129
Patient Main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 5.6 (-1.3 to 12.5) 6.1 (-3.2 to 15.4) -0.4 (-3.5 to 2.7)	 0.111 0.197 0.815
Continued education	0.3 (-1.5 to 2.0)	0.769
Degree	0.3 (-1.6 to 2.2)	0.762
No. of Comorbidities	0.2 (-0.8 to 1.2)	0.727
Years of HF Diagnosis	0.2 (-0.1 to 0.4)	0.147
Live alone	-2.7 (-5.5 to 0.2)	0.065
Caregiver Factors		
Caregiver age	0.0 (-0.1 to 0.1)	0.840
Caregiver gender	-0.1 (-2.3 to 2.1)	0.923
Caregiver continued education	0.9 (-0.8 to 2.7)	0.291
Caregiver main activity: Unemployed	 1.4 (-3.3 to 6.2)	 0.549

Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	**5.9 (0.4 to 11.3)** 1.0 (-1.0 to 3.1)	**0.035** 0.327
Caregiver degree	-0.3 (-2.2 to 1.6)	0.758
FAMQOL **N = 117**		
Patient Factors		
NYHA	**-3.3 (-5.9 to -0.7)**	**0.015**
Trial	0.6 (-4.0 to 5.4)	0.781
Patient Age	0.1 (-0.5 to 0.2)	0.175
Patient Gender	**4.3 (0.5 to 8.2)**	**0.026**
Patient Main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 -9.8 (-19.9 to 0.5) 8.2 (-11.5 to 28.1) 0.4 (-5.7 to 6.4)	 0.061 0.410
Continued education	-1.4 (-4.9 to 2.1)	0.424
Degree	-1.0 (-4.8 to 2.8)	0.611
No. of Comorbidities	-1.9 (-3.9 to 0.1)	0.071
Years of HF Diagnosis	**-0.4 (-0.8 to -0.1)**	**0.042**
Live alone	-0.3 (-5.7 to 4.9)	0.892
Patient Factors		
Caregiver age	-0.3 (-0.1 to 0.0)	0.578
Caregiver gender	-3.2 (-7.5 to 0.9)	0.129
Caregiver continued education	1.1 (-2.3 to 4.7)	0.507
Caregiver main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 4.2 (-5.0 to 13.5) -7.7 (-19.4 to 3.9) -1.4 (-5.6 to 2.7)	 0.365 0.191 0.489
Caregiver degree	-0.8 (-4.6 to 3.0)	0.675
EQ5D5L **N = 117**		
Patient Factors		
NYHA	**-0.7 (-1.2 to -0.2)**	**0.004**
Trial	0.0 (-0.0 to 0.1)	0.210
Patient Age	-0.0 (-0.0 to 0.0)	0.750
Patient Gender	0.0 (-0.0 to 0.1)	0.094
Patient Main activity: Unemployed Unpaid occupation (student/housework/volunteer) Retired (age/ill health)	 -0.1 (-0.3 to 0.1) -0.1 (-0.4 to 0.3) -0.0 (-0.1 to 0.1)	 0.274 0.713 0.831
Continued education	0.0 (-0.0 to 0.1)	0.212
Degree	0.0 (-0.0 to 0.1)	0.073
No. of Comorbidities	-0.0 (-0.0 to 0.0)	0.119
Years of HF Diagnosis	-0.0 (-0.0 to 0.0)	0.489
Live alone	**-0.1 (-0.2 to -0.0)**	**0.040**
Caregiver Factors		
Caregiver age	-0.0 (-0.0 to 0.0)	0.115
Caregiver gender	-0.0 (-0.0 to 0.0)	0.925
Caregiver continued education	0.0 (-0.0 to 0.1)	0.079
Caregiver main activity:		

Unemployed	-0.1 (-0.2 to 0.1)	0.548
Unpaid occupation (student/housework/volunteer)	-0.1 (-0.3 to 0.1)	0.549
Retired (age/ill health)	-0.0 (-0.1 to 0.0)	0.153
Caregiver degree	0.0 (-0.6 to 0.7)	0.942
CBQ PHYSICAL **N = 117**		
Patient Factors		
NYHA	**2.1 (0.9 to 3.3)**	**0.001**
Trial	-0.3 (-2.6 to 1.8)	0.720
Patient Age	-0.0 (-0.1 to 0.0)	0.307
Patient Gender	**-1.9 (-3.7 to -0.1)**	**0.033**
Patient Main activity:		
Unemployed	**5.9 (1.2 to 10.6)**	**0.014**
Unpaid occupation (student/housework/volunteer)	-1.3 (-10.4 to 7.9)	0.783
Retired (age/ill health)	0.3 (-2.5 to 3.1)	0.832
Continued education	-0.2 (-1.9 to 1.3)	0.733
Degree	0.1 (-1.6 to 1.9)	0.856
No. of Comorbidities	0.8 (-0.1 to 1.8)	0.085
Years of HF Diagnosis	0.0 (-0.1 to 0.2)	0.385
Live alone	0.2 (-2.2 to 2.7)	0.833
Caregiver Factors		
Caregiver age	0.0 (-0.0 to 0.0)	0.779
Caregiver gender	0.9 (-1.0 to 2.9)	0.351
Caregiver continued education	-0.7 (-2.3 to 0.9)	0.395
Caregiver main activity:		
Unemployed	-0.5 (-4.8 to 3.8)	0.829
Unpaid occupation (student/housework/volunteer)	3.4 (-2.0 to 8.8)	0.220
Retired (age/ill health)	0.6 (-1.3 to 2.6)	0.526
Caregiver degree	-0.8 (2.6 to 0.9)	0.346
CBQ EMOTIONAL **N = 117**		
Patient Factors		
NYHA	**4.9 (1.7 to 8.2)**	**0.003**
Trial	-2.2 (-8.1 to 3.5)	0.435
Patient Age	-0.1 (-0.3 to 0.0)	0.089
Patient Gender	-4.4 (-9.1 to 0.3)	0.068
Patient Main activity:		
Unemployed	**14.0 (1.4 to 26.6)**	**0.030**
Unpaid occupation (student/housework/volunteer)	1.0 (-23.4 to 25.4)	0.935
Retired (age/ill health)	1.5 (-5.6 to 9.3)	0.621
Continued education	-0.8 (-5.2 to 3.5)	0.702
Degree	1.0 (-3.7 to 5.8)	0.664
No. of Comorbidities	1.8 (-0.7 to 4.3)	0.160
Years of HF Diagnosis	0.2 (-0.2 to 0.8)	0.284
Live alone	0.6 (-5.9 to 7.1)	0.852
Caregiver Factors		
Caregiver age	0.0 (-0.1 to 0.1)	0.786
Caregiver gender	1.7 (-3.4 to 7.0)	0.505
Caregiver continued education	-1.4 (-5.8 to 2.9)	0.507

Caregiver main activity:		
Unemployed	-1.7 (-13.1 to 9.7)	0.768
Unpaid occupation (student/housework/volunteer)	11.3 (-2.9 to 25.7)	0.119
Retired (age/ill health)	0.9 (-4.1 to 6.1)	0.708
Caregiver degree	-1.9 (6.6 to 2.7)	0.410
CBQ SOCIAL **N = 117**		
Patient Factors		
NYHA	0.4 (-0.0 to 0.9)	0.068
Trial	-0.0 (-0.8 to 0.8)	0.989
Patient Age	-0.0 (-0.0 to 0.0)	0.078
Patient Gender	**-0.7 (1.4 to -0.1)**	**0.022**
Patient Main activity:		
Unemployed	**2.7 (0.9 to 4.4)**	**0.003**
Unpaid occupation (student/housework/volunteer)	2.3 (-1.1 to 5.6)	0.187
Retired (age/ill health)	0.3 (-0.7 to 1.4)	0.524
Continued education	0.4 (-0.1 to 1.1)	0.117
Degree	0.2 (-03 to 0.9)	0.413
No. of Comorbidities	0.1 (-0.2 to 0.4)	0.526
Years of HF Diagnosis	-0.0 (-0.0 to 0.0)	0.778
Live alone	0.0 (-0.8 to 0.9)	0.894
Caregiver Factors		
Caregiver age	0.0 (-0.0 to 0.0)	0.966
Caregiver gender	0.3 (-0.4 to 1.0)	0.377
Caregiver continued education	0.4 (-0.2 to 1.0)	0.203
Caregiver main activity:		
Unemployed	0.2 (-1.4 to 1.8)	0.810
Unpaid occupation (student/housework/volunteer)	1 (-1.0 to 3.0)	0.338
Retired (age/ill health)	0.2 (-0.6 to 0.9)	0.663
Caregiver degree	0.3 (-0.2 to 1.0)	0.262
CBQ LIFESTYLE **N = 117**		
Patient Factors		
NYHA	**1.1 (0.1 to 2.2)**	**0.023**
Trial	0.1 (-1.7 to 1.9)	0.902
Patient Age	-0.0 (-0.0 to 0.0)	0.533
Patient Gender	-1.0 (-2.5 to 0.4)	0.174
Patient Main activity:		
Unemployed	3.8 (-0.2 to 7.7)	0.058
Unpaid occupation (student/housework/volunteer)	-1.2 (-8.8 to 6.5)	0.761
Retired (age/ill health)	1.0 (-1.3 to 3.3)	0.395
Continued education	0.2 (-1.1 to 1.5)	0.771
Degree	0.5 (-0.8 to 2.0)	0.432
No. of Comorbidities	0.2 (-0.5 to 1.0)	0.474
Years of HF Diagnosis	0.0 (-0.0 to 0.2)	0.369
Live alone	0.1 (-1.8 to 2.2)	0.877
Caregiver Factors		
Caregiver age	0.0 (-0.0 to 0.0)	0.753
Caregiver gender	0.1 (-1.5 to 1.7)	0.888

Caregiver continued education	**-0.1 (-1.5 to 1.2)**	**0.829**
Caregiver main activity:		
Unemployed	-0.9 (-4.5 to 2.6)	0.605
Unpaid occupation (student/housework/volunteer)	4.1 (-0.4 to 8.5)	0.073
Retired (age/ill health)	0.3 (-1.3 to 1.9)	0.719
Caregiver degree	0.2 (-1.2 to 1.6)	0.784

Appendix 15 Within-group differences of caregiver outcomes

Outcome Measure **(Score range – best to worst)**	**4 months Mean within group difference Baseline v 4 months, Mean, (95% CI), p value**		**6 months Mean within group difference Baseline v 6 months, Mean, (95% CI), p value**	
	REACH-HF	**Control**	**REACH-HF**	**Control**
CBQ Physical (0-88)	-0.4 (-1.18 to 0.33), 0.264	0.2 (-0.75 to 1.14), 0.687	0.0 (-0.57 to 0.57),1.000	0.7 (-0.20 to 1.60), 0.126
CBQ Emotional (0-88)	0.0 (-1.53 to 1.60), 0.965	-0.4 (-2.44 to 1.65), 0.698	0.3 (-1.48 to 2.19), 0.702	1.6 (-0.81 to 4.11), 0.183
CBQ Social (0-88)	-0.4 (-0.83 to 0.05), 0.085	0.0 (-0.30 to 0.34), 0.896	0.0 (-0.28 to 0.32), 0.896	0.4 (-0.04 to to 0.96) 0.075
CBQ Lifestyle (0-88)	-0.4 (-1.10 to 0.29), 0.250	0.3 (-0.40 to 1.09), 0.356	-0.1 (-0.77 to 0.47), 0.623	**1.2 (0.35 to 2.06), 0.007**
FAMQoL Psychological (1-25)	0.4 (-0.44 to 1.24), 0.344	0.7 (-0.33 to 1.88), 0.167	0.0 (-0.82 to 0.83), 0.988	0.0 (-1.00 to 1.04), 0.967
FAMQoL Social (1-25)	0.0 (-0.86 to 0.93), 0.943	0.9 (-0.13 to 1.94), 0.086	-0.4 (-1.26 to 0.31), 0.232	0.0 (-0.96 to 0.98), 0.988
FAMQoL Physical (1-25)	0.3 (-0.43 to 1.02), 0.415	0.5 (-0.36 to 1.44), 0.234	-0.1 (-0.74 to 0.44), 0.608	-0.3 (-1.13 to 0.44), 0.387
FAMQoL Overall (1-100)	1.3 (-0.94 to 3.55), 0.250	**2.8 (0.33 to 5.32), 0.027**	-0.0 (-2.22 to 2.17), 0.983	0.0 (-2.18 to 2.38), 0.931
HADS Anxiety (0-21)	-0.3 (-1.09 to 0.31), 0.273	-0.6 (-1.36 to 0.15), 0.114	-0.5 (-1.19 to 0.02), 0.059	0.2 (-0.45 to 1.01), 0.454
HADS Depression (0-21)	0.9 (-0.40 to 2.32), 0.165	**1.8 (0.71 to 2.90), 0.002**	**-1.1 (-1.99 to -0.23), 0.014**	-0.0 (-0.92 to 0.83, 0.922
EQ-5D-5L (−0.285 to 1.00)	2.6 (-1.33 to 6.66), 0.185	-0.7 (-3.99 to 2.40), 0.617	-1.8 (-5.56 to 1.81), 0.310	-0.9 (-6.11 to 4.24), 0.715

Appendix 16 Interview Topic Guide

Topic	**Questions**	**Prompts**
Caregiver role pre-REACH-HF **2nd Interview**	**Pre-REACH-HF** Thinking back to before the programme started; can you describe your role in supporting your (husband, mother, son, and neighbour as relevant)? How did you learn what to do? What did you feel about your role? **During the last interview you said……** **How has your role changed since the last interview?** **What do you feel about your role?**	Specifically: emotional support, physical support, medicines management, supporting physical activity Explore other sources of learning about the role such as from heart failure specialist nurses, GP, hospital consultant, friends and family. Make it clear if talking about role pre, during or post-REACH-HF.
Engagement with the intervention	Before you started, what were your expectations of the REACH-HF programme?	Expect and explore ambivalence, uncertainty, reluctance, expectation of help and support. Explore priorities and goals.
Impact of the REACH-HF programme	**During REACH-HF** What sections of the manual and resource did you use and why? Which sections were not used and why? What did you learn from the programme? **Post-REACH-HF** How did the programme affect your role in supporting your ***? How has being involved in REACH-HF affected your	How were the sections used? Was there anything you did not like about the REACH-HF programme? What learning has been put into practice?

 2nd Interview	involvement in appointments with other health professionals including consultants or specialist nurses or GP? Has the programme changed the way you think or feel about your role? (Key question, confidence, sense of burden) **Have you used the manual or friends and family resource since the last interview? How what and why used?** **Where else have you looked for information about the condition or your role?** **Internet, GP, nurse** **How do you feel about your role now? (Look for evidence of development of expertise and confidence)**	Look for signs of development of expertise. How does the caregiver feel about becoming an ‘expert’ in managing heart failure? **Control/agency** **Medicines** **Stress/anxiety** **Exercise** **Symptom monitoring and control**
Relationship with cared for person **2nd Interview**	Tell me about any discussions with the person you are caring for about how you may support them in managing his/her heart failure? Since you started the REACH-HF programme, has what you do to support (name of cared for person) affected your relationship? **Has anything changed about your relationship with the person you are caring for?** **How do you fell about it?** **Is there anything that stops you doing your role?** **Is there anything that helps you do your role?**	What did the caregiver do to cope with resistance? (Where present) How did they manage their own feelings? What if anything has changed in the way you manage heart failure together?
Relationship with Reach-HF facilitator	Can you describe how the facilitator worked with you?	Explore the difference between the caregiver being included or just watching on.

2nd Interview	What did you like or dislike about how the facilitator worked with you? How were your needs included in the sessions? How do you feel now the facilitator is no longer in contact? **Have you been in contact with the facilitator?** **How do you feel now the facilitator is no longer in contact?** **Explore potential abandonment**	Did the facilitator show that he/she cared about the caregiver?

Appendix 17 Field notes template

Field notes –

Date of interview:

Start time: **Finish time**:

Location:

People present:

First impressions e.g. physical state of house/room, what's in the room e.g. other people, pets, how received? Friendly, nervous etc? Offered refreshments?

Atmosphere:

Interruptions:

Carer & cared for relationship: verbal & non-verbal communication etc?

Other information

How did interview go? Interviewer's assessment of their performance & influence, how caregiver responded & main points arising from interview

Summary

1.

Appendix 18 Fidelity Measure template

REACH-HF FIDELITY MEASURE

The rating scale

The six point scale (i.e. a 0-6 Likert scale) extends from (0) where the facilitator did not deliver the intervention element appropriately - either they didn't do it well or didn't do it sufficiently (low fidelity) to (6) where there is the element is delivered appropriately (high fidelity). Thus the scale assesses a composite of both adherence to the intended intervention techniques and the skill of the facilitator in delivering the techniques. To aid with the rating of items, an outline of the key features of each item is provided at the top of each section. A generic description of the rating criteria is given in Figure 1.

Adjusting for the presence of patient difficulties

Adjustments may be needed when patient difficulties are evident (e.g. excessive avoidance or resistance). In such circumstances, the rater needs to assess the facilitator's therapeutic skills in the application of the methods. Even though the facilitator may not facilitate change, credit should be given for attempting to use the intended techniques and demonstrating appropriate /skilful interaction.

Figure 1: The scoring system

Competence level*	Scoring	Examples
Incompetent	0	Absence of feature and /or highly inappropriate performance
	1	Minimal use of feature and /or inappropriate performance,
Novice	2	Evidence of competence, but numerous problems
Advanced beginner	3	Competent, but some problems or inconsistencies
Competent	4	Good features, but minor problems or inconsistencies
Proficient	5	Very good features, minimal problems or inconsistencies
Expert	6	Excellent performance

* The scale incorporates the Dreyfus system (Dreyfus, 1989) for denoting competence. Please note that the 'top marks' (i.e. near the 'expert' end of the continuum) are reserved for those facilitators demonstrating highly effective skills, particularly in the face of difficulties (i.e. patients with high resistance to change; high levels of emotional expression; and complex situational barriers). Please note that there are 5 competence levels but six potential scores.

When rating the item, you should first identify whether some of the 'Key Features' are present. If the facilitator includes most of the key features and uses them appropriately (i.e. misses few relevant opportunities to use them and delivers them well), the facilitator should be rated highly. It is important to remember that the scoring profile for this scale should approximate to a normal distribution, with relatively few people scoring at the extremes.

Dreyfus, H. L. (1989). The Dreyfus model of skill acquisition. In J. Burke (ed.) Competency based education and training. London: Falmer Press.

ITEM 1: ACTIVE PATIENT INVOLVEMENT

Key features: The facilitator should encourage the participant to be actively involved in the consultation. The idea is to maximise the participant's autonomy as the main agent of change, developing intrinsic rather than extrinsic motivation, and encouraging her /him to be the person coming up with ideas for improving the situation. However, the participant should not be allowed to ramble in an unstructured way and the consultation should be guided. A collaborative /shared decision-making style is appropriate and the facilitator may share his /her own expertise and ideas (as below). Overall, the participant should be increasingly empowered to take control of her /his self-care behaviour. Interactions should be encouraging, respectful and non-judgemental (the opposite of a didactic, telling or persuading style of interaction). The participant should ideally talk for at least half of the time. The interaction should also be *individually tailored* to the patient's specific information needs, beliefs, motivations and barriers. The facilitator should engender a clear sense of warmth, genuineness and empathy (within professional boundaries).

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries). Reflective listening may include simple reflections of content but may also be more sophisticated (e.g. amplified reflection; reflection with a twist) and used to direct the conversation or highlight key strengths or barriers. Summaries to reinforce patient choices and acknowledge patient effort are particularly desirable. Individual tailoring of techniques and responses to the individual patient's existing knowledge, skills, current activity levels, needs and preferences are also desirable. The Ask-Tell-Discuss technique should be used to exchange information (e.g. to address misconceptions, or offer helpful new information). The above empathy-building techniques and individual tailoring should be used throughout the consultations - from the initial consultation through action-planning through to review /maintenance sessions.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence of active patient involvement techniques. An overly 'directing', practitioner-led or 'lecturing' style of interaction, which may increase or sustain client's resistance.
1 Minimal patient involvement or use of active patient involvement techniques. The practitioner dominates the discussion.
2 use of patient involvement techniques, but not frequent enough. The practitioner sometimes dominates the discussion.
3 Appropriate and frequent use of patient involvement techniques. Teamwork evident, but some difficulties in content or method of delivery.
4 Appropriate and frequent use of patient involvement techniques. Minor problems evident (e.g. some reflection opportunities missed).
5 Highly appropriate and regular use of patient involvement techniques, facilitating shared understanding and decision making. Minimal problems.

6 Excellent / expert use of patient involvement techniques throughout all consultation. A clear sense of collaborative alliance is developed.

ITEM 2: ASSESSING THE PATIENT'S CURRENT SITUATION AND NEEDS.

Key features: The facilitator should work with the participant to assess the patient's current situation. They should seek to identify ALL of the following over the first 1-2 sessions: Identify and discuss the most important issue currently for the patient, how well are they managing their fluids, how appropriately are they using medications, is there any obvious immediate clinical need, how much stress or anxiety do they have, how much physical activity are they doing, and what other concerns or questions they may have.

Intervention techniques: Facilitators will use patient-centred communication techniques (as above) which may include the Ask-Tell-Discuss and 'tell me three things' technique to explore the patient's current situation.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of discussions to assess the patient's current situation.
1 Minimal (or poorly delivered) discussions to assess the patient's current situation.
2 Some discussions to assess the patient's current situation, but not in sufficient depth or detail.
3 Several examples of discussion to assess the patient's current situation. However some difficulties evident (e.g. missed opportunities, not covering all the key topics, or talking at odds with the patient).
4 Several examples of discussion to assess the patient's current situation. Minor problems evident.
5 Highly appropriate and sufficient discussion to assess the patient's current situation. Minimal problems.
6 Excellent / expert use of discussion to assess the patient's current situation. No real problems.

ITEM 3: FORMULATING AN APPROPRIATE (INDIVIDUALISED) TREATMENT PLAN

Key features: The facilitator should work with the participant to formulate an appropriate treatment plan based on the patient's current situation. This should aim to address (as a minimum) ALL of the following over the twelve weeks of the programme: What is the most important issue currently for the patient, are they managing their fluids well, are they using medications appropriately, any clinical needs identified, how much stress or anxiety do they have, how much physical activity are they doing, and any other concerns or questions they may have. The treatment plan will be staged over time, aiming to work on a few topics initially and introducing other elements as the programme continues.

Intervention techniques: Facilitators will use patient-centred communication techniques (as above) to discuss and agree what issues to address first and what order to do things in. An element of guiding to ensure the inclusion of clinical priorities (e.g. medication issues, physical activity, psychological well-being) as well as patient priorities may be appropriate. The facilitator will advise the patient (and caregiver if appropriate) to read relevant sections of the manual ahead of their next meeting.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of discussion to formulate an appropriate treatment plan based on the patient’s current situation.
1 Minimal (or poorly delivered) discussion to formulate an appropriate treatment plan based on the patient’s current situation.
2 Some discussion to formulate an appropriate treatment plan based on the patient’s current situation, but not in sufficient depth or detail
3 Several examples of discussion to formulate an appropriate treatment plan based on the patient’s current situation. However some difficulties evident (e.g. missed opportunities,).
4 Several examples of discussion to formulate an appropriate treatment plan based on the patient’s current situation. Minor problems evident.
5 Highly appropriate and sufficient discussion to formulate an appropriate treatment plan based on the patient’s current situation. Minimal problems.
6 Excellent / expert use of discussion to formulate an appropriate treatment plan based on the patient’s current situation. No real problems.

ITEM 4: BUILD THE PATIENT’S UNDERSTANDING OF HEART FAILURE /MAKING A LINK BETWEEN SELF-CARE ACTIVITIES AND THEIR HEART FAILURE SYMPTOMS

Key features: Participants’ ability to make sense of how HF works and how self-care behaviours might influence the course of the illness will be crucial for the success of the intervention as belief in the benefit of the suggested self-care activities will increase motivation to engage in them. The facilitator should elicit the patient’s current understanding of heart failure and seek to build their ‘illness model’ in terms of understanding the Identity, Causes, Consequences, Cure /control options and Timeline[1] associated with the condition. This process may take several weeks and should be reinforced as the programme progresses.

Intervention techniques: Facilitators will provide the REACH-HF Manual, provide a brief overview of how the manual works and, after assessing the patient’s individual needs and concerns (as above), they will identify some key sections for the patient to read before the next contact, specifically including the Understanding HF section. Facilitators will use patient-centred communication techniques (as above) to elicit and build understanding. This should include the use of the Ask-Tell-Discuss technique and reflective listening to reinforce elements of the patient’s understanding that are factually correct or which predispose towards positive self-care behaviours. They should seek to reframe negative attitudes and exchange information (Ask-Tell-Discuss) to address any misconceptions or to fill any important gaps in understanding. The facilitator will advise the patient (and caregiver if appropriate) to read relevant sections of the manual (including the Understanding HF chapter) to build and reinforce understanding /to address misconceptions. The way HF works should be explicitly discussed and referred back to /reinforced at subsequent sessions when this reinforces perceived benefits of the proposed self-care behaviours.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process.

0 Absence (or very poor delivery) of any exploration or discussion of how HF works. Understanding of HF is assumed or not mentioned or discussed.
1 Minimal (or poor delivery of) exploration or discussion of how HF works.
2 Some exploration or discussion of the how HF works, or understanding is not checked.
3 Appropriate exploration and discussion of how HF works. However, some difficulties evident (e.g. moving on before understanding is fully established).
4 Appropriate exploration or discussion of how HF works, linking changes in symptoms or mood with changes in self-care behaviour. Minor problems evident (e.g. some inconsistencies).
5 Highly appropriate and sufficient exploration or discussion of how HF works, facilitating a clear understanding of the process and linking changes in symptoms and mood with changes in self-care behaviour. Minimal problems.
6 Excellent / expert exploration and discussion facilitating a clear understanding of how HF works and the reasons for change. No real problems.

1. Leventhal H, Nerenz DR, Steele DJ: Illness representations and coping with health threats. In: *Handbook of Psychology and Health*. Volume IV. Edited by Baum AE, et al. Hillsdale NJ: Lawrence Erlbaum; 1984: 219-67.

ITEM 5a: SUPPORTING SELF-PROGRESS-TRACKING)

Key features: The facilitator should agree a verbal plan of action for the following week(s) with the patient. Discuss the use of the progress-tracking tools in the HF Manual to keep track of progress and as a way of recording any problems in completing the activities and any benefits that might be associated with the planned activities.

Intervention techniques: The facilitator should encourage the participant to monitor /keep track of their activities using the progress-tracking tools in the HF Manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of encouragement of self-monitoring.
1 Minimal (or poor deliver) encouragement of self-monitoring. Activities planned are not sustainable, or poorly specified.
2 Some encouragement of self-monitoring but lacking detail /patient involvement in the activity may be limited.
3 Appropriate encouragement of self-monitoring. However, some difficulties evident (e.g. not explaining the using the tool as a basis for monitoring, sometimes providing rather than eliciting ideas).
4 Appropriate encouragement of self-monitoring. Minor problems evident (e.g. the plan is a bit less specific than it could be).

5 Highly appropriate encouragement of self-monitoring. The participant has a clear understanding of the plan for the week ahead and how to monitor progress. Minimal problems

6 Excellent / expert encouragement of self-monitoring. The participant has a clear and realistic understanding of how to monitor progress. No real problems.

ITEM 5b: REVIEWING PROGRESS

Key features: The facilitator should work with the participant to review progress with all planned changes and with achieving the targets set out in the action plan. The facilitator should celebrate and reinforce and reflect on any successes. The participant and facilitator should discuss any setbacks and the patient's plans should be revised.

Intervention techniques: The facilitator should reinforce any self-monitoring activity and any successes in behaviour change (by giving praise/ using Affirmation techniques). Reframing should be used to normalise setbacks and see them as an opportunity to learn from experience (trial and error) rather than as failures. Problem-solving should use OARS (Open questions, Affirmation, Reflective listening, Summaries) and information exchange (Ask-Tell-Discuss) techniques to identify barriers and explore ways to overcome them. Problem-solving may specifically focus on issues of connectedness (social influences, involvement of others in supporting activities) and sustainability, or on breaking the problem down into more manageable chunks. Goals /action plans should be reviewed and revised if necessary.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of any progress review. No reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans.

1 Minimal (or poor delivery) of progress review. Minimal reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans.

2 Some progress review. Some reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving and reviewing action plans, but lacking sufficient depth or detail.

3 Appropriate progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, and reviewing action plans. However, some difficulties evident (e.g. not reframing setbacks, not attempting to identify problems, or possible solutions).

4 Appropriate progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, and reviewing action plans. Minor problems evident.

5 Highly appropriate and sufficient progress review. Appropriate reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, or reviewing action plans. Minimal problems.

6 Excellent / expert progress review. Excellent reinforcement of success and discussion of setbacks or barriers in relation to the previous weeks planned activities /problem-solving, and reviewing action plans. No real problems.

ITEM 6: MAKE A SPECIFIC ACTION PLAN FOR PHYSICAL ACTIVITY, BASED ON THE ACTIVITIES SELECTED BY THE PATIENT

Key features: Using the template in the HF manual, the facilitator should work with the participant to agree a written plan of action for engaging in one of the physical activity /exercise options over the following week(s). This should include discussion to ensure an appropriate intensity (moderate) of any activity included in the action plan.

Intervention techniques: Making a written action plan, using the planning tool in the manual. The facilitator should ensure that goal-setting is realistic. The facilitator may also employ some problem-solving techniques at this stage to pre-empt and address potential problems.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of activity /exercise planning for the following week(s).
1 Minimal use (or poor delivery) of activity /exercise planning for the following week(s).
2 Activities planned are not sustainable, or representative of the routine, pleasurable and necessary activities previously identified.
3 Some use of action-planning techniques using the HF Manual planning tool but lacking detail /patient involvement in the activity may be limited.
4 Appropriate use of action planning techniques. However, some difficulties evident (e.g. not, sometimes providing rather than eliciting ideas).
5 Highly appropriate and sufficient use of action-planning techniques. The participant has a clear understanding of the plan for the week(s) ahead. Minimal problems.
6 Excellent / expert use of action-planning techniques. The participant has a clear understanding of the rationale behind planning for the week(s) ahead, and has a clear and realistic action plan for the week(s) ahead. No real problems.

ITEM 7: ADDRESSING EMOTIONAL CONSEQUENCES OF HEART FAILURE

Key features: The facilitator should help the patient to recognise and address any significant stress, anxiety, anger depression that related to having heart failure. S/he should seek to normalise such feelings and help the patient to access and work through relevant sections of the manual. If these problems are severe or prolonged the facilitator should facilitate a referral to relevant care services.

Intervention techniques: Patient centred counselling techniques (OARS) for assessment and exchanging information to build patient's understanding of the situation. Facilitation of cognitive behavioural therapy techniques and stress management techniques contained within the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

1 Minimal (or poor deliver) attempts to address emotional consequences
2 Some attempts to address emotional consequences, but lacking sufficient depth or detail.
3 Appropriate attempts to address emotional consequences. However, some difficulties evident (e.g. sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual).
4 Appropriate attempts to address emotional consequences. Minor problems evident
5 Highly appropriate and sufficient addressing of emotional consequences. Minimal problems.
6 Excellent / expert addressing of emotional consequences. No real problems.

ITEM 8: ADDRESSING MEDICATION ISSUES

Key features: The facilitator should help the patient to recognise and address any significant problems or concerns relating to the patient's heart failure medications. S/he should help the patient to work through relevant sections of the manual. This might include problems in organising /taking the medications, knowing what to do if they get a cold or forget a dose, identifying possible side effects and seeking help to minimise them, avoiding over-the-counter medications. For some patients, it may include discussing self-titration of diuretics (water tablets) in response to symptoms /swelling (using the Traffic Light plan as a guide).

Intervention techniques: Patient centred counselling techniques (OARS) for assessment and to exchange information to build patient's understanding of the situation. Facilitation of medication planning /monitoring tools (in the Progress Tracker) and tips provided in the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

1 Minimal (or poor delivery) attempts to address medication issues.
2 Some attempts to address medication issues, but lacking sufficient depth or detail
3 Appropriate attempts to address medication issues. However, some difficulties evident (e.g. sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual).
4 Appropriate attempts to address medication issues. Minor problems evident.
5 Highly appropriate and sufficient addressing of medication issues. Minimal problems.
6 Excellent / expert addressing of medication issues. No real problems.

ITEM 9: CAREGIVER INVOLVEMENT (as applicable)

Key features: The facilitator should engage the caregiver as much as possible as a co-facilitator of the intervention. S/he should tailor the intervention to work with the caregiver's abilities and availability to provide support to the cared for person with self-management of their heart failure. Facilitators will provide the Caregiver Resource, a brief overview of what it contains, and identify some key sections for the caregiver to read.

Intervention techniques: Person centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation and their ability to support the person with heart failure with their self-management. The facilitator should facilitate a conversation between the patient and the caregiver to agree their roles and responsibilities and how these might change if the patient's condition declines. Attention should be given to the caregiver's needs and concerns about being a caregiver /providing care as well as those of the patient.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

1 Absence (or very poor delivery) of any attempts to involve the caregiver or to address his /her needs.
2 Minimal (or poor delivery) attempts to involve the caregiver or to address his /her needs.
3 Some attempts to involve the caregiver or to address his /her needs, but lacking sufficient depth or detail
4 Appropriate attempts to involve the caregiver or to address his /her needs. However, some difficulties evident (e.g. Leaving roles and responsibilities between patient and caregiver unclear in some respects).
5 Appropriate attempts to involve the caregiver or to address his /her needs. Minor problems evident.
6 Highly appropriate and sufficient involvement of the caregiver and addressing his /her needs. Minimal problems.
7 Excellent / expert involvement of the caregiver and addressing his /her needs. No real problems.

ITEM 10: ADDRESSING EMOTIONAL CONSEQUENCES OF BEING A CAREGIVER (as applicable)

Key features: The facilitator should help the caregiver to recognise and address any significant stress, anxiety, anger depression that related to becoming a caregiver and supporting someone with heart failure. S/he should seek to normalise such feelings and help the caregiver to access and work through relevant sections of the Caregiver Resource. This includes facilitating a referral for a carer's assessment if the caregiver wishes, plus referral to other relevant care services as appropriate.

Intervention techniques: Person centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation. Facilitation of cognitive behavioural therapy techniques and stress management techniques contained within the manual.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of any attempts to address emotional consequences.
1 Minimal (or poor deliver) attempts to address emotional consequences.
2 Some attempts to address emotional consequences, but lacking sufficient depth or detail.

3 Appropriate attempts to address emotional consequences. However, some difficulties evident (e.g. sometimes being prescriptive rather than patient-centred, not identifying all relevant sections of the manual, not facilitating onward referrals).
4 Appropriate attempts to address emotional consequences. Minor problems evident.
5 Highly appropriate and sufficient addressing of emotional consequences. Minimal problems
6 Excellent / expert addressing of emotional consequences. No real problems.

ITEM 11: CAREGIVER HEALTH AND WELL-BEING (as applicable)

Key features: The facilitator should help the caregiver to prioritise and look after their own health and well-being.

Intervention techniques: Person centred counselling techniques (OARS) for assessment and to exchange information to build the caregiver's understanding of the situation – helping them recognise and manage their own health needs including mental health, physical health, and social needs. This may be a separate conversation with the caregiver alone.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of any attempts to involve the caregiver or to address his /her health needs.
1 Minimal (or poor delivery) attempts to involve the caregiver or to address his /her health needs.
2 Some attempts to involve the caregiver or to address his /her needs, but lacking sufficient depth or detail
3 Appropriate attempts to involve the caregiver or to address his /her needs. However, some difficulties evident (e.g. sometimes being prescriptive rather than patient-centred, failing to identify the appropriate sections of the Caregiver's Resource).
4 Appropriate attempts to involve the caregiver or to address his /her needs. Minor problems evident.
5 Highly appropriate and sufficient involvement of the caregiver and addressing his /her needs. Minimal problems.
6 Excellent / expert involvement of the caregiver and addressing his /her needs. No real problems.

ITEM 12: BRINGING THE PROGRAMME TO A CLOSE

Key features: Progress should be consolidated and reinforced. Plans for long-term sustainability of activities and strategies learned for managing heart failure should be discussed.

Intervention techniques: The facilitator will review progress since the start of the intervention and reinforce what has been learnt. Useful strategies that were helpful should be identified. Plans to stay well /prevent relapse should be discussed as well as 'cues for action' and plans to revisit the manual in the future. The facilitator will discuss plans to sustain any new activities, identifying any potential problems and coping strategies to overcome these. The possibility of good and bad days should be discussed and normalised.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the facilitator has delivered this intervention process

0 Absence (or very poor delivery) of discussion to bring the intervention to a close. Not considering progress and long term planning using the above strategies.
1 Minimal (or poorly delivered) discussion to bring the intervention to a close. Minimal consideration of progress and long term planning using the above strategies.
2 Some discussion to bring the intervention to a close. Some consideration of progress and long term planning using the above strategies, but not in sufficient depth or detail.
3 Appropriate discussions to bring the intervention to a close. Appropriate consideration of progress and long term planning using the above strategies. However some difficulties evident (e.g. missed opportunities to reinforce what has been learnt, facilitator sometimes dominating the conversation /telling rather than facilitating development of the patient's own ideas).
4 Several examples of appropriate discussion to bring the intervention to a close and examples of consideration of progress and long term planning the above strategies. Minor problems evident.
5 Highly appropriate and sufficient discussion to bring the intervention to a close and to consider progress and long term planning using the above strategies. Minimal problems.
6 Excellent / expert discussions to bring the intervention to a close and to consider progress and long term planning using the above strategies. No real problems.

CONTENT CHECKLIST - PATIENT

How much did the facilitator cover the following topics in this session with regard to the patient…	**Not at all**	**<-**	**Partially**	**->**	**Thoroughly**
1. … Understanding heart failure	1	2	3	4	5
2. … Management of stress or anxiety	1	2	3	4	5
3. … Physical activity	1	2	3	4	5
4. … Low mood /depression	1	2	3	4	5
5. … Taking medications	1	2	3	4	5
6. … Deciding priorities/ setting goals	1	2	3	4	5
7. … Tracking and reviewing progress	1	2	3	4	5

8. … Using the HF Manual	1	2	3	4	5
9. …Support from others	1	2	3	4	5
10. … Other (please state) Outlook Southwest and Age Concern	1	2	3	4	5

Item	Consultation scores
1.Understanding heart failure	2 2 3 1 3 1 2 1 1 2 2
2. Management of stress or anxiety	3 3 3 4 3 3 3 3 2 2 4
3.Physical activity	3 3 3 3 3 2 3 2 1 2 4
4. Low mood /depression	3 4 3 3 3 2 3 3 1 2 4
5.Taking medications	2 2 3 3 4 1 2 1 1 1 2
6. Deciding priorities/ setting goals	2 3 4 2 3 2 3 1 1 1 3
7.Tracking and reviewing progress	3 4 2 3 4 2 3 2 1 1 3
8. Using the HF Manual	2 2 2 1 3 1 2 1 1 1 2
9. Support from others	2 2 2 1 1 2 3 1 1 1 1
10. … Other (please state) Outlook Southwest and age concern	2 4 4 2 3 4 4 3 1 1 2

CONTENT CHECKLIST - CAREGIVER

How much did the facilitator cover the following topics in this	**Not at all**	**<-**	**Partially**	**->**	**Thoroughly**

session with regard to the caregiver …					
1. … Assessing the caregiver’s needs e.g. understanding of HF, how to facilitate self care	1	2	3	4	5
2. … Managing the caregiver’s own health and well-being	1	2	3	4	5
3. … Facilitating discussion of /decisions about care-giving roles and responsibilities	1	2	3	4	5
4. … Promoting physical activity for the patient	1	2	3	4	5
5. …Encouraging self-monitoring and management for the patient	1	2	3	4	5
6. … Helping patients who feel stressed or depressed	1	2	3	4	5
7. … Understanding and managing the patient’s medications	1	2	3	4	5
8. … Other (please state) e.g. financial management, getting help from friends, uncertainty	1	2	3	4	5

Item	10/07/15	20/07/15	27/07/15	10/08/15	06/10/15
How much did the facilitator cover the following topics in this session with regard to the caregiver …	Caregiver Not present		NA	NA	

1. Assessing the caregiver’s needs e.g. understanding of HF, how to facilitate self care	1 2 1 2 1
2. Managing the caregiver’s own health and well-being	1 1 1 1 1
3. Facilitating discussion of /decisions about care-giving roles and responsibilities	1 3 1 1 1
4. Promoting physical activity for the patient	1 2 1 1 1
5. Encouraging self-monitoring and management for the patient	1 1 1 1 1
6. Helping patients who feel stressed or depressed	1 3 1 1 1
7.Understanding and managing the patient’s medications	1 1 1 2 1
8.Other (please state) e.g. financial management, getting help from friends, uncertainty	1 4 1 2 1

Appendix 19 Summary of caregiver background data

Name of participant	
Address	
Telephone/e-mail	
Length of time as a carer	
Relationship to person cared for	
Age of participant	
Type of Heart Failure person cared for has (If known)	
Length of time of Heart Failure	
Ethnic group of caregiver	
Participant’s description of own health	
Employment status of participant	
Level of education of participant	
Home ownership	
No. of people living in participant’s home (If living with cared for person)	
Main method of transport	
Area of residence	
Date of interview	
Interviewer(s) present:	
Date of signature(s)	
Signature(s)	

Appendix 20 Summary of patient background data

Name of participant	
Address	
Telephone/e-mail	
Length of time with HF (date of diagnosis)	
Caregiver in intervention (yes/no)	
Age of participant	
Type of Heart Failure	
Length of time of Heart Failure	
Ethnic group	
Participant’s description of own health	
Employment status of participant	
Level of education of participant	
Home ownership	
No. of people living in participant’s home (If living with cared for person)	
Main method of transport	
Area of residence	
Date of interview	
Interviewer(s) present:	
Date of signature(s)	
Signature(s)	

Appendix 21 Variable oriented mapping and analysis

(informed by REACH-HF Logic Model)

CG
4 months CG 4015
12 months CG 4015

PT
4 Months PT 4015
12 months PT 4015

FIDELITY SCORES/FIELD NOTES

	Personal Determinants	External Determinants	Environmental Factors	Psychological Factors	Behavioural Factors	Quality of Life	Long Term Outcomes
4 MONTHS	**Father (pt.) reaching out asking for help.** Mother unwell – Dementia - *I basically said, "You can't, and you can't go on like this, 'cause you've got this issue with my mum."* Pt reports his personal motivation is to give something back to the research Pt talks in terms of "you" as opposed to "I" i.e. you want to know	**CG working full time.** Sister also work full time, sister has a family but HF needs and Dementia needs impacts the whole family. *"And it spreads to the family, and then to get one part- the other partner poorly as well. That maybe as a result of stress, and fatigue, and then picking up an illness because you're not caring for yourself as much as you should."* Reluctance to seek help external to the family, patient	*"you're not dealing with one person's issue here. You're dealing with two people. – patient doesn't really understand HF and thinks they are getting better; the spouse is too unwell to be a carer "* *"And the problem that adds on is that, it appears to me that part of the symptoms of heart failure, and the issues around it, and what you need to do to recover, like rest and stuff like that, is impacted on the fact that he spends half his time wondering what my*	*"One thing he is very good at, though, if I'm honest with you, is guilt-tripping.* *So if I don't actually ring him on the prescribed ay, or, etc., erm, that's quite difficult, and I suspect, my friend- I suspect it's similar for most carers."* "I go through various emotions. I go through guilt, and then I get extremely angry. And I have had to say something to him in the	**Change in patient behaviour**– past would have done it all on his own, now reaching out for help – **change in family dynamic – wife (Dementia)** *CG describes self as more informed – cg also reports positive and negative behaviour changes of father to HCPs -* ***Motivator*** Pt attributes positive changes to a combination of lifestyle changes **CG learnt about what HF is from REACH HF –** attributed symptoms to other factors diet, weight etc. CG demonstrating new knowledge by stating viewing ankles to observe for fluid retention	**Strategy when telling parent things needed to change:** *"When it's really bad, when it was really bad, he pretty much listened to what I had to say."* *Because I basically just put my foot down and said, "I'm not having this."* *"since he started to come back on track, and he's feeling a lot better, he's less prone to listening now."* – **the continual change between cg and patient roles, over and back (locus of control)**	Cg wants father to maintain his health changes to be able to care for his spouse at home – **external motivator for patient is being carer for spouse – cg sees it as his duty to remind pt/father of this**

	about medication Would like to be back to before dx – gardening *“That's, that's my main thing with it. And that's why I try to- that's why we sort of got involved in this. Erm, one, to find out how he, how he can get better.”* Goal for engagement with REACH-HF – wanting the patient back to how they were prior to “all this” – return to being active and not worry about being breathless – understand HF *“Obviously I haven't got a power, power of attorney in*	listening to wife – **wider impact of illness on the family** **CG having a spouse and living away** Pt identifies that sons job gets in the way of him being involved in REACH-HF Differing perspective on cg retirement, pt. perceives son (cg) should be winding down in his job before retirement. Appears to appreciate that – different to how he (pt) would have approached retirement – **element of telling son what to do?** NO ENGAGEMENT WITH REACH-HF FACILITATOR – CG hasn't given this any thought – **doesn't see REACH**	*mum's gonna do next.”* **Work role provides cg with transferable skills i.e. CPR training** *Carer when need to be there but it's not 24/7 – doesn't live with the patient. “when I can't get there, or I'm working late, there seems to be a lack of understanding on that side of it, from my perspective”* *“there just needs to be some consideration, erm, of care, er, you know, impact on two people being ill.”* *“What they don't realise is the worry and stress it causes to the other partner.”* *“The other partner who's got heart failure. It has a massive impact.”* *Sister “lives in a farm about, er, two minutes away. - So*	past, but generally it's just, “Yeah, okay,” put the phone down, and then feel guilty, and, and angry, that, you know, you feel unappreciated.” Dx – was a knock to the pt. **Did not read section about caregiver getting help** – thinks at 4 month interview he should have read this part Depression – understanding and speaking about it and the culture of not speaking about mental health – **communication difficulty, cg wonder how to approach pt about this**	*CG read book and spoke to Doctor to understand HF – **being proactive in sourcing information, informing oneself*** ***Knowledge of the patient – i.e. “****I just know, him being him, erm, won't, it won't make any difference”* ***– informs caregivers approach to the patient when communicating about self-management/maintenance*** *“you just got- at the moment, for me, it's just picking the right time to ring, or pop across. Ones where he's in a, he's, er, in a reasonable mood, or if he's in a more receptive mood, I think is the best way of describing it.”* *“I'm convinced he's still managing it, but only just.”* *“To tell him, erm, what to do, and advise him. Erm, he thinks he's pretty much on the, er, road to recovery, and he, he doesn't need the interference.”* **Picked out bits of the manual that were**	**Perspective of HF and caregiving** -*“it's all hard”* ***Cg reports the lack of preparation to becoming a carer.*** *“it impacts on me, because then I get, I feel like I should be dashing across to sort it out”.* *“And then I get, when I do that I get thanked, but then that has a knock-on effect in that, by the time I get over there, get stuff sorted out, get back, and then I'm at work again at seven o'clock in the morning, it starts to affect me being able to sleep and stuff.”* **Balancing multiple obligations Complexities of providing**	

	relation to medical matters, and they couldn't tell me a great deal, but I just wanted to check that they'd actually been making his appointments.”	**Facilitator having a role with him – sees it for his father** Culture of both father/sons occupations and how this informs their relationship/coping communication (police force) – **Relatively new in this role** and period of adjustment, **son not realising the magnitude of being a caregiver** and coming to terms with the impact of it. Field notes at 4 months report he is constantly worried due to vigilance from afar **Fidelity score – highlights changes in pt. behaviour** i.e. him learning to say no to family requests e.g. going to agricultural show – which he feels	*she pop, pops across and just makes sure he's okay.”* *“So effectively, I would become involved, and he's just continued from there.”* Would like dgtr more involved but states she has her own family and obligations – *“loads her with far too much responsibility”* In reference to her husband Dgtr keeps a “***watching brief”*** pt. acknowledges that family are **observing** Grand-dgtr 12 – involved with visiting and relays information to mother **– observing! -**gets him to show her how is using pedometer **– participatory action**	Cg **NOTICES** dad stressed and symptoms like breathlessness and fatigue are present then “Never considered the impact it would have on own health as much as it has” – **the impact of caring** *“It distracts me from what I've got to do. It makes me- it makes me doubt, which is my priority, if I'm honest.”* – ***being a caregiver, the balancing act*** More honest completing questionnaires for REACH-HF the second time around – it does affect CG and it is a hard situation – **feeling lack of appreciation for cg other roles e.g. working** **Type of relationship** is a factor – thinks it would be easier to communicate if spouse to spouse rather than parent to child – feels there is a flip between patient not listening and not wanting help but also guilt tripping him when he is not available *“Occasionally they, they don't know what to lash out at, so they lash out at the*	**applicable to him** – learnt in this way - **knowledge** Progress Tracker – **physical object to help manage/maintain self-care** Identifies son (carer) wasn't telling him what to do “*wasn't a member of the sohuld're squad by any means*” Describes son as “astute” and acknowledges how son printed off information about his HF meds – **pt/cg relationship – (pt perspective different to sons at 4 months)** CG Transports Pt. to apts initially refusing to attend hospital – to ensure he attended Cg contributes in healthcare appointments now – *“Yeah. Yeah, I do, sort of. Because I fuss. If I think he's telling fibs, I tell, I grass him up, and tell- that's the best way to describe it”* – ***Change since REACH*-HF** *“I've basically just carried on doing what I've done, from the point I've sort of described. Er, just checking if he needs to go*	**support work, caring, living away** *“it also has a knock-on effect that it affects my partner, because it makes me, er, either distracted, distant, or argumentative.”*-***HF effects more than just the patient*** Natural aging process with the overlay of a HF condition - ? influences on engaging with self-care **(is age a motivator or a deterrent)** *“nothing that I've seen or read has any, er, takes into consideration. It looks at the person with heart failure, but there's nothing to do with the person who is with, with the person who's got heart failure, if they've got a medical condition.”*-***carers who have their own health needs – (did they start to***	

		is too much. Also highlights the tension that was present in the family unit. Pt perceptions on depression addressed and how managing it is multifaceted. Using the progress tracker to guide the interaction and keep in patient orientated. Fac. unable to engage son (caregiver). Pt did not wish for dgtr. to be identified as caregiver	**Family approach:** *“they’ve all got their own sort of role”* *who would, who is the main carer out of you and your sister? Between me and my sister? Mmm. (Pause) Hard to say, really. Me for my dad, my sister for my mum.* *“before, erm, the, the research project, had you had any discussions as a family about, erm, your respective roles, and who's doing what?* *C: No.”* -***REACH-HF prompted the family to discuss caregiver role, facilitated communication about diagnosis and long term*** No assistance from services **Read certain areas of F&F**	*person who's trying to help them out”* – **Understanding the patients’ needs** *“it's really difficult to try and tell a parent what to do”* – ***communication/relationship*** “I'd like him to be a little bit less, erm, putting me on a guilt trip, but I don't think that ever's gonna happen.” – **relationship between patient and caregiver/emotional health impact** Back off when patient doesn’t want to hear what cg has to say Family can be a source of stress, pt uses example of dgtr venting on the phone about work, pt. absorbs this stressor – **communication** **REACH-HF gave patient impetus to make changes (motivation)**	*to the hospital for, er, for part of his thing, I'll run him down there, check up on him.”* Pt not taking prescribed meds *“I actually went and trawled the internet for some of the stuff that he was taking, drug-wise and things, to see what effects that had on him.”* ***– being proactive in sourcing information, informing oneself*** *Amount of tablets and patient concerned about warfarin* **Difficulty communicating with father (pt) and mum – it’s never been easy…to tell them what they need to do** *I started checking up on him, making sure he were doing his medication, making sure that, er, any appointments he was invited to, I contacted the doctors.* *“I sort of, for once in my life, which, as we had a talk the other day, it's really difficult to try and tell*	***address their own self-care)***	

			resource – *“around, er, identifying symptoms, and, er, good and bad days.”* *“when I've thought, “I wonder what's happening there?”” – active use of manual – checking and re-checking over time. Use it as a “reference” (patient word)* **Accessing support from caregiver perspective – “***I'm as perhaps in some ways as bad as he is, in that I keep everything my side and just not bother anybody. I, I work on a thing that I don't like, erm, tying people up”* *“I'd see [facilitator] as, she's got a lot on, she's busy. She's dealing with Dad, she doesn't really need to start- she doesn't really need to speak to me. I'm not, I'm not that way inclined.”*	Appreciated motivation from son “*you have lost weight”*	*a parent what to do. I mean, a parent tells you what to do, all your, pretty much all your life.”* ***Observing*** *that patient has kept weight off, reduced alcohol and maintain changes, when chatting to patient about his health – patient is more active –* ***increased communication (i.e. checking in) about HF self –mgt. due to REACH***		

			Don't view self as a caregiver because not living with patient.					
12 MONTHS	Mum's (pt. wife) illness progressing- Dementia Want greater access to medical information on parents so as a family decisions can be made – having this conversation with pt. (**communication has moved is ongoing)** Wife's needs – caring for another **Consider type of dx and age of person with dx**	**CG partner worried about CG** – e.g. returning to work and everything going back to how it once was **18 months – two years on since diagnosis** cg observes change in attitude , acceptance of help, son able to advise more but patient also engaging in self-care more therefore son does not feel he has to tell/advise as much – **continual change in roles (this potentially highlights why there needs to be ongoing long term healthcare support – even just to check in as patient/carer roles are constantly evolving in relation to the**	Wife also observes i.e. will comment to him if ankles swollen Navigating the system as a carer *Family involved in decision making re: dog. View it as a coping strategy* *Shares caring tasks for both parents with sister i.e. she's more vocal at asking, he does research –* ***family approach to caregiving*** **Uses F&F resource as a reference if needed –** reports his and pt's awareness of signs and symptoms has improved due to REACH-HF – NOTICES changes i.e. breathlessness	Change in relationship – dad (pt) sees cg differently, communication open, pt (dad) more accepting when cg advises about what he needs to do **Before REACH-HF; resentful and pt was causing caregiver angst due to the demands placed on him** **REACH-HF and self-mgt./maintenance.** CG is less tired now as not worrying as much **NB** – "he has taken pressure off me without really knowing it" "because getting his own act in gear" **CG worries less when patient engaged with REACH-HF**	*"He's a little bit less demanding now"* ***Reducing alcohol intake*** ***CG sharing stories with friends – how they cope/strategies- talking to others in similar situations*** **Observing/Monitoring is ongoing** – noticed anxiety in dad/patient when going for apts, observed he recognised he needed to change himself in order to care for his wife, noticing change in patient Looking up sources of support for both parents (**proactive information sourcing**)– e.g. Dementia UK. **Notices** both parents go out less, preserving **patient dignity** – embarrassed about their health conditions Now taking as prescribed and has now reduced some e.g. water tablet	Patient responsibilities i.e. caring for wife, 24/7 (i.e. waking him up in the night) Locus of control with Dad/pt. i.e. cg (son) awareness of medication but not responsible for administering etc. Pt. maintains responsibility ***"we're going back to my Dad's sort of side of it"*** Change again in pt/cg role. Cg now view self as providing Dad (HF pt) respite from looking after mum	**For Dad (pt) to maintain his health longer to care for mother (pt wife) at home – this family are united in a common goal** *Sourced external help - carer helping with wife* *Leisure time with son (carer) – looking at boat* **CG will be returning to work full time (hope this will be more flexible and less responsibility this time)** ***Likes to be able to refer***

		current life situation) **Buying a puppy – facilitating engagement in exercise** CG retired *“Since I’ve retired, erm, I’m able to go over a lot more frequently and, erm, do a bit of running around, et cetera, and it’s just doing the odd job. So it’s not as problematic.”* **At 12 months field note comments how cg sounds noticeable more relaxed** (**Circa 2 years since dx – is this optimum time to intervene?)**	if they are talking on the phone, talk every other day CG thinks they are a dysfunctional family, *“had a lot of soul-searching” “we’re doing better than we probably did because we’ve got a common goal”* **family approach to caregiving** Grandaughters as a motivator i.e. comment about his weight! CG views self as helping dad (pt) out and by doing these he in turn can help support his wife – **Caring has layers of complexity and HF effects more than just the patient** Son rings everyday – aware the son is observing. Son offers to help with tasks Dgtr assists with organising e.g. paid carer for wife		*“Your own involvement and how you approach it” re: REACH-HF”* *“you have got to come to terms with it” - heart failure and making lifestyle change* *Health has been stable for past 12 months* *“read what pertains to you* Reluctant to seek help ***Likes to be able to refer to the manual as needed – a reference point***		***to the manual as needed – a reference point***

			“we’ve all come together”,,,,”we all take a part” “anything we do out of the norm is properly discussed as a family” - **Communication** CG believes going back to work is manageable as he has more understanding now, **has a relationship with healthcare professionals** involved with pt. and he is **forward planning putting strategies in place** **CG does not think facilitator absence was an issue due to improvement** made by Dad (pt) - REACH-HF “*got him on the right track”, “her moving aside and handing over autonomy back to him”* **advocates patient active in self-mgt.** Niece 12 – taking a more active role in visiting grandparents and being available as a				

			support *"one of the younger one, about twelve years old, started to come of age of some form, and started to pop across and make sure they're both okay, and stuff. And doing little errands for them, and making sure that they could get food out and stuff. So it took a bit of pressure off me, if I'm honest."* **Observing signs/symptoms and behaviour** ie. whether Dad weighs self every day e.g. weighing dog food and scale not being used before that				

CG

4 months CG 4061
12 months CG 4061

PT

4 Months PT 4061
12 months PT 4061

Field notes

	Personal Determinants	**External Determinants**	**Environmental Factors**	**Psychological Factors**	**Behavioural Factors**	**Quality of Life**	**Long Term Outcomes**
4 MONTHS	Describe self as "semi-carer", pt not as active as she is – **perspective of caring** **Both present at interview** **Both aware they have a difference of opinion re HF mgt.** Fac. comment cg is very supportive. Cg sees deterioration, pt. does not. CG more orientated towards future than pt. Expert caregiver pre-REACH-HF. Own life outside of home	**Enjoy retired life** Cg hoped REACH would encourage pt/motivate him to set goals – exercise and weight are cg priorities for pt goals. Cg does not think REACH-HF achieved this Cg's father is also in hospital (94) **CG read the HF manual** *"I sat down one afternoon and I*	7grandchildren – moved to the area to be nearer to family Dgtr is a district nurse. CG states she goes to internet for information first before asking dgtr **(independent in seeking information – uses NHS website)** Own a house in Spain **Learnt from REACH about not eating green leafy veg when on warfarin. Also**	*"I'm very happy to do, this is no complaint at all because I'm, I'm very happy to do all that." – re driving in Spain and organising travel/house in Spain* ***"I don't feel it's a burden."*** ***"I'm happy with it" – regarding caregiving*** *"I do feel tension actually, I do feel quite tense because I know that you're not giving yourself the best lifestyle*	*"I think I probably taken over the role of, that perhaps you had in earlier times, haven't I? Where I do a lot of the driving, look after the finances…"* – ***role change in relationship*** *"I feel that I natter [MP4061] a bit too much, that he doesn't like." – clarifies that she means nag, ? hint of conflict between pt and cg.* **Diet is main issue re: conflict.** Stepped back when he turned 70 (HF dx x 10 years	He wants to start bowling but she worries he won't be able to do it because of the weight he has around the middle Doesn't feel as good as when he had the ablation – last 7 years and it no longer functioning Can recognise if he is deteriorating by his breathing and the way he falls asleep - **observing** Pt health is stable, arthritis and h/o left knee replacement *"it's hard to say but I just knew something*	*"I haven't changed my lifestyle really, I mean I'm happy to be retired. I was a head teacher and I was really busy, and you were very supportive of me then because you weren't, you were retired weren't you?"* **Retired** Wants to continue healthier eating Re: relaxation *"I might put it on, yeah. I'm not, sort of, saying I'm committing to it, but, er, erm, there are certain times when I want to*

	Married 25 years. MI age 60 (13 years ago) **Asked about her needs by facilitator** Cg goals are for pt *"I would like to [MP4061] to carry on with this."* *"I don't claim to be an expert at all, but it may be that we know a bit more about heart failure than others."* *"we've had time to accumulate some information" –* **length of dx, caring for 12 years** **Retired head teacher** Also dx with A.Fib, one or two hospitalisations over the years. Thought he was managing HF well and has learned a lot. Participated in REACH as "it's	*read it all, yeah, yeah,"* *"I mean I, I thought it was, I thought it was really good. I thought if you embrace it and use it it's a great way of, of, sort of, motivating yourself to, to improving your lifestyle." – CG perspective of REACH* **Read F&F resource but got more out of HF manual** **REACH-HF has not changed relationship – stated by both pt and cg** CG present for two f2f apts Pt had one other telephone contact also	**learnt about decision making i.e. symptoms and whether to contact GP or take tablet** - ? TLAP she is referring to here although not explicitly stated *"So it's quite good to have a checklist to think, "Mhm…" you know, "These, these things are happening, perhaps we should call the doctor."* When booking holidays has to be mindful of the environment e.g. hills **Can't talk to family about medical queries – dgtr/sister** Re: his weight and wifes input	*that you could have."* **CG very thoughtful about not hurting pt when describing what HF is** *"I feel we have a, I feel we have a good life, you know, it's not all perfect but then who's is?"* RE: frustrations – states she just gets on with it. **(pragmatic person)** **Pt a-motivated "***I think I might be more willing, you know, more keen to do it now than I perhaps was at the outset. I, I don't know why." "I mean I want you to support you to do but it always ends up with*	at this time), he put on a stone when she stepped back from being pro-active about diet. She sees this as a need for her to step in and manage *"I said this to you before in the other meetings, only because I love you and because I want you to live a long time, so I don't want you to feel that I'm trying to, I'm not going against you at all. But it's a bit like you can't teach an old dog new tricks and I just feel like, erm, you'll go and buy a fizzy drink or you buy… I'll like buy a small loaf thinking that one slice is less than a large loaf, but then you'll say, "Well I like a large loaf really" and you'll go and buy a large loaf that you can slice yourself. And your slice is like*	*about your lip looked a bit swollen or didn't look quite right"*- **in depth knowledge of pt** **Engages in own self-care** Pilates, yoga. Did look at CBE didn't participate. Knows that husband does relaxation CD – falls asleep Has a friend she walks with who she chats to (friends husband also has health issues) - **sharing** *"we empathise with each other." "I find that incredibly useful and really ex-"* Would like to walk with husband and if he walked a bit more briskly, gets frustrated by his slow pace *"But I used to go blue round there."* "That's not trying to take away from	*feel calmer, and that's the time you get it out"*

	always good to learn a bit more” *“I’m very happy for [wife] to be involved, yeah.”* ***“Yeah, she’s, er, she nags me a bit, but, er, but I have to say that, all in all, that I value it greatly. Her, her involvement.”” I wouldn’t want to do it without her”*** .	**This cg does not see REACH as being for her** **CG was truth teller in apts with Fac** (i.e. telling about pt being lightheaded) cg found fac helpful, supportive, Pt used to be very physically active **Used tracker more than manual, reports he scanned the manual and referred to it but mainly used the tracker** *“I’m very happy for [wife] to read it and then raise some points that she might pick up from them.” –* **passive to wife**	*“I think [wife] adopted a fairly passive attitude towards it.” And “Although once or twice I could, er, sense that she was a bit uptight about it, but, erm, no, I think she handled it very professionally, just like a head teacher would have done”* - **CG vocation informing their role** Working in same direction – him and wife *“perhaps I wasn’t working hard enough. I don’t know”*	*me, sort of, nagging and the you won’t, you know, di-discuss it, which is not productive at all.” –* ***discussion between pt and cg in interview*** *“I can’t, can’t get that self-motivation in you somehow.”* Recognises he gets stressed easily (cg agrees), relaxation cd helpful to him (references playing golf, felt relaxed first time after trying cd). Didn’t use relaxation techniques outside of listening to the CD Take the worry away from pt. Pt worries a lot more now	*three slices of normal bread, laden with butter and things like that.”* 3 years ago gave up smoking, lost three stone – had MI – Links weight loss with MI **To pt: “*I think you struggled with setting goals, really. I, erm, you know, like small, short- term goals.*”** Pt can’t find or remember what goals he set at 4 month interview – mentions losing weight *“trying to encourage [MP4061] to be active and, and to manage his weight and enjoy life really”*	doing it but, er, I did, I did find the exercise to be a bit, a bit simple and not, if I was doing exercises previously I would’ve been doing a circuit but I, as I can’t do circuits now.” – rationalising why he didn’t engage with goals *“I hate it that I can’t do the sports that I always did” “I can’t abide non-competitive sport.”* **He dislikes walking. Pt. not motivated by exercises in REACH** CG does recognise competition motivates him	

		Pt defers to wife to clarify things in interview – passive pt/active cg/? stereotypical r/ship understanding and explained things Cg left one of the apts early to pick up g.child		**Struggles to motivate and frustrated by this** *“I just don’t know how to motivate him to do it.”* CG does worry about pts health – him being overweight *“I’m very happy to, I did love it though but I love being retired more.”*	Engaged with relaxation CD and CBE DVD **CG talks to family about what’s happening more than pt does Caregiver self-care, also engage in social tasks together as a couple** *“we both play golf, [MP4061] plays golf and when I retired I took up golf because it was something we could both do.”* *“it’s something we can do together, which is, which is really nice.”* *States didn’t have a role with physical activity – “had a look at it with him, sort of tried to encourage him.”* *“I don’t think I encouraged you to do it, maybe I should’ve encouraged you*		

					more to do it. Usually when you’ve decided to do it yourself I’ll, you might be in the lounge doing it, I might be in the kitchen but I will keep popping through to see how it’s going and, and just having a look at it and, you know, just say…” – ***not acknowledging her role*** **Cg directive in what activity he should do** Pt dislikes Fruosemide due to impact on his lifestyle, made decision self to take in the morning so he is not waking at night for bathroom **Found info useful but nothing majorly new but doesn’t know why he weighs daily.**		

					Checks ankles for fluid Caregiver goes walking (own self-care) *“But [MP4061] finds that really difficult. But I do try and encourage him to walk but it’s not his favourite occupation, so that’s a little bit of a slight bone of contention sometimes isn’t it?”* -re: walking, difficult to motivate/encourage. Can be a source of conflict. *“we can’t make excuses all the time, your health is more important than his health. He’s 94, you know, your health is the most important. When we go to the hospital and you say you’re thirsty and you buy a fizzy drink, buy a bottle*		

					of water. But you won’t.” **Pt in interview – cg states to him that she’s not getting at him** (re:weight) Checks his pulse **Reports not doing anything different since REACH. REACH has confirmed things - ? given confidence in her decision making** *“Has that time of when you would call a doctor changed?” ”I don’t think so but it’s confirmed, probably, what I thought because sometimes you think, “Do we need to call the doctor or don’t we?”* Walked together – got light headed on walk, wife had to go get the car. **Wore pedometer and wrote steps –**		

					but ? he sees this as another task without meaning/relevance as to why **Plays down her role – as with all spousal caregivers?** He manages meds himself but she prompts him *“We keep them in a bag and I normally put them out, I have one or two as well, but I normally put them out*		

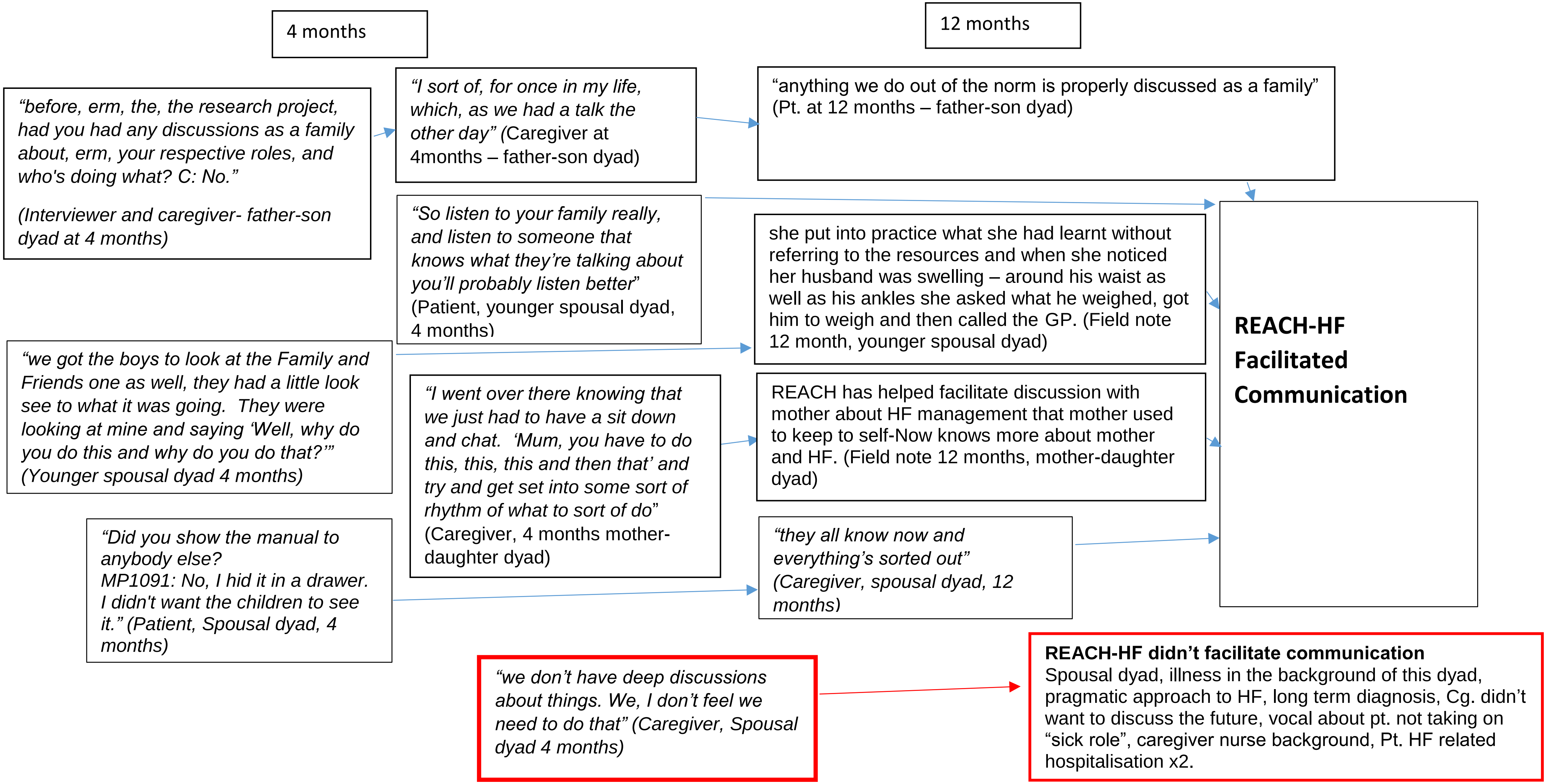
Appendix 22 Case oriented analysis

Dyad 4015	
CG @ 4 months: CG does not live with patient - one hour away CG is patients son Patient is a carer for his wife who has Dementia Incongruence in dyad The relationship is a key source of stress for CG - pt + + deterioration, only then will seek and receive help from CG therefore ? relationship type is moderated by caregiving/care receiving type relationship HF impacts the (family) unit not just the patient CG purpose for engaging in the programme was for pt. health improvement not for any personal goals CG is actively sourcing further info/knowledge from a variety of sources/ / Contrast here with CG (4061). This cg states I don't want to just get on with it; other cg states she just gets on with it BUT both at different points in their lives (retired v working) and different relationship with the patient (spousal v child) This cg did not meet with REACH-HF facilitator (He says he was more honest completing the research forms than at baseline. - this is from field notes from interviewer)	@ 4 MONTHS This patient is also a caregiver- what happens when the patient has other responsibilities i.e. carer, job, children, wife/parent to care for Active self-manager Reluctance to seek help - does not want to "bother" healthcare staff, also unlikely to seek support from family unless in crisis External motivator is caring for his wife (Dementia) Times of stability (unlikely to seek support) vs change or disease uncertainty Medical support - talks about his HF nurse ++ this contrasts with MP 4061 who's primary medical support appears to be his GP ? Patients acceptance of his condition and his ability - he talks a lot about getting back to oneself and using the term recovery ? if this patient is ambivalent - does he understand the trajectory of HF Use of manual/self-care - "pick out parts important to you" Reconciling past behaviour with current health status He wishes son as primary caregiver was more involved, describes taking step back from daughter as she is busy Family unit - everyone does their bit to care Stress management - family/wife. Intersection of family life This patient is taking a holistic approach - all things combined to manage HF Weight is his ref. points. Concerned about his weight and uses it regularly as an example when providing answers for his self-care
CG @ 12 months: CG perspective: Pt health stable, pt has increased awareness of his needs CG managing better + + External influencers on caregiving: Family support; CG has retired from his job Mother (Dementia) requires more care/support Father (pt) got a puppy, encourages him to go out walking Dyad more congruous now Pt. active self-manager - this in turn is impacting on cg; positively Family unit is very strong in this home managing HF and Dementia REACH intervention sparked conversation and catalyst for change within this family unit	@ 12 MONTHS Family unit - togetherness and discussing things, working through things together is prevalent throughout the interview Pt has increased awareness of physical limitations and own physical needs He is taking personal responsibility and has learned about self. Priority for him is his wife and trying to keep her active, well and living at home Got a puppy - good external influence Difference between support received from facilitator and medical support form Consultant and other medical services At times this patient is answering the interviewer questions from the general research perspective as opposed to himself and his own needs His role as a caregiver wasn't considered in the intervention process/HF self-mgt. programme.

	More consideration required for environmental impacts on health Patient appears to discuss much more his limitations, his increased self-awareness of his (physical) abilities Patient has stayed remained stable over past 12 months At time this patient talks about the intervention in generic terms i.e. from the research process and how it can benefit HF patients in general as opposed to himself and his own needs.
Dyad 4061	
4 months: This caregiver is an active manager in patient self-care Caregiver is retired from a head teacher role Cg primary focus appears to be patients weight management (patient frequently discussed weight mgt. in his interviews also) Cg is active in her own self-care; yoga, walking Has a friend with a similar situation, views as vital source of support. They go walking and share their experience Family unity - family/sons involved; cg emphasises that HF affects all not just the patient CG worries for patient health due to his weight CG frustrated with patient, doesn't know how to motivate him, struggles and exasperated, main frustration is his weight. CG reports she does not feel burdened and is happy CG doesn't see changes as a result of the programme - pt. does Dyad incongruent	@ 4 MONTHS Pt seems to be justifying his past and present and coming to terms with his illness even though he has HF over twelve years Psychologically believes weight loss and reduction in smoking resulted in Heart attack - as this was the timeline (Past trauma shaping current experience/actions) Mental health - doesn't use the words anxiety and stress but describes experiencing these, wife agrees Rationalising with himself about past actions and present situation Patient is very open in discussing his mind set Caregiver is present also for this interview and contributing at times At times patient is? seeking reassurance from caregivers as he seeks an answer from her. Patient struggled with some of the self-mgt tasks i.e. relaxation? how meaningful is this to him and is this why he is passive in self-mgt. it's not important to him, therefore a goal he will struggle with. Unable for the exercise, due to his knees (arthritis) thus unable to engage fully with exercise but perhaps this is an? excuse for not actively engaging in exercise Evidence of incongruence between couple - for example wife contradicting distance he walked. Weight is a recurring theme for this gentleman in self-mgt - but? is he conflicted, he seems to state he needs to lose weight but caregiver is in interview and encourages on this Appears to like practical/action tasks i.e. filling progress tracker instead of reading manual. Short sharp info. ? patients memory; ability to retain/recall information Patient contradicts himself at times; talks throught points then rationalises his actions i.e. exercise and weight Medication is having a significant lifestyle impact Up and down of the illness - patient likes to be in control Relationship with wife – pt. perspective: using positive words - value her, wouldn't do it without her, some negative words: weight/exercise is a consternation, wife passive about it according to patient (contradicts wife's

	interview where she expresses exasperation as she doesn't know how to motivate him anymore) ? does tasks because he is told without taking personal responsibility or fully understanding
12 months: Traditional marital relationship. Very honest communication with husband. Looks after him Worries about his weight Only change from REACH-HF was she learned about dietary aspects - ? was this her only focus as this is key worry for her with husband Good to engage in own self- care - retired. Has social network. Stressor of work for caregivers and trying to engage with REACH-HF, cg 1091 identified change in himself and stress levels when he retired and was able to be more available as a caregiver to his father. Hoped that an external outlet i.e. REACH-HF would motivate husband Optimistic as he is talking about re-joining gym – credits REACH-HF for this	@12 months Appears to not fully understand why he does some of his self-mgt. tasks i.e. weighing or what he would do if weight went up; not thinking about fluid retention – more so thinking that it would be due to eating excessively ? ties in with literature on cognition and self-care in HF - paper on same Reports HF stable but also reports he gets very breathless and not able to go like he once was Slight issue with BP doesn't know why Holidays Medication (furosemide) remains a difficulty Trusts GP - seeks advice Problem solved himself about a good time to take Furosemide so it would have minimal impact on his day Loss apparent - transition from playing sports to now not being able to; has to adapt from past meaningful interests but does not appear to have found a replacement interest which is of meaning and value to him Wife is very into fitness - does this create a discrepancy between the couple Some joint activity with wife - very appreciative of her Motivation remains questionable Logically can state what he needs to do Weight remains a focus for him Ds. a long time - lived experience and development of knowledge over long period He appears to just go along with it i.e. what Doc says, what wife says - my thoughts I would describe him as a passive self-manager ? Ambivalence and fear of pushing himself

Appendix 23 Chain of Evidence
Theme: REACH – HF facilitated communication



4 months

12 months

“before, erm, the, the research project, had you had any discussions as a family about, erm, your respective roles, and who's doing what? C: No.”

(Interviewer and caregiver- father-son dyad at 4 months)

“I sort of, for once in my life, which, as we had a talk the other day” (Caregiver at 4months – father-son dyad)

“So listen to your family really, and listen to someone that knows what they’re talking about you’ll probably listen better” (Patient, younger spousal dyad, 4 months)

“we got the boys to look at the Family and Friends one as well, they had a little look see to what it was going. They were looking at mine and saying ‘Well, why do you do this and why do you do that?’” (Younger spousal dyad 4 months)

“I went over there knowing that we just had to have a sit down and chat. ‘Mum, you have to do this, this, this and then that’ and try and get set into some sort of rhythm of what to sort of do” (Caregiver, 4 months mother-daughter dyad)

“Did you show the manual to anybody else? MP1091: No, I hid it in a drawer. I didn't want the children to see it.” (Patient, Spousal dyad, 4 months)

“anything we do out of the norm is properly discussed as a family” (Pt. at 12 months – father-son dyad)

she put into practice what she had learnt without referring to the resources and when she noticed her husband was swelling – around his waist as well as his ankles she asked what he weighed, got him to weigh and then called the GP. (Field note 12 month, younger spousal dyad)

REACH has helped facilitate discussion with mother about HF management that mother used to keep to self-Now knows more about mother and HF. (Field note 12 months, mother-daughter dyad)

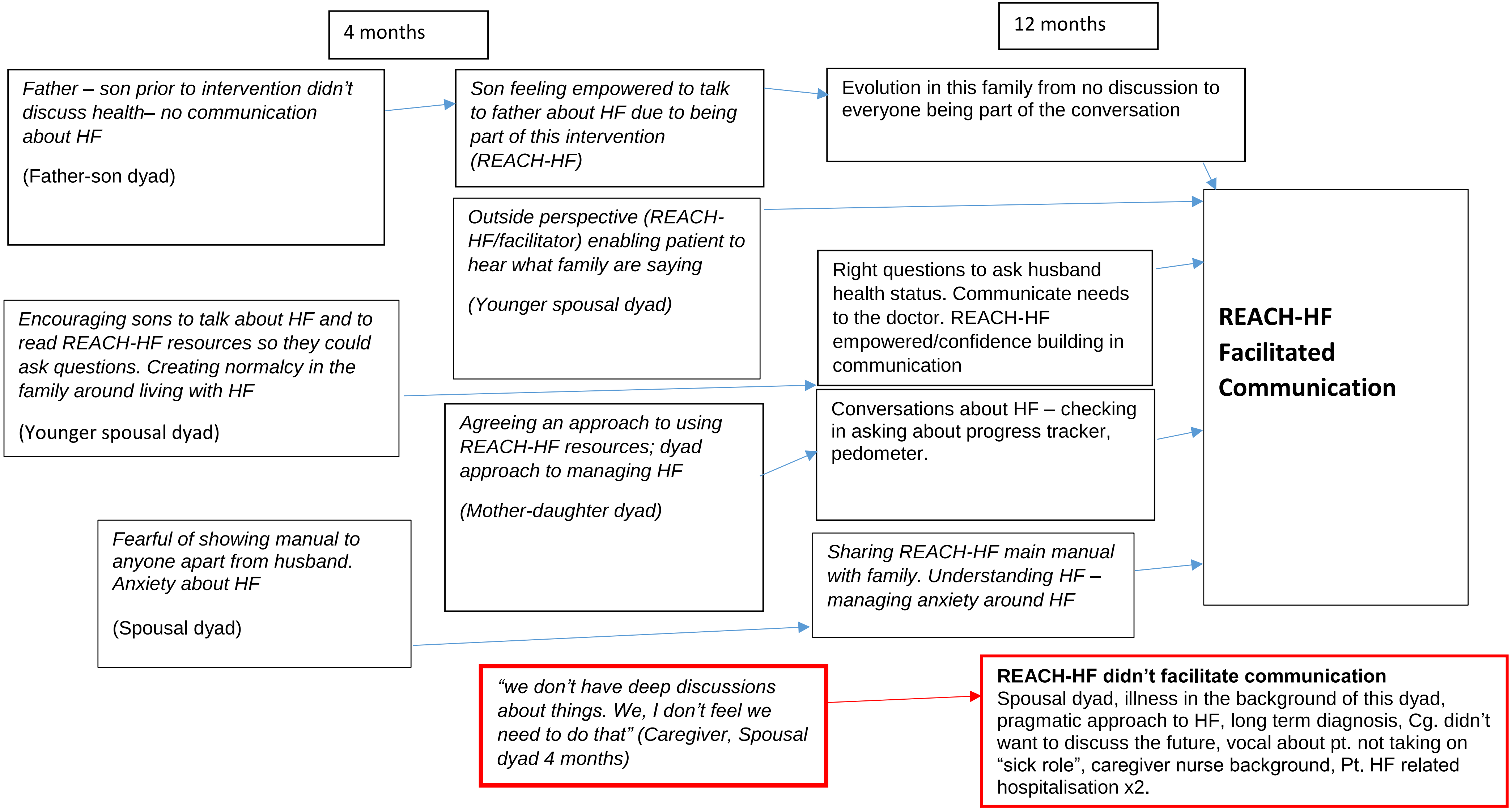
“they all know now and everything’s sorted out” (Caregiver, spousal dyad, 12 months)

REACH-HF Facilitated Communication

“we don’t have deep discussions about things. We, I don’t feel we need to do that” (Caregiver, Spousal dyad 4 months)

REACH-HF didn’t facilitate communication
Spousal dyad, illness in the background of this dyad, pragmatic approach to HF, long term diagnosis, Cg. didn’t want to discuss the future, vocal about pt. not taking on “sick role”, caregiver nurse background, Pt. HF related hospitalisation x2.

Appendix 24 Chain of Evidence – Theme: REACH – HF facilitated communication



4 months

12 months

Father – son prior to intervention didn't discuss health– no communication about HF

(Father-son dyad)

Son feeling empowered to talk to father about HF due to being part of this intervention (REACH-HF)

Evolution in this family from no discussion to everyone being part of the conversation

Outside perspective (REACH-HF/facilitator) enabling patient to hear what family are saying

(Younger spousal dyad)

Right questions to ask husband health status. Communicate needs to the doctor. REACH-HF empowered/confidence building in communication

REACH-HF Facilitated Communication

Encouraging sons to talk about HF and to read REACH-HF resources so they could ask questions. Creating normalcy in the family around living with HF

(Younger spousal dyad)

Agreeing an approach to using REACH-HF resources; dyad approach to managing HF

(Mother-daughter dyad)

Conversations about HF – checking in asking about progress tracker, pedometer.

Fearful of showing manual to anyone apart from husband. Anxiety about HF

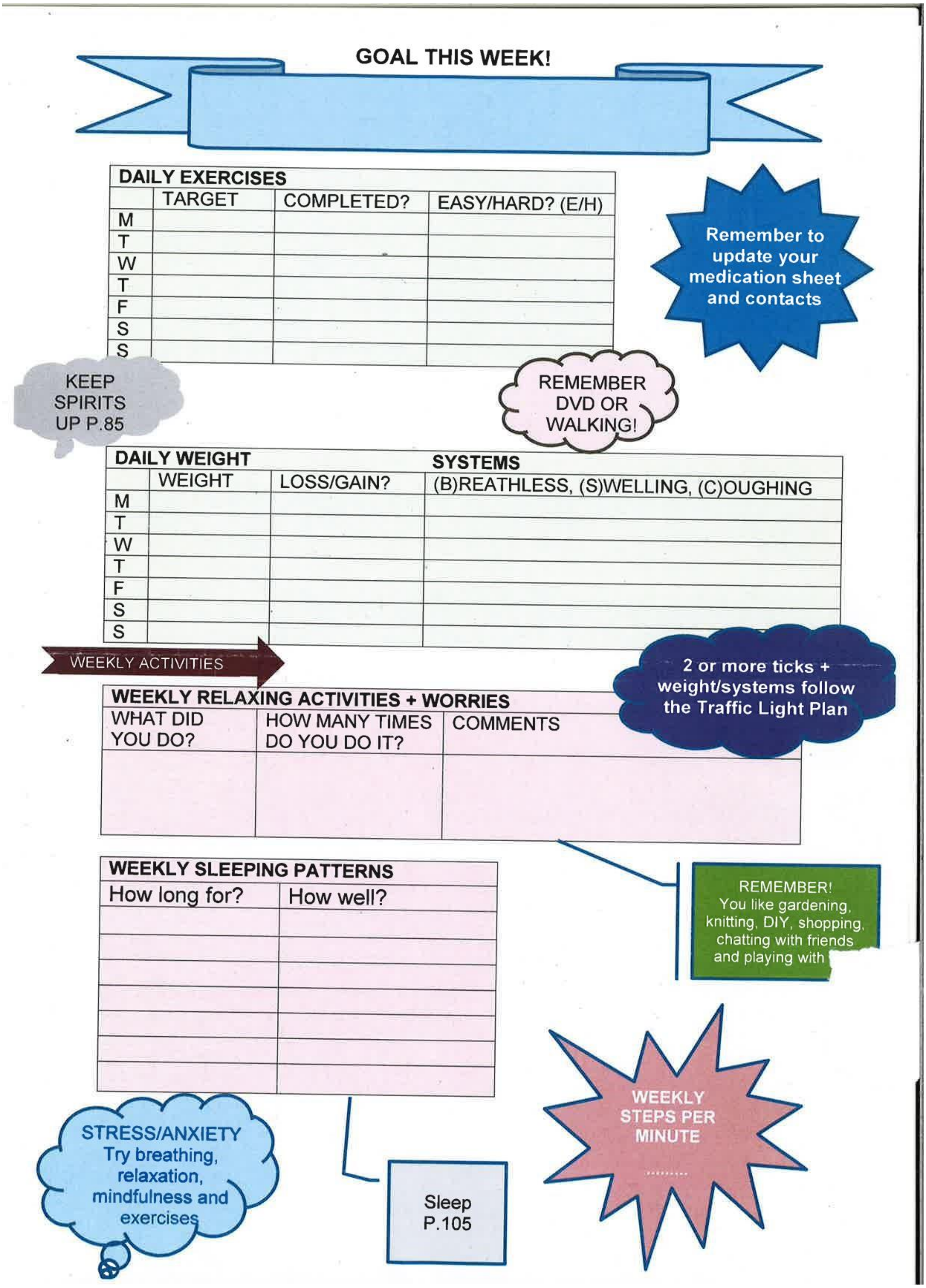
(Spousal dyad)

Sharing REACH-HF main manual with family. Understanding HF – managing anxiety around HF

"we don't have deep discussions about things. We, I don't feel we need to do that" (Caregiver, Spousal dyad 4 months)

REACH-HF didn't facilitate communication
Spousal dyad, illness in the background of this dyad, pragmatic approach to HF, long term diagnosis, Cg. didn't want to discuss the future, vocal about pt. not taking on "sick role", caregiver nurse background, Pt. HF related hospitalisation x2.

Appendix 25 One page progress tracker adapted by caregiver



GOAL THIS WEEK!

DAILY EXERCISES

	TARGET	COMPLETED?	EASY/HARD? (E/H)
M			
T			
W			
T			
F			
S			
S			

Remember to update your medication sheet and contacts

KEEP SPIRITS UP P.85

REMEMBER DVD OR WALKING!

DAILY WEIGHT

	WEIGHT	LOSS/GAIN?	**SYSTEMS** (B)REATHLESS, (S)WELLING, (C)OUGHING
M			
T			
W			
T			
F			
S			
S			

WEEKLY ACTIVITIES

2 or more ticks + weight/systems follow the Traffic Light Plan

WEEKLY RELAXING ACTIVITIES + WORRIES

WHAT DID YOU DO?	HOW MANY TIMES DO YOU DO IT?	COMMENTS

WEEKLY SLEEPING PATTERNS

How long for?	How well?

REMEMBER!
You like gardening, knitting, DIY, shopping, chatting with friends and playing with

WEEKLY STEPS PER MINUTE
....

STRESS/ANXIETY
Try breathing, relaxation, mindfulness and exercises

Sleep
P.105

References

1. World Health Organisation. Global Health Observatory (GHO) data [Internet]. World Health Organisation; [updated 2020, March 25; cited 2020 March 25]. Available from: https://www.who.int/gho/mortality_burden_disease/en/

2. National Health Service. Improving care for older people [Internet]. National Health Service; [updated 20th March 2020; cited 2020 March 25]. Available from: https://www.england.nhs.uk/ourwork/clinical-policy/

3. Carers UK. State of Caring [Internet]. 2019 [cited February 2020 15]. Available from: carersuk.org/stateofcaring-report

4. The Kings Fund and Centre for Mental Health. Long-term conditions and mental health. The cost of co-morbidities [Internet]. 2012 [2020 March 20] Available from: https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/long-term-conditions-mental-health-cost-comorbidities-naylor-feb12.pdf

5. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002; 288(19):2469–2475.doi:10.1001/jama.288.19.2469

6. Department of Health. Improving the health and well-being of people with long term conditions, 298720. [Internet]. 2010 [cited 2020 March 10] Available from: https://www.yearofcare.co.uk/sites/default/files/pdfs/dh_improving%20the%20h&wb%20of%20people%20with%20LTCs.pdf

7. Department of Health. Improving the health and well-being of people with long term conditions, 298720. [Internet]. 2010 [cited 2020 March 10] Available from: https://www.yearofcare.co.uk/sites/default/files/pdfs/dh_improving%20the%20h&wb%20of%20people%20with%20LTCs.pdf

8. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. American Journal of Public Health. 2014;104(8):e25-e31.

9. Janssen DJ, Franssen FM, Wouters EF, Schols JM, Spruit MA. Impaired health status and care dependency in patients with advanced COPD or chronic heart failure. Quality of life research. 2011;20(10):1679-88.

10. Simpson AC, Young J, Donahue M, Rocker G. A day at a time: caregiving on the edge in advanced COPD. International journal of chronic obstructive pulmonary disease. 2010;5:141-51.

11. Trivedi RB, Bryson CL, Udris E, Au DH. The influence of informal caregivers on adherence in COPD patients. Ann Behav Med. 2012; 44(1):66-72. doi:10.1007/s12160-012-9355-8

12. Buck HG, Harkness K, Wion R, Carroll SL, Cosman T, Kaasalainen S, et al. Caregivers’ contributions to heart failure self-care: A systematic review. European

Journal of Cardiovascular Nursing. 2015;14(1):79-89. doi:10.1177/1474515113518434

13. Lee D-C, Artero EG, Xuemei S, Blair SN. Review: Mortality trends in the general population: the importance of cardiorespiratory fitness. Journal of Psychopharmacology. 2010;24(4_suppl):27-35.

14. Carers UK. Facts about carers [Internet]. 2019. [cited 2020 January 19] Available from: https://www.carersuk.org/images/Facts_about_Carers_2019.pdf

15. Office for National Statistics. Census Analysis: unpaid care in England and Wales, 2011 and comparison with 2001 [Internet]. 2013 [cited February 15 2020] Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/articles/2011censusanalysisunpaidcareinenglandandwales2011andcomparisonwith2001/2013-02-15

16. Carers Trust. About carers [Internet]. 2015. [cited 2020 January 19] Available from: https://carers.org/

17. Reblin M. Care Recipients. In: Gellman MD, Turner JR, editors. Encyclopedia of Behavioral Medicine. New York, NY: Springer New York; 2013. p. 350-1.

18. Butterworth P, Pymont C, Rodgers B, Windsor TD, Anstey KJ. Factors that explain the poorer mental health of caregivers: Results from a community survey of older Australians. Australian & New Zealand Journal of Psychiatry. 2010;44(7):616-24.

19. Francesca, C, Ana, LN, Jrome, M, Frits, T. OECD Health Policy Studies Help Wanted? Providing and Paying for Long-Term Care: Providing and Paying for Long-Term Care. OECD Publishing; 2011. Chapter 3: The impact of caring on family carers; p. 85-120

20. Hill P, Broady TR. Understanding the social and emotional needs of carers: final report (SPRC Report 2/19). [Internet]. 2019 [cited 2020 January 18] Available from: http://doi.org/10.26190/5c59202697201

21. Vitaliano PP, Zhang J, Scanlan JM. Is caregiving hazardous to one's physical health? A meta-analysis. Psychol Bull. 2003; 129 (6):946-972. doi:10.1037/0033-2909.129.6.946

22. Larkin M, Henwood M, Milne A. Carer-related research and knowledge: Findings from a scoping review. Health Soc Care Community. 2019; 27(1):55-67. doi:10.1111/hsc.12586

23. Chi NC, Demiris G, Pike KC, Washington K, Parker Oliver D. Exploring the Challenges that Family Caregivers Faced When Caring for Hospice Patients with Heart Failure. J Soc Work End Life Palliat Care. 2018;14(2-3):162-76.

24. Doherty LC, Fitzsimons D, McIlfatrick SJ. Carers' needs in advanced heart failure: A systematic narrative review. European journal of cardiovascular nursing. 2016;15(4):203-12.

25. Kitko L, McIlvennan CK, Bidwell JT, Dionne-Odom JN, Dunlay SM, Lewis LM, et al. Family Caregiving for Individuals With Heart Failure: A Scientific Statement From the American Heart Association. Circulation. 2020:Cir0000000000000768.

26. Strömberg A. The situation of caregivers in heart failure and their role in improving patient outcomes. Current heart failure reports. 2013;10(3):270-5.

27. Farquhar M. Assessing carer needs in chronic obstructive pulmonary disease. Chronic respiratory disease. 2018;15(1):26-35.

28. Greaves CJ, Wingham J, Deighan C, Doherty P, Elliott J, Armitage W, et al. Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. Pilot and feasibility studies. 2016;2(1):37.

29. Dalal HM, Taylor RS, Jolly K, Davis RC, Doherty P, Miles J, et al. The effects and costs of home-based rehabilitation for heart failure with reduced ejection fraction: The REACH-HF multicentre randomized controlled trial. European Journal of Preventive Cardiology. 2019;26(3):262-72.

30. Lang CC, Smith K, Wingham J, Eyre V, Greaves CJ, Warren FC, et al. A randomised controlled trial of a facilitated home-based rehabilitation intervention in patients with heart failure with preserved ejection fraction and their caregivers: the REACH-HFpEF Pilot Study. BMJ Open. 2018;8(4):e019649.

31. Chi N-C, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. Journal of telemedicine and telecare. 2015;21(1):37-44.

32. Stoltz P, Uden G, Willman A. Support for family carers who care for an elderly person at home–a systematic literature review. Scandinavian journal of caring sciences. 2004;18(2):111-9.

33. Wolff JL, Spillman BC, Freedman VA, Kasper JD. A national profile of family and unpaid caregivers who assist older adults with health care activities. JAMA internal medicine. 2016;176(3):372-9.

34. Lorig KR, Holman HR. Self-management education: history, definition, outcomes, and mechanisms. Annals of behavioral medicine. 2003;26(1):1-7.

35. Carers UK. Valuing carers 2015 – the rising value of carers' support. [Internet]. 2015 [cited Jan 18 2020]. Available from: https://www.carersuk.org/for-professionals/policy/policy-library/valuing-carers-2015

36. Carers UK. State of Caring 2016. [Internet]. 2016 [cited Jan 18 2020]. Available from: https://www.carersuk.org/for-professionals/policy/policy-library/state-of-caring-2016

37. The Kings Fund. The NHS budget and how it has changed. [Internet]. London: The Kings Fund; [2020 Mar 13; cited 2020 Apr 4]. Available from: https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/nhs-budget

38. International Alliance of Carer Organisations. Global carer facts [Internet]. Washington USA: IACO; [2018 Mar 5; cited 2020 May 10]. Available from: http://www.internationalcarers.org/carer-facts/global-carer-stats/

39. Kang X, Li Z, Nolan MT. Informal caregivers' experiences of caring for patients with chronic heart failure: systematic review and metasynthesis of qualitative studies. J Cardiovasc Nurs. 2011;26(5):386-394. doi:10.1097/JCN.0b013e3182076a69

40. Reinhard SC, Feinberg LF, Choula R, Houser A. Valuing the invaluable: 2015 update. Insight on the Issues. 2015 Jul; 104:89-98

41. Donelan K, Hill CA, Hoffman C, et al. Challenged to care: informal caregivers in a changing health system. Health Aff (Millwood). 2002;21(4):222-231. doi:10.1377/hlthaff.21.4.222

42. Pickard S, Jacobs S, Kirk S. Challenging professional roles: lay carers’ involvement in health care in the community. Soc Policy Adm. 2003;37(1):82-96. doi: 10.1111/1467-9515.00325

43. Moorman SM, Macdonald C. Medically complex home care and caregiver strain. Gerontologist. 2013;53(3):407-417. doi:10.1093/geront/gns067

44. Knowles S, Combs R, Kirk S, Griffiths M, Patel N, Sanders C. Hidden caring, hidden carers? Exploring the experience of carers for people with long-term conditions. Health & social care in the community. 2016;24(2):203-13.

45. Mattock S, McIntyre A. Exploring the role of occupation for spouse-carers before and after the death of a spouse with dementia. British Journal of Occupational Therapy. 2016;79(2):69-77.

46. Frederick J, Fast J. Eldercare in Canada: who does how much? Canadian Social Trend. 1999, Sep 9;86:26-32. Available from: https://www150.statcan.gc.ca/n1/pub/11-008-x/1999002/article/4661-eng.pdf

47. European Network of Economic Policy Research Institutes. The long-term care system for the elderly in England [Internet]. London, United Kingdom: The Stationary Office; 2010 [cited May 2019 5]. Available from: http://www.ancien-longtermcare.eu/sites/default/files/ENEPRI%20_ANCIEN_%20RRNo%2074England.pdf

48. Hughes Z, O'Sullivan L. Defining and profiling family carers: reflections from Ireland. IJCC. 2017;1(3):421-7. doi.org/10.1332/239788217X15018372247977

49. Feinberg LF. Recognizing and supporting family caregivers: The time has come. Public Policy & Aging Report. 2014;24(2):65-9. doi:org/10.1093/ppar/pru007

50. Lacey RE, McMunn A, Webb E. Informal caregiving patterns and trajectories of psychological distress in the UK Household Longitudinal Study. Psychological medicine. 2019;49(10):1652-60.

51. Marking C. 'Enabling carers to care': making the case for a European Union action plan on carers. International Journal of Care and Caring. 2017;1(2):289-92. doi:10.1332/239788217X14951899318087

52. EUROCARERS. European Parliament Informal Carers Interest Group. [Internet]. Belgium: European Parliament; [2019 Sept 25; 2020 June 12]. Available from: https://eurocarers.org/eurocarers-epig/

53. Cacchione PZ. The Recognize, Assist, Include, Support and Engage (RAISE) Family Caregivers Act. Clin Nurs Res. 2019;28(8):907-910. doi:10.1177/1054773819876130

54. Department of Health and Social Care. Carers Action Plan 2018 - 2020 supporting carers today. [Internet]. London: Department of Health and Social Care; 2018 [updated 2018 Jun; cited 2020 Jun 12]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/713781/carers-action-plan-2018-2020.pdf

56. Magid M, Jones J, Allen LA, McIlvennan CK, Magid K, Thompson JS, et al. The Perceptions of Important Elements of Caregiving for a Left Ventricular Assist Device Patient: A Qualitative Meta-Synthesis. The Journal of cardiovascular nursing. 2016;31(3):215-25.

57. Schulz R, Sherwood PR. Physical and mental health effects of family caregiving. Journal of Social Work Education. 2008;44(sup3):105-13.

58. O'Dwyer ST, Moyle W, Zimmer-Gembeck M, De Leo D. Suicidal ideation in family carers of people with dementia: a pilot study. International journal of geriatric psychiatry. 2013;28(11):1182-8.

59. Stansfeld S, Smuk M, Onwumere J, Clark C, Pike C, McManus S, et al. Stressors and common mental disorder in informal carers–an analysis of the English adult psychiatric morbidity survey 2007. Social Science & Medicine. 2014;120:190-8.

60. Office for National Statistics. More than one in four sandwich carers report symptoms of mental ill-health. Health and Social Care [Internet]. 2013 [cited February 15 2020] Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/articles/morethanoneinfoursandwichcarersreportsymptomsofmentalillhealth/2019-01-14#:~:text=More%20than%2033%25%20of%20sandwich,than%20five%20hours%20each%20week.

61. Pressler SJ, Gradus-Pizlo I, Chubinski SD, Smith G, Wheeler S, Sloan R, et al. Family caregivers of patients with heart failure: a longitudinal study. Journal of Cardiovascular Nursing. 2013;28(5):417-28.

62. Wingham J, Frost J, Britten N, Jolly K, Greaves C, Abraham C, et al. Needs of caregivers in heart failure management: A qualitative study. Chronic Illn. 2015;11(4):304-19.

63. Agren S, Evangelista LS, Hjelm C, Stromberg A. Dyads affected by chronic heart failure: a randomized study evaluating effects of education and psychosocial support to patients with heart failure and their partners. Journal of cardiac failure. 2012;18(5):359-66.

64. Dionne-Odom JN, Hooker SA, Bekelman D, Ejem D, McGhan G, Kitko L, et al. Family caregiving for persons with heart failure at the intersection of heart failure and palliative care: a state-of-the-science review. Heart failure reviews. 2017;22(5):543-57.

65. O'Dwyer ST, Moyle W, Taylor T, Creese J, Zimmer-Gembeck MJ. Homicidal ideation in family carers of people with dementia. Aging & mental health. 2016;20(11):1174-81.

66. O'Dwyer ST, Moyle W, Zimmer-Gembeck M, De Leo D. Suicidal ideation in family carers of people with dementia. Aging Ment Health. 2016;20(2):222-30.

67. Bom J, Bakx P, Schut F, van Doorslaer E. The Impact of Informal Caregiving for Older Adults on the Health of Various Types of Caregivers: A Systematic Review. The Gerontologist. 2019;59(5):e629-e42.

68. Pinquart M, Sörensen S. Correlates of physical health of informal caregivers: a meta-analysis. The Journals of Gerontology Series B: Psychological Sciences and Social Sciences. 2007;62(2):P126-P37.

69. Lambert SD, Duncan LR, Kapellas S, Bruson A-M, Myrand M, Santa Mina D, et al. A Descriptive Systematic Review of Physical Activity Interventions for Caregivers: Effects on Caregivers’ and Care Recipients’ Psychosocial Outcomes, Physical Activity Levels, and Physical Health. Annals of Behavioral Medicine. 2016;50(6):907-19.

70. Bushman B, Wang MC. Vote-counting procedures in meta-analysis. The handbook of research synthesis and meta-analysis. 2009:207-20.

71. Sharma N, Chakrabarti S, Grover S. Gender differences in caregiving among family - caregivers of people with mental illnesses. World J Psychiatry. 2016;6(1):7-17.

72. Greenwood N, Smith R. The oldest carers: a narrative review and synthesis of the experiences of carers aged over 75 years. Maturitas. 2016;94:161-72.

73. Hogstel MO, Curry LC, Walker C. Caring for Older Adults: The Benefits of Informal Family Caregiving. Journal of Theory Construction & Testing. 2005;9(2).

74. Kramer BJ. Gain in the caregiving experience: where are we? What next? Gerontologist. 1997;37(2):218-32.

75. Mackenzie A, Greenwood N. Positive experiences of caregiving in stroke: a systematic review. Disability and Rehabilitation. 2012;34(17):1413-22.

76. Quinn C, Toms G. Influence of positive aspects of dementia caregiving on caregivers' well-being: A systematic review. The Gerontologist.

77. Grigorovich A, Lee A, Ross H, Woodend AK, Forde S, Cameron JI. A longitudinal view of factors that influence the emotional well-being of family caregivers to individuals with heart failure. Aging & mental health. 2017;21(8):844-50.

78. Curran PJ, Obeidat K, Losardo D. Twelve Frequently Asked Questions About Growth Curve Modeling. J Cogn Dev. 2010;11(2):121-36.

79. Jones J, Nowels CT, Sudore R, Ahluwalia S, Bekelman DB. The future as a series of transitions: qualitative study of heart failure patients and their informal caregivers. Journal of general internal medicine. 2015;30(2):176-82.

80. Pearlin LI. The life course and the stress process: Some conceptual comparisons. Journals of Gerontology Series B: Psychological Sciences and Social Sciences. 2010;65(2):207-15.

81. Pearlin LI, Menaghan EG, Lieberman MA, Mullan JT. The stress process. Journal of Health and Social behavior. 1981:337-56.

82. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: An overview of concepts and their measures. The gerontologist. 1990;30(5):583-94.

83. Bolden L, Wicks MN. The clinical utility of the Stress Process Model in family caregivers of liver transplant candidates. Progress in Transplantation. 2008;18(2):74-9.

84. Au A. The sociological study of stress. European Journal of mental health. 2017;12(01):53-72.

85. Whitlatch CJ, Schur D, Noelker LS, Ejaz FK, Looman WJ. The Stress Process of Family Caregiving in Institutional Settings. The Gerontologist. 2001;41(4):462-73.

86. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychological review. 1977;84(2):191.

87. Khan F, Pallant J, Brand C. Caregiver strain and factors associated with caregiver self-efficacy and quality of life in a community cohort with multiple sclerosis. Disability and Rehabilitation. 2007;29(16):1241-50.

88. Thomas Hebdon MC, Coombs LA, Reed P, Crane TE, Badger TA. Self-efficacy in caregivers of adults diagnosed with cancer: An integrative review. European Journal of Oncology Nursing. 2021;52:101933.

89. Lyons KS, Zarit SH, Sayer AG, Whitlatch CJ. Caregiving as a dyadic process: Perspectives from caregiver and receiver. The Journals of Gerontology Series B: Psychological Sciences and Social Sciences. 2002;57(3):P195-P204.

90. Buck HG, Stromberg A, Chung ML, Donovan KA, Harkness K, Howard AM, et al. A systematic review of heart failure dyadic self-care interventions focusing on intervention components, contexts, and outcomes. International journal of nursing studies. 2018;77:232-42.

91. Dwarswaard J, Bakker EJ, van Staa A, Boeije HR. Self-management support from the perspective of patients with a chronic condition: a thematic synthesis of qualitative studies. Health Expectations. 2016;19(2):194-208.

92. Lopez-Hartmann M, Wens J, Verhoeven V, Remmen R. The effect of caregiver support interventions for informal caregivers of community-dwelling frail elderly: a systematic review. International journal of integrated care. 2012;12.

93. Riegel B, Lee CS, Dickson VV. Self care in patients with chronic heart failure. Nature Reviews Cardiology. 2011;8(11):644-54.

94. Riegel B, Jaarsma T, Strömberg A. A Middle-Range Theory of Self-Care of Chronic Illness. Advances in Nursing Science. 2012;35(3):194-204.

95. Riegel B, Jaarsma T, Lee CS, Strömberg A. Integrating Symptoms Into the Middle-Range Theory of Self-Care of Chronic Illness. Advances in Nursing Science. 2019;42(3):206-15.

96. National Health Service. Digital Transformation [Internet]. National Health Service; [updated 20th March 2020; cited 2020 March 25]. Available from: https://www.longtermplan.nhs.uk/areas-of-work/digital-transformation/

97. Irani E, Niyomyart A, Hickman RL. Systematic Review of Technology-Based Interventions Targeting Chronically Ill Adults and Their Caregivers. Western Journal of Nursing Research. 2020;42(11):974-92.

98. Martire LM, Lustig AP, Schulz R, Miller GE, Helgeson VS. Is it beneficial to involve a family member? A meta-analysis of psychosocial interventions for chronic illness. Health psychology. 2004;23(6):599.

99. Hartmann M, Bäzner E, Wild B, Eisler I, Herzog W. Effects of interventions involving the family in the treatment of adult patients with chronic physical diseases: a meta-analysis. Psychotherapy and psychosomatics. 2010;79(3):136-48.

100. Carr RM, Prestwich A, Kwasnicka D, Thøgersen-Ntoumani C, Gucciardi DF, Quested E, et al. Dyadic interventions to promote physical activity and reduce sedentary behaviour: systematic review and meta-analysis. Health Psychol Rev. 2019;13(1):91-109.

101. Carr RM, Prestwich A, Kwasnicka D, Thøgersen-Ntoumani C, Gucciardi DF, Quested E, et al. Dyadic interventions to promote physical activity and reduce

sedentary behaviour: systematic review and meta-analysis. Health Psychology Review. 2019;13(1):91-109.

102. Chesla CA. Do Family Interventions Improve Health? Journal of Family Nursing. 2010;16(4):355-77.

103. Hu Y, Liu T, Li F. Association between dyadic interventions and outcomes in cancer patients: a meta-analysis. Supportive Care in Cancer. 2019;27(3):745-61.

104. Griffin JM, Meis LA, MacDonald R, Greer N, Jensen A, Rutks I, et al. Effectiveness of family and caregiver interventions on patient outcomes in adults with cancer: A systematic review. Journal of general internal medicine. 2014;29(9):1274-82.

105. Ekstam L, Johansson U, Guidetti S, Eriksson G, Ytterberg C. The combined perceptions of people with stroke and their carers regarding rehabilitation needs 1 year after stroke: a mixed methods study. BMJ open. 2015;5(2):e006784.

106. Gage H, Hamilton L, Goodman C, Ashaye K, Iliffe S, Manthorpe J, et al. Managing behavioural and psychological symptoms in community dwelling older people with dementia: 1. A systematic review of the effectiveness of interventions. Dementia (14713012). 2019;18(7/8):2925-49.

107. Trivedi DP, Braun A, Dickinson A, Gage H, Hamilton L, Goodman C, et al. Managing behavioural and psychological symptoms in community dwelling older people with dementia: 1. A systematic review of the effectiveness of interventions. Dementia. 2018;18(7-8):2925-49.

108. Schulz R, Burgio L, Burns R, Eisdorfer C, Gallagher-Thompson D, Gitlin LN, et al. Resources for Enhancing Alzheimer's Caregiver Health (REACH): overview, site-specific outcomes, and future directions. The Gerontologist. 2003;43(4):514-20.

109. Burns R, Nichols LO, Martindale-Adams J, Graney MJ, Lummus A. Primary care interventions for dementia caregivers: 2-year outcomes from the REACH study. Gerontologist. 2003;43(4):547-55.

110. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. Jama. 1999;282(23):2215-9.

111. Luttik ML, Jaarsma T, Stromberg A. Changing needs of heart failure patients and their families during the illness trajectory: A challenge for health care. European Journal of Cardiovascular Nursing. 2016;15(5):298-300.

112. Giacomini M, DeJean D, Simeonov D, Smith A. Experiences of living and dying with COPD: a systematic review and synthesis of the qualitative empirical literature. Ontario health technology assessment series. 2012;12(13):1.

113. Schulz R, O'Brien A, Czaja S, Ory M, Norris R, Martire LM, et al. Dementia caregiver intervention research: in search of clinical significance. Gerontologist. 2002;42(5):589-602.

114. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with Family Caregivers of Cancer Patients: Meta-Analysis of Randomized Trials. CA: A Cancer Journal for Clinicians. 2010;60(5):317-39.

115. Kreitzer N, Kurowski BG, Bakas T. Systematic Review of Caregiver and Dyad Interventions After Adult Traumatic Brain Injury. Arch Phys Med Rehabil. 2018;99(11):2342-54.

116. Oyebode J. Assessment of carers' psychological needs. Advances in Psychiatric Treatment. 2003;9(1):45-53.

117. Henwood M, Larkin M, Milne A. Seeing the wood for the trees. Carer related research and knowledge: A scoping review. 2017.

118. Members ATF, Dickstein K, Cohen-Solal A, Filippatos G, McMurray JJ, Ponikowski P, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM). European heart journal. 2008;29(19):2388-442.

119. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al. Heart disease and stroke statistics--2015 update: a report from the American Heart Association. Circulation. 2015;131(4):e29-322.

120. National Institute for Health and Care Excellence. Chronic heart failure in adults. Quality standard 9 [Internet]. 2018 [cited 2020 Mar 4]. Available from: https://www.nice.org.uk/guidance/qs9/chapter/Quality-statement-6-Programme-of-cardiac-rehabilitation

121. Gardner RS, McDonagh TA. Chronic heart failure: epidemiology, investigation and management. Medicine. 2014;42(10):562-7.

122. Cowie MR, Mendez GF. BNP and congestive heart failure. Progress in Cardiovascular Diseases. 2002;44(4):293-321.

123. Cowie MR, Jourdain P, Maisel A, Dahlstrom U, Follath F, Isnard R, et al. Clinical applications of B-type natriuretic peptide (BNP) testing. European Heart Journal. 2003;24(19):1710-8.

124. Galasko GIW, Lahiri A, Barnes SC, Collinson P, Senior R. What is the normal range for N-terminal pro-brain natriuretic peptide? How well does this normal range screen for cardiovascular disease? European Heart Journal. 2005;26(21):2269-76.

125. Doust J, Lehman R, Glasziou P. The role of BNP testing in heart failure. American family physician. 2006;74(11):1893-8.

126. Sakane K, Kanzaki Y, Tsuda K, Maeda D, Sohmiya K, Hoshiga M. Disproportionately low BNP levels in patients of acute heart failure with preserved vs. reduced ejection fraction. International Journal of Cardiology. 2021;327:105-10.

127. Anjan VY, Loftus TM, Burke MA, Akhter N, Fonarow GC, Gheorghiade M, et al. Prevalence, Clinical Phenotype, and Outcomes Associated With Normal B-Type Natriuretic Peptide Levels in Heart Failure With Preserved Ejection Fraction. The American Journal of Cardiology. 2012;110(6):870-6.

128. Doust JA, Pietrzak E, Dobson A, Glasziou P. How well does B-type natriuretic peptide predict death and cardiac events in patients with heart failure: systematic review. Bmj. 2005;330(7492):625.

129. Ho JE, Lyass A, Lee DS, Vasan RS, Kannel WB, Larson MG, et al. Predictors of new-onset heart failure: differences in preserved versus reduced ejection fraction. Circulation: heart failure. 2013;6(2):279-86.

130. Pearse SG, Cowie MR. Heart failure: classification and pathophysiology. Medicine. 2014;42(10):556-61.

131. Pfeffer MA, Shah AM, Borlaug BA. Heart Failure With Preserved Ejection Fraction In Perspective. Circulation Research. 2019;124(11):1598-617.

132. Savarese G, Lund LH. Global Public Health Burden of Heart Failure. Card Fail Rev. 2017;3(1):7-11.

133. National Institute for Health and Care Excellence. Chronic obstructive pulmonary disease in over 16s: diagnosis and management. [Internet]. 2018 [cited 2020 Mar 4]. Available from: https://www.nice.org.uk/guidance/ng115

134. Dalal HM, Wingham J, Palmer J, Taylor R, Petre C, Lewin R. Why do so few patients with heart failure participate in cardiac rehabilitation? A cross-sectional survey from England, Wales and Northern Ireland. BMJ Open. 2012;2(2):e000787.

135. Galiè N, Humbert M, Vachiery J-L, Gibbs S, Lang I, Torbicki A, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). 2015;46(4):903-75.

136. Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive lung disease 2017 report. GOLD executive summary. American journal of respiratory and critical care medicine. 2017;195(5):557-82.

137. Mannino DM, Buist AS. Global burden of COPD: risk factors, prevalence, and future trends. The Lancet. 2007;370(9589):765-73.

138. Miravitlles M, Vogelmeier C, Roche N, Halpin D, Cardoso J, Chuchalin AG, et al. A review of national guidelines for management of COPD in Europe. European Respiratory Journal. 2016;47(2):625-37.

139. Celli B, Decramer M, Kesten S, Liu D, Mehra S, Tashkin DP. Mortality in the 4-Year Trial of Tiotropium (UPLIFT) in Patients with Chronic Obstructive Pulmonary Disease. American Journal of Respiratory and Critical Care Medicine. 2009;180(10):948-55.

140. Sin DD, Anthonisen N, Soriano J, Agusti A. Mortality in COPD: role of comorbidities. European Respiratory Journal. 2006;28(6):1245-57.

141. Barnett M. Chronic obstructive pulmonary disease: a phenomenological study of patients' experiences. Journal of clinical nursing. 2005;14(7):805-12.

142. Jeon Y-H, Kraus SG, Jowsey T, Glasgow NJ. The experience of living with chronic heart failure: a narrative review of qualitative studies. BMC health services research. 2010;10(1):77.

143. Gore J, Brophy C, Greenstone M. How well do we care for patients with end stage chronic obstructive pulmonary disease (COPD)? A comparison of palliative care and quality of life in COPD and lung cancer. Thorax. 2000;55(12):1000-6.

144. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JG, Coats AJ, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. European journal of heart failure. 2016;18(8):891-975.

145. Solano JP, Gomes B, Higginson IJ. A comparison of symptom prevalence in far advanced cancer, AIDS, heart disease, chronic obstructive pulmonary disease and renal disease. Journal of pain and symptom management. 2006;31(1):58-69.

146. Agustí A. Systemic effects of chronic obstructive pulmonary disease: what we know and what we don't know (but should). Proceedings of the American Thoracic Society. 2007;4(7):522-5.

147. Britton M. The burden of COPD in the UK: results from the Confronting COPD survey. Respiratory medicine. 2003;97:S71-S9.

148. Gardener AC, Ewing G, Kuhn I, Farquhar M. Support needs of patients with COPD: a systematic literature search and narrative review. Int J Chron Obstruct Pulmon Dis. 2018;13:1021-35.

149. Mansfield E, Bryant J, Regan T, Waller A, Boyes A, Sanson-Fisher R. Burden and unmet needs of caregivers of chronic obstructive pulmonary disease patients: a systematic review of the volume and focus of research output. COPD: Journal of Chronic Obstructive Pulmonary Disease. 2016;13(5):662-7.

150. Nakken N, Janssen DJ, van den Bogaart EH, Wouters EF, Franssen FM, Vercoulen JH, et al. Informal caregivers of patients with COPD: Home Sweet Home? European Respiratory Review. 2015;24(137):498-504.

151. Buck HG, Kitko L, Hupcey JE. Dyadic heart failure care types: qualitative evidence for a novel typology. J Cardiovasc Nurs. 2013;28(6):E37.

152. Ivziku D, Clari M, Matarese M. Dyadic Symptom Management types in Chronic Obstructive Pulmonary Disease. European Respiratory Journal. 2018;52:PA2065.

153. Wade DT. Describing rehabilitation interventions. SAGE Publications Sage CA: Thousand Oaks, CA; 2005.

154. Casaburi R. Whither pulmonary rehabilitation? Will alternative modes help or hurt? Eur Respiratory Soc; 2018.

155. Sagar VA, Davies EJ, Briscoe S, Coats AJ, Dalal HM, Lough F, et al. Exercise-based rehabilitation for heart failure: systematic review and meta-analysis. Open Heart. 2015;2(1):e000163.

156. Stiel S, Heckel M, Wendt KN, Weber M, Ostgathe C. Palliative Care Patients' Quality of Dying and Circumstances of Death—Comparison of Informal Caregivers' and Health-Care Professionals' Estimates. American Journal of Hospice and Palliative Medicine®. 2018;35(7):1023-9.

157. Mi E, Mi E, Ewing G, Mahadeva R, Gardener AC, Butcher HH, et al. Associations between the psychological health of patients and carers in advanced COPD. International journal of chronic obstructive pulmonary disease. 2017;12:2813.

158. Felce D, Perry J. Quality of life: Its definition and measurement. Research in Developmental Disabilities. 1995;16(1):51-74.

159. Carr AJ, Gibson B, Robinson PG. Is quality of life determined by expectations or experience? BMJ. 2001;322(7296):1240-3.

160. Bullinger M, Anderson R, Cella D, Aaronson N. Developing and evaluating cross-cultural instruments from minimum requirements to optimal models. Quality of life Research. 1993;2(6):451-9.

161. Karimi M, Brazier J. Health, Health-Related Quality of Life, and Quality of Life: What is the Difference? PharmacoEconomics. 2016;34(7):645-9.

162. Hammell KW. Quality of life, participation and occupational rights: A capabilities perspective. Australian Occupational Therapy Journal. 2015;62(2):78-85.

163. Barnes S, Gott M, Payne S, Parker C, Seamark D, Gariballa S, et al. Characteristics and views of family carers of older people with heart failure. International journal of palliative nursing. 2006;12(8):380-7.

164. Pinto RA, Holanda MA, Medeiros MM, Mota RM, Pereira ED. Assessment of the burden of caregiving for patients with chronic obstructive pulmonary disease. Respiratory medicine. 2007;101(11):2402-8.

165. Bevans M, Sternberg EM. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. Jama. 2012;307(4):398-403.

166. Chiao CY, Wu HS, Hsiao CY. Caregiver burden for informal caregivers of patients with dementia: A systematic review. International nursing review. 2015;62(3):340-50.

167. Strachan PH, Currie K, Harkness K, Spaling M, Clark AM. Context matters in Heart Failure self-care: A Qualitative Systematic Review. Journal of Cardiac Failure. 2014;20(6):448-55.

168. Cicutto L, Brooks D, Henderson K. Self-care issues from the perspective of individuals with Chronic Obstructive Pulmonary Disease. Patient Education and Counseling. 2004;55(2):168-76.

169. Bryant J, Mansfield E, Boyes AW, Waller A, Sanson-Fisher R, Regan T. Involvement of informal caregivers in supporting patients with COPD: a review of intervention studies. International journal of chronic obstructive pulmonary disease. 2016;11:1587.

170. Kim EY, Oh S, Son YJ. Caring experiences of family caregivers of patients with heart failure: A meta-ethnographic review of the past 10 years. Eur J Cardiovasc Nurs. 2020:1474515120915040.

171. Harkness KI, Tranmer JE. Measurement of the caregiving experience in caregivers of persons living with heart failure: a review of current instruments. J Card Fail. 2007;13(7):577-87.

172. Buck HG, Hupcey J, Juárez-Vela R, Vellone E, Riegel B. Heart Failure Care Dyadic Typology: Initial Conceptualization, Advances in Thinking, and Future Directions of a Clinically Relevant Classification System. Journal of Cardiovascular Nursing. 2019;34(2):159-65.

173. Retrum JH, Nowels CT, Bekelman DB. Patient and caregiver congruence: the importance of dyads in heart failure care. Journal of Cardiovascular Nursing. 2013;28(2):129-36.

174. Wingham J, Harding G, Britten N, Dalal H. Heart failure patients’ attitudes, beliefs, expectations and experiences of self-management strategies: A qualitative synthesis. Chronic Illness. 2013;10(2):135-54.

175. Russell S, Ogunbayo OJ, Newham JJ, Heslop-Marshall K, Netts P, Hanratty B, et al. Qualitative systematic review of barriers and facilitators to self-management of chronic obstructive pulmonary disease: views of patients and healthcare professionals. npj Primary Care Respiratory Medicine. 2018;28(1):2.

176. Kralik D, Price K, Telford K. The meaning of self-care for people with chronic illness. Journal of Nursing and Healthcare of Chronic Illness. 2010;2(3):197-204.

177. McCarthy MJ, Craddock WS, Acquavita SP, Black K. A mixed-methods study of smoking attitudes and behaviors among dual-smoker stroke survivor–caregiver dyads. Journal of health psychology. 2018;23(13):1659-67.

178. Kitko LA, Hupcey JE, Pinto C, Palese M. Patient and caregiver incongruence in advanced heart failure. Clinical nursing research. 2015;24(4):388-400.

179. Akbarin M, Aarts C. Being a close relative of a patient with a left ventricular assist device. European journal of cardiovascular nursing. 2013;12(1):64-8.

180. Gysels MH, Higginson IJ. Caring for a person in advanced illness and suffering from breathlessness at home: threats and resources. Palliative & supportive care. 2009;7(2):153-62.

181. Gusdal AK, Josefsson K, Adolfsson ET, Martin L. Informal Caregivers' Experiences and Needs When Caring for a Relative With Heart Failure: An Interview Study. J Cardiovasc Nurs. 2016;31(4):E1-8.

182. Srisuk N, Cameron J, Ski CF, Thompson DR. Heart failure family-based education: a systematic review. Patient education and counseling. 2016;99(3):326-38.

183. Agren S, Evangelista LS, Hjelm C, Stromberg A. Dyads Affected by Chronic Heart Failure: A Randomized Study Evaluating Effects of Education and Psychosocial Support to Patients With Heart Failure and Their Partners. Journal of Cardiac Failure. 2012;18(5):359-66.

184. Kamath D, k.b B, Selvaraj D, Xavier D, Varghese K, Salazar L, et al. Patient and caregiver reported facilitators of self-care among patients with chronic heart failure: report from a formative qualitative study. Wellcome Open Research. 2020;5:10.

185. Wu J-R, Mark B, Knafl GJ, Dunbar SB, Chang PP, DeWalt DA. A multi-component, family-focused and literacy-sensitive intervention to improve medication adherence in patients with heart failure–A randomized controlled trial. Heart & Lung. 2019;48(6):507-14.

186. Evangelista LS, Strömberg A, Dionne-Odom JN. An integrated review of interventions to improve psychological outcomes in caregivers of patients with heart failure. Current Opinion in Supportive and Palliative Care. 2016;10(1):24-31.

187. Vellone E, D’Agostino F, Buck HG, Fida R, Spatola CF, Petruzzo A, et al. The key role of caregiver confidence in the caregiver’s contribution to self-care in adults with heart failure. European Journal of Cardiovascular Nursing. 2015;14(5):372-81.

188. Cruz J, Marques A, Figueiredo D. Impacts of COPD on family carers and supportive interventions: a narrative review. Health & Social Care in the Community. 2017;25(1):11-25.

189. McIlfatrick S, Doherty LC, Murphy M, Dixon L, Donnelly P, McDonald K, et al. ‘The importance of planning for the future’: Burden and unmet needs of caregivers’ in advanced heart failure: A mixed methods study. Palliative medicine. 2018;32(4):881-90.

190. Agren S, Berg S, Svedjeholm R, Stromberg A. Psychoeducational support to post cardiac surgery heart failure patients and their partners--a randomised pilot study. Intensive Crit Care Nurs. 2015;31(1):10-8.

191. Durante A, Paturzo M, Mottola A, Alvaro R, Dickson VV, Vellone E. Caregiver contribution to self-care in patients with heart failure: a qualitative descriptive study. Journal of Cardiovascular Nursing. 2019;34(2):E28-E35.

192. Vellone E, Sansoni J, Cohen MZ. The Experience of Italians Caring for Family Members with Alzheimer's Disease. Journal of Nursing Scholarship. 2002;34(4):323-9.

193. Durante A, Greco A, Annoni AM, Steca P, Alvaro R, Vellone E. Determinants of caregiver burden in heart failure: does caregiver contribution to heart failure patient self-care increase caregiver burden? European Journal of Cardiovascular Nursing. 2019;18(8):691-9.

194. Lowyck B, De Hert M, Peeters E, Wampers M, Gilis P, Peuskens J. A study of the family burden of 150 family members of schizophrenic patients. European Psychiatry. 2004;19(7):395-401.

195. Siltanen H, Jylhä V, Holopainen A, Paavilainen E. Family members' experiences and expectations of self-management counseling while caring for a person with chronic obstructive pulmonary disease: a systematic review of qualitative evidence. JBI Database System Rev Implement Rep. 2019;17(11):2214-47.

196. Strang S, Fährn J, Strang P, Ronstad A, Danielsson L. Support to informal caregivers of patients with severe chronic obstructive pulmonary disease: a qualitative study of caregivers' and professionals' experiences in Swedish hospitals. BMJ open. 2019;9(8):e028720-e.

197. Grant M, Cavanagh A, Yorke J. The impact of caring for those with chronic obstructive pulmonary disease (COPD) on carers' psychological well-being: a narrative review. Int J Nurs Stud. 2012;49(11):1459-71.

198. Bazeley P. Integrating analyses in mixed methods research: Sage; 2017.

199. Deek H, Hamilton S, Brown N, Inglis SC, Digiacomo M, Newton PJ, et al. Family-centred approaches to healthcare interventions in chronic diseases in adults: a quantitative systematic review. Journal of advanced nursing. 2016;72(5):968-79.

200. Vellone E, Riegel B, Alvaro R. The Situation-Specific Theory of Caregiver Contributions to Heart Failure Self-Care. In: Im E-O, Meleis AI, editors. Situation Specific Theories: Development, Utilization, and Evaluation in Nursing. Cham: Springer International Publishing; 2021. p. 193-206.

201. Vellone E, Riegel B, Alvaro R. A Situation-Specific Theory of Caregiver Contributions to Heart Failure Self-care. J Cardiovasc Nurs. 2019;34(2):166-73.

202. Chen Y, Zou H, Zhang Y, Fang W, Fan X. Family Caregiver Contribution to Self-care of Heart Failure: An Application of the Information-Motivation-Behavioral Skills Model. J Cardiovasc Nurs. 2017;32(6):576-83.

203. Lyons KS, Lee CS. The theory of dyadic illness management. Journal of Family Nursing. 2018;24(1):8-28.

204. Vellone E, Bidwell JT, Lyons KS, D'Agostino F, Hiatt SO, Juarez-Vela R, et al. Patient-caregiver dyadic determinants of self-care maintenance and self-care management in heart failure. European Journal of Cardiovascular Nursing. 2015;14:S73-S4.

205. Vellone E, Biagioli V, Durante A, Buck HG, Iovino P, Tomietto M, et al. The Influence of Caregiver Preparedness on Caregiver Contributions to Self-care in Heart Failure and the Mediating Role of Caregiver Confidence. J Cardiovasc Nurs. 2020;35(3):243-52.

206. McGee HM. Chronic Illness: Quality of Life. In: Smelser NJ, Baltes PB, editors. International Encyclopedia of the Social & Behavioral Sciences. Oxford: Pergamon; 2001. p. 1779-82.

207. Aggar C. Implications of caregiving. Journal of the Australasian Rehabilitation Nurses Association. 2016;19(2):15.

208. Clark AM, Reid ME, Morrison CE, Capewell S, Murdoch DL, McMurray JJ. The complex nature of informal care in home-based heart failure management. Journal of advanced nursing. 2008;61(4):373-83.

209. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Annals of internal medicine. 2009;151(4):264-9.

210. Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a definition of mixed methods research. Journal of mixed methods research. 2007;1(2):112-33.

211. The World Bank. Countries and Economies [Internet]. World Bank Group; [updated 2017, March 14; cited 2017 July 1]. Available from: http://data.worldbank.org/country

212. CASP. CASP Checklists [Internet]. Oxford: Critical Appraisal Skills Programme; [updated 2016 November 30; cited 2017 February 18]. Available from: https://casp-uk.net/casp-tools-checklists/

213. Sandelowski M, Voils CI, Barroso J. Defining and designing mixed research synthesis studies. Research in the schools: a nationally refereed journal sponsored by the Mid-South Educational Research Association and the University of Alabama. 2006;13(1):29.

214. Pluye P, Hong QN. Combining the power of stories and the power of numbers: mixed methods research and mixed studies reviews. Annual review of public health. 2014;35:29-45.

215. Hong QN, Pluye P, Bujold M, Wassef M. Convergent and sequential synthesis designs: implications for conducting and reporting systematic reviews of qualitative and quantitative evidence. Systematic reviews. 2017;6(1):61.

216. Tashakkori A, Teddlie C, Teddlie CB. Mixed methodology: Combining qualitative and quantitative approaches: Sage; 1998.

217. Noblit G, Hare R. Meta-Ethnography: Synthesizing Qualitative studies. Thousand Oaks, CA: SAGE Publications; 1988.

218. Tashakkori A, Teddlie C. Foundations of Mixed Methods Research:

integrating quantitative and qualitative approaches in the social and

behavioural sciences. . Thousand Oaks, CA: SAGE Publications; 2009.

219. Frantzen KK, Fetters MD. Meta-integration for synthesizing data in a systematic mixed studies review: insights from research on autism spectrum disorder. Quality & Quantity. 2016;50(5):2251-77.

220. Chung ML, Lennie TA, Mudd-Martin G, Dunbar SB, Pressler SJ, Moser DK. Depressive symptoms in patients with heart failure negatively affect family caregiver outcomes and quality of life. European journal of cardiovascular nursing. 2016;15(1):30-8.

221. Dixon-Woods M, Fitzpatrick R, Roberts K. Including qualitative research in systematic reviews: opportunities and problems. Journal of evaluation in clinical practice. 2001;7(2):125-33.

222. Ågren S, Evangelista L, Strömberg A. Do partners of patients with chronic heart failure experience caregiver burden? European Journal of Cardiovascular Nursing. 2010;9(4):254-62.

223. Al-Rawashdeh SY, Lennie TA, Chung ML. The Association of Sleep Disturbances With Quality of Life in Heart Failure Patient–Caregiver Dyads. Western journal of nursing research. 2017;39(4):492-506.

224. Badr H, Federman AD, Wolf M, Revenson TA, Wisnivesky JP. Depression in individuals with chronic obstructive pulmonary disease and their informal caregivers. Aging & mental health. 2017;21(9):975-82.

225. Bakas T, Pressler SJ, Johnson EA, Nauser JA, Shaneyfelt T. Family caregiving in heart failure. Nursing research. 2006;55(3):180-8.

226. Cossette S, Lévesque L. Caregiving tasks as predictors of mental health of wife caregivers of men with chronic obstructive pulmonary disease. Research in nursing & health. 1993;16:251-63.

227. Evangelista LS, Dracup K, Doering L, Westlake C, Fonarow GC, Hamilton M. Emotional well-being of heart failure patients and their caregivers. Journal of cardiac failure. 2002;8(5):300-5.

228. Figueiredo D, Gabriel R, Jácome C, Marques A. Caring for people with early and advanced chronic obstructive pulmonary disease: how do family carers cope? Journal of Clinical Nursing. 2014;23(1-2):211-20.

229. Halm MA, Bakas T. Factors associated with caregiver depressive symptoms, outcomes, and perceived physical health after coronary artery bypass surgery. Journal of Cardiovascular Nursing. 2007;22(6):508-15.

230. Halm MA, Treat-Jacobson D, Lindquist R, Savik K. Correlates of caregiver burden after coronary artery bypass surgery. Nursing Research. 2006;55(6):426-36.

231. Hooley PJ, Butler G, Howlett JG. The relationship of quality of life, depression, and caregiver burden in outpatients with congestive heart failure. Congestive Heart Failure. 2005;11(6):303-10.

232. Hwang B, Fleischmann KE, Howie-Esquivel J, Stotts NA, Dracup K. Caregiving for patients with heart failure: impact on patients' families. American Journal of Critical Care. 2011;20(6):431-42.

233. Karmilovich S. Burden and stress associated with spousal caregiving for individuals with heart failure. Progress in cardiovascular nursing. 1994;9(1):33-8.

234. Loftus L. The influence of illness and psychological factors on patient and caregiver outcomes in heart failure: University of Liverpool; 2004.

235. Nakken N, Janssen DJ, van Vliet M, de Vries GJ, Clappers-Gielen GA, Michels AJ, et al. Gender differences in partners of patients with COPD and their perceptions about the patients. International journal of chronic obstructive pulmonary disease. 2017;12:95.

236. Saunders MM. Factors Associated with Caregiver Burden in Heart Failure Family Caregivers. Western Journal of Nursing Research. 2008;30(8):943-59.

237. Saunders MM. Indicators of health-related quality of life in heart failure family caregivers. Journal of Community Health Nursing. 2009;26(4):173-82.

238. Saunders MM. Working and caregiving: a comparison of employed and unemployed caregivers of older heart failure patients. Holistic Nursing Practice. 2010;24(1):16-22.

239. Schwarz KA, Dunphy G. An examination of perceived stress in family caregivers of older adults with heart failure. Experimental Aging Research. 2003;29(2):221-35.

240. Scott LD. Caregiving and care receiving among a technologically dependent heart failure population. Advances in Nursing Science. 2000;23(2):82-97.

241. Takata S, Washio M, Moriwaki A, Tsuda T, Nakayama H, Iwanaga T, et al. Burden among caregivers of patients with chronic obstructive pulmonary disease with long-term oxygen therapy. International Medical Journal. 2008;15(1):53-7.

242. Woolfe P, McMillan M, Conway J. The needs of caregivers of people with COPD: A study. Australian Journal of Primary Health. 2007;13:28-35.

243. Yeh PM, Bull M. Use of the resiliency model of family stress, adjustment and adaptation in the analysis of family caregiver reaction among families of older people with congestive heart failure. International Journal of Older People Nursing. 2012;7(2):117-26.

244. Andersen KL. Family caregivers to a patient with chronic heart failure living at home:«co-workers» in a blurred health care system. Journal of Cardiovascular Nursing. 2015;20:8.

245. Baker K, Flattery M, Salyer J, Haugh KH, Maltby M. Caregiving for patients requiring left ventricular assistance device support. Heart & Lung: The Journal of Acute and Critical Care. 2010;39(3):196-200.

246. Bove DG, Zakrisson AB, Midtgaard J, Lomborg K, Overgaard D. Undefined and unpredictable responsibility: a focus group study of the experiences of informal caregiver spouses of patients with severe COPD. Journal of clinical nursing. 2016;25(3-4):483-93.

247. Burke RE, Jones J, Ho PM, Bekelman DB. Caregivers' perceived roles in caring for patients with heart failure: what do clinicians need to know? Journal of cardiac failure. 2014;20(10):731-8.

248. Figueiredo D, Jácome C, Gabriel R, Marques A. Family care in chronic obstructive pulmonary disease: what happens when the carer is a man? Scandinavian journal of caring sciences. 2016;30(4):721-30.

249. Halm MA. Specific needs, concerns, strategies and advice of caregivers after coronary artery bypass surgery. Heart & Lung. 2016;45(5):416-22.

250. Halm MA. Age and gender influences on the needs, concerns and strategies of CABG caregivers. Heart & Lung. 2017;46(3):159-65.

251. Hynes G, Stokes A, McCarron M. Informal care-giving in advanced chronic obstructive pulmonary disease: lay knowledge and experience. Journal of clinical nursing. 2012;21(7-8):1068-77.

252. Imes CC, Dougherty CM, Pyper G, Sullivan MD. Descriptive study of partners' experiences of living with severe heart failure. Heart & Lung: The Journal of Acute and Critical Care. 2011;40(3):208-16.

253. Kitko L. The work of spousal caregiving in heart failure. Pennsylvania: State College, PA: Pennsylvania State University, ; 2010.

254. Liljeroos M, Ågren S, Jaarsma T, Strömberg A. Perceived caring needs in patient–partner dyads affected by heart failure: A qualitative study. Journal of clinical nursing. 2014;23(19-20):2928-38.

255. Lindqvist G, Albin B, Heikkilä K, Hjelm K. Conceptions of daily life in women living with a man suffering from chronic obstructive pulmonary disease. Primary health care research & development. 2013;14(1):40-51.

256. Luttik ML, Blaauwbroek A, Dijker A, Jaarsma T. Living with heart failure: partner perspectives. Journal of Cardiovascular Nursing. 2007;22(2):131-7.

257. Marcuccilli L, Casida J, Bakas T, Pagani FD. Family caregivers' inside perspectives: caring for an adult with a left ventricular assist device as a destination therapy. Progress in Transplantation. 2014;24(4):332-40.

258. Marcuccilli L, Casida JM. From insiders' perspectives: adjusting to caregiving for patients with left ventricular assist devices. Progress in Transplantation. 2011;21(2):137-43.

259. Pattenden J, Roberts H, Lewin R. Living with heart failure; patient and carer perspectives. European Journal of Cardiovascular Nursing. 2007;6(4):273-9.

260. Rolley J, Smith J, DiGiacomo M, Salamonson Y, Davidson P. The caregiving role following percutaneous coronary intervention. Journal of clinical nursing. 2011;20(1-2):227-35.

261. Spence A, Hasson F, Waldron M, Kernohan G, McLaughlin D, Cochrane B, et al. Active carers: living with chronic obstructive pulmonary disease. International journal of palliative nursing. 2008;14(8):368-72.

262. Strøm A, Andersen KL, Korneliussen K, Fagermoen MS. Being “on the alert” and “a forced volunteer”: a qualitative study of the invisible care provided by the next of kin of patients with chronic heart failure. Journal of multidisciplinary healthcare. 2015;8:271.

263. Wallin E, Larsson IM, Rubertsson S, Kristoferzon ML. Relatives' experiences of everyday life six months after hypothermia treatment of a significant other′ s cardiac arrest. Journal of clinical nursing. 2013;22(11-12):1639-46.

264. Näsström L, Luttik ML, Idvall E, Strömberg A. Exploring partners’ perspectives on participation in heart failure home care: a mixed-method design. Journal of advanced nursing. 2017;73(5):1208-19.

265. AM. H. The health literacy, self-care, and medication hassles of patients with heart failure and their caregivers. West Lafayette, IN: Purdue University: Purdue University; 2009.

266. Kneeshaw MF, Considine RM, Jennings J. Mutuality and preparedness of family caregivers for elderly women after bypass surgery. Appl Nurs Res. 1999;12(3):128-35.

267. Park EO, Yates BC, Schumacher KL, Meza J, Kosloski K, Pullen C. Caregiving demand and difficulty in older adult spousal caregivers after coronary artery bypass surgery. Geriatric Nursing. 2013;34(5):383-7.

268. Riegner J. The relationship of role strain, perceived social support, and humor to quality of life among couples experiencing the lifelimiting illness of chronic obstructive pulmonary disease [PhD]. Tallahassee, Florida: Florida State University; 1996.

269. Miravitlles M, Peña-Longobardo LM, Oliva-Moreno J, Hidalgo-Vega Á. Caregivers' burden in patients with COPD. International journal of chronic obstructive pulmonary disease. 2015;10:347.

270. Lum HD, Lo D, Hooker S, Bekelman DB. Caregiving in heart failure: relationship quality is associated with caregiver benefit finding and caregiver burden. Heart & lung. 2014;43(4):306-10.

271. Luttik ML, Jaarsma T, Lesman I, Sanderman R, Hagedoorn M. Quality of life in partners of people with congestive heart failure: gender and involvement in care. Journal of Advanced Nursing. 2009;65(7):1442-51.

272. Aasbø G, Solbrække KN, Kristvik E, Werner A. Between disruption and continuity: challenges in maintaining the 'biographical we'when caring for a partner with a severe, chronic illness. Sociology of health & illness. 2016;38(5):782-96.

273. Wingham J, Frost J, Britten N. Behind the smile: qualitative study of caregivers' anguish and management responses while caring for someone living with heart failure. BMJ open. 2017;7(7):e014126.

274. Lawton MP, Moss M, Kleban MH, Glicksman A, Rovine M. A two-factor model of caregiving appraisal and psychological well-being. Journal of gerontology. 1991;46(4):P181-P9.

275. Lee CS, Bidwell JT, Paturzo M, Alvaro R, Cocchieri A, Jaarsma T, et al. Patterns of self-care and clinical events in a cohort of adults with heart failure: 1 year follow-up. Heart & Lung. 2018;47(1):40-6.

276. Mahoney DF. Vigilance: evolution and definition for caregivers of family members with Alzheimer's disease. Journal of Gerontological Nursing. 2003;29(8):24-30.

277. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A. Synthesising qualitative and quantitative evidence: a review of possible methods. Journal of health services research & policy. 2005;10(1):45-53.

278. Foster F, Piggott R, Teece L, Beech R. Patients with COPD tell their stories about living with the long-term condition: an innovative and powerful way to impact primary health care professionals' attitudes and behaviour? Educ Prim Care. 2016;27(4):314-9.

279. Boote J, Baird W, Sutton A. Public involvement in the systematic review process in health and social care: A narrative review of case examples. Health Policy. 2011;102(2):105-16.

280. Mills SL, Pumarino J, Clark N, Carroll S, Dennis S, Koehn S, et al. Understanding how self-management interventions work for disadvantaged populations living with chronic conditions: protocol for a realist synthesis. BMJ open. 2014;4(7).

281. Jonkman NH, Schuurmans MJ, Jaarsma T, Shortridge-Baggett LM, Hoes AW, Trappenburg JC. Self-management interventions: proposal and validation of a new operational definition. Journal of clinical epidemiology. 2016;80:34-42.

282. Corbin JM, Strauss A. Unending work and care: Managing chronic illness at home: Jossey-Bass; 1988.

283. Man WD, Chowdhury F, Taylor RS, Evans RA, Doherty P, Singh SJ, et al. Building consensus for provision of breathlessness rehabilitation for patients with chronic obstructive pulmonary disease and chronic heart failure. Chronic respiratory disease. 2016;13(3):229-39.

284. Kennedy BM, Jaligam V, Conish BK, Johnson WD, Melancon B, Katzmarzyk PT. Exploring patient, caregiver, and healthcare provider perceptions of caring for patients with heart failure: what are the implications? Ochsner Journal. 2017;17(1):93-102.

285. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient education and counseling. 2002;48(2):177-87.

286. Candy B, Jones L, Drake R, Leurent B, King M. Interventions for supporting informal caregivers of patients in the terminal phase of a disease. Cochrane Database Syst Rev. 2011(6):Cd007617.

287. Piamjariyakul U, Smith CE, Werkowitch M, Elyachar A. Part I: heart failure home management: patients, multidisciplinary health care professionals and family caregivers' perspectives. Applied nursing research. 2012;25(4):239-45.

288. Piamjariyakul U, Smith CE, Werkowitch M, Elyachar A. Part 2: Enhancing heart failure home management: integrated evidence for a new family caregiver educational plan. Applied Nursing Research. 2012;25(4):246-50.

289. Bergs D. " The Hidden Client"--women caring for husbands with COPD: their experience of quality of life. Journal of clinical nursing. 2002;11(5):613-21.

290. Caldwell DM, Ades AE, Higgins JP. Simultaneous comparison of multiple treatments: combining direct and indirect evidence. Bmj. 2005;331(7521):897-900.

291. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ (Clinical research ed). 2014;348:g1687.

292. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:a1655.

293. Higgins J, Green S, (editors) . Cochrane handbook for systematic reviews of interventions Cochrane book series [Internet] 5.1.0 ed. England: John Wiley & Sons Ltd; 2018 [cited 2018 Nov 9]. Available from: http://handbook-5-1.cochrane.org/

294. Cochrane Training. Cochrane RevMan [Internet]. Cochrane Community; [updated 2014 June 24; cited 2018 Nov 30] Available from: https://community.cochrane.org/help/tools-and-software/revman-5

295. Azad N, Molnar F, Byszewski A. Lessons learned from a multidisciplinary heart failure clinic for older women: a randomised controlled trial. Age and ageing. 2008;37(3):282-7.

296. Cline CMJ, Israelsson BYA, Willenheimer RB, Broms K, Erhardt LR. Cost effective management programme for heart failure reduces hospitalisation. Heart. 1998;80(5):442-6.

297. Deek H, Chang S, Newton PJ, Noureddine S, Inglis SC, Arab GA, et al. An evaluation of involving family caregivers in the self-care of heart failure patients on hospital readmission: Randomised controlled trial (the FAMILY study). International Journal of Nursing Studies. 2017;75:101-11.

298. Farquhar MC, Prevost AT, McCrone P, Brafman-Price B, Bentley A, Higginson IJ, et al. The clinical and cost effectiveness of a Breathlessness Intervention Service for patients with advanced non-malignant disease and their informal carers: mixed findings of a mixed method randomised controlled trial. Trials. 2016;17(1):185.

299. Hasanpour-Dehkordi A, Khaledi-Far A, Khaledi-Far B, Salehi-Tali S. The effect of family training and support on the quality of life and cost of hospital readmissions in congestive heart failure patients in Iran. Applied Nursing Research. 2016;31:165-9.

300. Jonsdottir H, Amundadottir OR, Gudmundsson G, Halldorsdottir BS, Hrafnkelsson B, Ingadottir TS, et al. Effectiveness of a partnership-based self-management programme for patients with mild and moderate chronic obstructive pulmonary disease: a pragmatic randomized controlled trial. Journal of advanced nursing. 2015;71(11):2634-49.

301. Liljeroos M, Ågren S, Jaarsma T, Årestedt K, Strömberg A. Long term follow-up after a randomized integrated educational and psychosocial intervention in patient-partner dyads affected by heart failure. PloS one. 2015;10(9):e0138058.

302. Marques A, Jácome C, Cruz J, Gabriel R, Brooks D, Figueiredo D. Family-based psychosocial support and education as part of pulmonary rehabilitation in COPD: a randomized controlled trial. Chest. 2015;147(3):662-72.

303. Mårtensson J, Strömberg A, Dahlström U, Karlsson JE, Fridlund B. Patients with heart failure in primary health care: effects of a nurse-led intervention on health-related quality of life and depression. European journal of heart failure. 2005;7(3):393-403.

304. Naylor MD, Brooten DA, Campbell RL, Maislin G, McCauley KM, Schwartz JS. Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial. Journal of the American Geriatrics Society. 2004;52(5):675-84.

305. Srisuk N, Cameron J, Ski CF, Thompson DR. Randomized controlled trial of family-based education for patients with heart failure and their carers. Journal of advanced nursing. 2017;73(4):857-70.

306. Witham MD, Fulton RL, Greig CA, Johnston DW, Lang CC, van der Pol M, et al. Efficacy and cost of an exercise program for functionally impaired older patients with heart failure: a randomized controlled trial. Circulation: Heart Failure. 2012;5(2):209-16.

307. Pillemer K, Suitor JJ, Wethington E. Integrating theory, basic research, and intervention: Two case studies from caregiving research. The Gerontologist. 2003;43(suppl_1):19-28.

308. Cho E. A proposed theoretical framework addressing the effects of informal caregivers on health-related outcomes of elderly recipients in home health care. Asian Nursing Research. 2007;1(1):23-34.

309. Noonan MC, Wingham J, Taylor RS. 'Who Cares?'The experiences of caregivers of adults living with heart failure, chronic obstructive pulmonary disease and coronary artery disease: a mixed methods systematic review. BMJ open. 2018;8(7):e020927.

310. Sörensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. The gerontologist. 2002;42(3):356-72.

311. Zakrisson A-B, Theander K, Anderzén-Carlsson A. The experience of a multidisciplinary programme of pulmonary rehabilitation in primary health care from the next of kin's perspective: a qualitative study. Primary Care Respiratory Journal. 2013;22(4):459.

312. Alvariza A, Årestedt K, Boman K, Brännström M. Family members' experiences of integrated palliative advanced home and heart failure care: A qualitative study of the PREFER intervention. Palliative & supportive care. 2018;16(3):278-85.

313. Nissen NK, Madsen M, Olsen Zwisler A-D. Health service interventions targeting relatives of heart patients: a review of the literature. Scandinavian journal of public health. 2008;36(8):818-26.

314. Cruz J, Marques A, Machado A, O'Hoski S, Goldstein R, Brooks D. Informal caregiving in COPD: A systematic review of instruments and their measurement properties. Respiratory medicine. 2017;128:13-27.

315. Warsi A, Wang PS, LaValley MP, Avorn J, Solomon DH. Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. Archives of internal medicine. 2004;164(15):1641-9.

316. Rotheram-Borus MJ, Ingram BL, Swendeman D, Lee A. Adoption of self-management interventions for prevention and care. Primary Care: Clinics in Office Practice. 2012;39(4):649-60.

317. Laidsaar-Powell RC, Butow PN, Bu S, Charles C, Gafni A, Lam WW, et al. Physician–patient–companion communication and decision-making: a systematic review of triadic medical consultations. Patient education and counseling. 2013;91(1):3-13.

318. Keeling DI, Laing A, De Ruyter K. Evolving roles and structures of triadic engagement in healthcare. Journal of Service Management. 2018.

319. Mok E, Chan F, Chan V, Yeung E. Perception of empowerment by family caregivers of patients with a terminal illness in Hong Kong. International Journal of Palliative Nursing. 2002;8(3):137-45.

320. Li H, Melnyk BM, McCann R, Chatcheydang J, Koulouglioti C, Nichols LW, et al. Creating avenues for relative empowerment (CARE): a pilot test of an intervention to improve outcomes of hospitalized elders and family caregivers. Research in nursing & health. 2003;26(4):284-99.

321. NIHR. National Institute for Health Research [Internet]. [updated 2019 October 19; cited 2020 January 5]. Available from: https://www.nihr.ac.uk/explore-nihr/funding-programmes/programme-grants-for-applied-research.htm

322. Mills T, Lawton R, Sheard L. Advancing complexity science in healthcare research: the logic of logic models. BMC medical research methodology. 2019;19(1):1-11.

323. Savaya R, Waysman M. The logic model: A tool for incorporating theory in development and evaluation of programs. Administration in Social Work. 2005;29(2):85-103.

324. Taylor RS, Hayward C, Eyre V, Austin J, Davies R, Doherty P, et al. Clinical effectiveness and cost-effectiveness of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) facilitated self-care rehabilitation intervention in heart failure patients and caregivers: rationale and protocol for a multicentre randomised controlled trial. Bmj Open. 2015;5(12).

325. NIHR. School for Social Care Research [Internet]. [updated 2019 December 5; cited January 2020 5]. Available from: https://www.sscr.nihr.ac.uk/

326. Piepoli MF, Conraads V, Corrà U, Dickstein K, Francis DP, Jaarsma T, et al. Exercise training in heart failure: from theory to practice. A consensus document of the Heart Failure Association and the European Association for Cardiovascular Prevention and Rehabilitation. European Journal of Heart Failure. 2011;13(4):347-57.

327. Wingham J, Frost J, Britten N, Greaves C, Abraham C, Warren FC, et al. Caregiver outcomes of the REACH-HF multicentre randomized controlled trial of home-based rehabilitation for heart failure with reduced ejection fraction. European

journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. 2019;18(7):611-20.

328. National Health Service. NHS England Commissioning for Carers. Who is considered a carer? [Internet]. [updated 2018 August 8; cited 2020 February 13]. Available from: https://www.england.nhs.uk/commissioning/comm-carers/carers/

329. Rector TS, Kubo SH, Cohn JN. Patients' Self-Assessment of Their Congestive Heart Failure: content, reliability and validity of a new measure, the Minnesota living with heart failure questionnaire. Heart Fail. 1987;3:198-209

330. McClure NS, Sayah FA, Xie F, Luo N, Johnson JA. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. Value in Health. 2017;20(4):644-50.

331. The EuroQoL Group. EuroQol-a new facility for the measurement of health-related quality of life. Health policy. 1990 Dec 1;16(3):199-208

332. Nauser JA, Bakas T, Welch JL. A new instrument to measure quality of life of heart failure family caregivers. J Cardiovasc Nurs. 2011;26(1):53-64.

333. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983;67(6):361-70.

334. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res. 2002;52(2):69-77.

335. Humphrey L, Kulich K, Deschaseaux C, Blackburn S, Maguire L, Strömberg A. The caregiver Burden questionnaire for heart failure (CBQ-HF): face and content validity. Health and quality of life outcomes. 2013;11(1):84.

336. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. The gerontologist. 1980;20(6):649-55.

337. Morse JM, Field PA. Qualitative approaches. Nursing Research: Springer; 1996. p. 124-40.

338. European Union. General Data Protection Regulation 2018 [Internet]. European Union [updated 2018 May 25; cited Dec 5 2019]. Available from: https://www.google.com/search?q=eugdpr&rlz=1C1GCEU_en-gbGB821GB821&oq=eugdpr&aqs=chrome..69i57j0l7.1985j0j4&sourceid=chrome&ie=UTF-8

339. Noonan MC, Wingham J, Dalal HM, Taylor RS. Involving caregivers in self-management interventions for patients with heart failure and chronic obstructive pulmonary disease. A systematic review and meta-analysis. Journal of Advanced Nursing. 2019;75(12):3331-45.

340. Stamp KD, Dunbar SB, Clark PC, Reilly CM, Gary RA, Higgins M, et al. Family partner intervention influences self-care confidence and treatment self-

regulation in patients with heart failure. European Journal of Cardiovascular Nursing. 2015;15(5):317-27.

341. Gallagher R, Luttik M-L, Jaarsma T. Social support and self-care in heart failure. Journal of Cardiovascular Nursing. 2011;26(6):439-45.

342. Sebern MD, Woda A. Shared Care Dyadic Intervention: Outcome Patterns for Heart Failure Care Partners. Western Journal of Nursing Research. 2011;34(3):289-316.

343. Dunbar SB, Clark PC, Quinn C, Gary RA, Kaslow NJ. Family influences on heart failure self-care and outcomes. The Journal of cardiovascular nursing. 2008;23(3):258-65.

344. Bidwell JT, Lyons KS, Lee CS. Caregiver Well-being and Patient Outcomes in Heart Failure: A Meta-analysis. The Journal of cardiovascular nursing. 2017;32(4):372-82.

345. Burton AM, Sautter JM, Tulsky JA, Lindquist JH, Hays JC, Olsen MK, et al. Burden and well-being among a diverse sample of cancer, congestive heart failure, and chronic obstructive pulmonary disease caregivers. Journal of pain and symptom management. 2012;44(3):410-20.

346. Pihl E, Jacobsson A, Fridlund B, Strömberg A, Måtensson J. Depression and health-related quality of life in elderly patients suffering from heart failure and their spouses: a comparative study. European Journal of Heart Failure. 2005;7(4):583-9.

347. Chung ML, Pressler SJ, Dunbar SB, Lennie TA, Moser DK. Predictors of depressive symptoms in caregivers of patients with heart failure. The Journal of cardiovascular nursing. 2010;25(5):411-9.

348. Otuguor U-O, Higgins MK, Dunbar SB. Abstract 17165: Factors Associated With Heart failure Family Caregiver Sleep Quality. Circulation. 2016;134(suppl_1):A17165-A.

349. Luttik ML, Lesman-Leegte I, Jaarsma T. Quality of Life and Depressive Symptoms in Heart Failure Patients and Their Partners: The Impact of Role and Gender. Journal of Cardiac Failure. 2009;15(7):580-5.

350. Rigby H, Gubitz G, Phillips S. A Systematic Review of Caregiver Burden following Stroke. International Journal of Stroke. 2009;4(4):285-92.

351. Gaugler JE. The longitudinal ramifications of stroke caregiving: a systematic review. Rehabilitation psychology. 2010;55(2):108.

352. Seeher K, Low L-F, Reppermund S, Brodaty H. Predictors and outcomes for caregivers of people with mild cognitive impairment: a systematic literature review. Alzheimer's & Dementia. 2013;9(3):346-55.

353. Greenwell K, Gray WK, Van Wersch A, Van Schaik P, Walker R. Predictors of the psychosocial impact of being a carer of people living with Parkinson's disease: a systematic review. Parkinsonism & related disorders. 2015;21(1):1-11.

354. Barker KL, Minns Lowe CJ, Toye F. 'It is a big thing': exploring the impact of osteoarthritis from the perspective of adults caring for parents–the sandwich generation. Musculoskeletal Care. 2017;15(1):49-58.

355. Chiang L-C, Chen W-C, Dai Y-T, Ho Y-L. The effectiveness of telehealth care on caregiver burden, mastery of stress, and family function among family caregivers of heart failure patients: A quasi-experimental study. International Journal of Nursing Studies. 2012;49(10):1230-42.

356. Etemadifar S, Bahrami M, Shahriari M, Farsani AK. The effectiveness of a supportive educative group intervention on family caregiver burden of patients with heart failure. Iranian journal of nursing and midwifery research. 2014;19(3):217-23.

357. Piamjariyakul U, Smith CE, Russell C, Werkowitch M, Elyachar A. The feasibility of a telephone coaching program on heart failure home management for family caregivers. Heart & Lung: The Journal of Acute and Critical Care. 2013;42(1):32-9.

358. Jaarsma T, Cameron J, Riegel B, Stromberg A. Factors Related to Self-Care in Heart Failure Patients According to the Middle-Range Theory of Self-Care of Chronic Illness: a Literature Update. Current Heart Failure Reports. 2017;14(2):71-7.

359. Cassidy L, McGaughey J, Hill L, Fitzsimons D. The impact of psychoeducational interventions on the outcomes of caregivers of patients with heart failure: systematic review and meta-analysis. International Journal of Nursing Studies. 2020:103806.

360. Evangelista LS, Stromberg A, Dionne-Odom JN. An integrated review of interventions to improve psychological outcomes in caregivers of patients with heart failure. Current Opinion in Supportive and Palliative Care. 2016;10(1):24-31.

361. Drummond M, Johnston B, Quinn TJ. Measuring the success of interventions for caregivers: a focussed systematic review. Current Opinion in Supportive and Palliative Care. 2019;13(4):351-9.

362. Piette JD, Striplin D, Marinec N, Chen J, Aikens JE. A randomized trial of mobile health support for heart failure patients and their informal caregivers: impacts on caregiver-reported outcomes. Medical care. 2015;53(8):692.

363. Molloy GJ, Johnston DW, Witham MD. Family caregiving and congestive heart failure. Review and analysis. European Journal of Heart Failure. 2005;7(4):592-603.

364. Puhan MA, Frey M, Büchi S, Schünemann HJ. The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. Health and Quality of Life Outcomes. 2008;6(1):46.

365. Gough K, Hudson P. Psychometric Properties of the Hospital Anxiety and Depression Scale in Family Caregivers of Palliative Care Patients. Journal of Pain and Symptom Management. 2009;37(5):797-806.

366. Clark AM, Reid ME, Morrison CE, Capewell S, Murdoch DL, McMurray JJ. The complex nature of informal care in home-based heart failure management. Journal of Advanced Nursing. 2008;61(4):373-83.

367. Frost J, Wingham J, Britten N, Greaves C, Abraham C, Warren FC, et al. Home-based rehabilitation for heart failure with reduced ejection fraction: mixed methods process evaluation of the REACH-HF multicentre randomised controlled trial. BMJ open. 2019;9(8):e026039.

368. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health. 2015;42(5):533-44.

369. Cheng HG, Phillips MR. Secondary analysis of existing data: opportunities and implementation. Shanghai archives of psychiatry. 2014;26(6):371.

370. Heaton J. Secondary analysis of qualitative data: An overview. Historical Social Research/Historische Sozialforschung. 2008:33-45.

371. Long-Sutehall T, Sque M, Addington-Hall J. Secondary analysis of qualitative data: a valuable method for exploring sensitive issues with an elusive population? Journal of Research in Nursing. 2011;16(4):335-44.

372. Heaton J. Secondary Analysis of Qualitative Data. In: Alasuutari P, Bickman, L., & Brannen, J. , editor. The SAGE Handbook of Social Research Methods. London: SAGE Publications; 2008.

373. Hinds PS, Vogel. R.J. , Clarke-Steffen, L. The Possibilities and Pitfalls of Doing a Secondary Analysis of a Qualitative Data Set. Qualitative Health Research. 1997;7(3):408-24.

374. Miles MB, Huberman, A.M., Saldana, J. Qualitative Data Analysis A methods sourcebook. 3 ed. Thousand Oaks California: SAGE Publications; 2014. 381 p.

375. Irwin S. Qualitative secondary data analysis: Ethics, epistemology and context. Progress in Development Studies. 2013;13(4):295-306.

376. Boyatzis RE. Transforming qualitative information Thematic analysis and code development. Thousand Oaks: Sage Publications, Incorporated; 1998.

377. Ritchie J, Lewis. J. . Qualitative Research Practice: A Guide for Social Science Students and Researchers. London: Sage Publications; 2003.

378. Thorne S. Secondary Analysis in Qualitative Research: Issues and Implications. In: Morse JM, editor. Critical issues in qualitative research methods. Thousand Oaks: Sage Publications; 1994.

379. Tashakkori A, Teddlie C. Mixed Methodology: Combining Qualitative and Quantiative Approaches. Applied Social Research Methods Series. California: Sage Publications, Thousand Oaks; 1998.

380. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research: SAGE Publications.; 2011.

381. Kaushik V, Walsh CA. Pragmatism as a Research Paradigm and Its Implications for Social Work Research. Social Sciences. 2019;8(9):255.

382. Evans BC, Coon DW, Ume E. Use of theoretical frameworks as a pragmatic guide for mixed methods studies: a methodological necessity? Journal of mixed methods research. 2011;5(4):276-92.

383. Morgan DL. Pragmatism as a Paradigm for Social Research. Qualitative Inquiry. 2014;20(8):1045-53.

384. Doyle L, Brady A-M, Byrne G. An overview of mixed methods research. Journal of research in nursing. 2009;14(2):175-85.

385. McCready JS. Jamesian pragmatism: a framework for working towards unified diversity in nursing knowledge development. Nursing Philosophy. 2010;11(3):191-203.

386. Johnson RB, Onwuegbuzie AJ. Mixed methods research: A research paradigm whose time has come. Educational researcher. 2004;33(7):14-26.

387. Nowell L. Pragmatism and integrated knowledge translation: exploring the compatabilities and tensions. Nursing Open. 2015;2(3):141-8.

388. Smith J, Bekker H, Cheater F. Theoretical versus pragmatic design in qualitative research. Nurse researcher. 2011;18(2):39-51.

389. Simons H. Evolution and concept of case study research. Case study research in practice. 2009:12-28.

390. Crowe S, Cresswell K, Robertson A, Huby G, Avery A, Sheikh A. The case study approach. BMC medical research methodology. 2011;11:100-.

391. Miles M, Huberman M. Qualitative Data Analysis: An expanded sourcebook. Beverly Hills, California: Sage Publications; 1984.

392. Crowe S, Cresswell K, Robertson A, Huby G, Avery A, Sheikh A. The case study approach. BMC Med Res Methodol. 2011;11:100.

393. Khan S, VanWynsberghe R, editors. Cultivating the under-mined: Cross-case analysis as knowledge mobilization. Forum qualitative Sozialforschung/forum: Qualitative social research; 2008.

394. Green J, Willis K, Hughes E, Small R, Welch N, Gibbs L, et al. Generating best evidence from qualitative research: the role of data analysis. Australian and New Zealand Journal of Public Health. 2007;31(6):545-50.

395. Crabtree BF, Miller WL. Doing qualitative research: sage publications; 1999.

396. Roberts K, Dowell A, Nie J-B. Attempting rigour and replicability in thematic analysis of qualitative research data; a case study of codebook development. BMC Medical Research Methodology. 2019;19(1):66.

397. Srivastava P, Hopwood N. A Practical Iterative Framework for Qualitative Data Analysis. International Journal of Qualitative Methods. 2009;8:76-84.

398. Mortari L. Reflectivity in Research Practice:An Overview of Different Perspectives. International Journal of Qualitative Methods. 2015;14(5):1609406915618045.

399. Fischer CT. Bracketing in qualitative research: Conceptual and practical matters. Psychotherapy Research. 2009;19(4-5):583-90.

400. Ivankova NV, Creswell JW, Stick SL. Using Mixed-Methods Sequential Explanatory Design: From Theory to Practice. Field Methods. 2006;18(1):3-20.

401. Maxwell JA. Qualitative Research Design: An Interactive Approach: SAGE Publications; 2005.

402. Elliott V. Thinking about the coding process in qualitative data analysis. The Qualitative Report. 2018;23(11):2850-61.

403. Tufford L, Newman P. Bracketing in qualitative research. Qualitative social work. 2012;11(1):80-96.

404. Yin RK. Case study research: design and methods. 5 ed. Thousand Oaks: SAGE; 2013.

405. Della Porta D. 11 Comparative analysis: case-oriented versus variable-oriented research. Approaches and methodologies in the social sciences. 2008:198.

406. Bergman LR, Trost K. The Person-Oriented Versus the Variable-Oriented Approach: Are They Complementary, Opposites, or Exploring Different Worlds? Merrill-Palmer Quarterly. 2006;52(3):601-32.

407. Bazeley P. Analysing qualitative data: More than ‘identifying themes’. Malaysian Journal of Qualitative Research. 2009;2(2):6-22.

408. Fossey E, Harvey C, McDermott F, Davidson L. Understanding and evaluating qualitative research. Australian & New Zealand Journal of Psychiatry. 2002;36(6):717-32.

409. Creswell JW, Poth CN. Qualitative inquiry and research design: Choosing among five approaches: Sage publications; 2016.

410. Patton MQ. Qualitative research & evaluation methods: Integrating theory and practice: Sage publications; 2014.

411. Ngulube P. Qualitative data analysis and interpretation: systematic search for meaning. Addressing research challenges: making headway for developing researchers. 2015:131-56.

412. Ben-Ari A, Enosh G. Processes of Reflectivity: Knowledge Construction in Qualitative Research. Qualitative Social Work. 2010;10(2):152-71.

413. Houghton C, Casey D, Shaw D, Murphy K. Rigour in qualitative case-study research. Nurse Res. 2013;20(4):12-7.

414. Sandelowski M. Whatever happened to qualitative description? Research in nursing & health. 2000;23(4):334-40.

415. Clark AM, Spaling M, Harkness K, Spiers J, Strachan PH, Thompson DR, et al. Determinants of effective heart failure self-care: a systematic review of patients' and caregivers' perceptions. Heart. 2014;100(9):716-21.

416. Lyons KS, Vellone E, Lee CS, Cocchieri A, Bidwell JT, D'Agostino F, et al. A dyadic approach to managing heart failure with confidence. Journal of Cardiovascular Nursing. 2015;30(4S):S64-S71.

417. Annema C, Luttik M-L, Jaarsma T. Reasons for readmission in heart failure: perspectives of patients, caregivers, cardiologists, and heart failure nurses. Heart & Lung. 2009;38(5):427-34.

418. Clark AM, Freydberg CN, McAlister FA, Tsuyuki RT, Armstrong PW, Strain LA. Patient and informal caregivers' knowledge of heart failure: necessary but insufficient for effective self-care. European Journal of Heart Failure. 2009;11(6):617-21.

419. Bahrami M, Etemadifar S, Shahriari M, Farsani AK. Informational needs and related problems of family caregivers of heart failure patients: A qualitative study. J Educ Health Promot. 2014;3:113.

420. Walsh A, Kitko L, Hupcey J. The Experiences of Younger Individuals Living With Heart Failure. Journal of Cardiovascular Nursing. 2018;33(6).

421. Hupcey JE, Fenstermacher K, Kitko L, Penrod J. Achieving medical stability: Wives' experiences with heart failure. Clinical nursing research. 2010;19(3):211-29.

422. Lee CS, Vellone E, Lyons KS, Cocchieri A, Bidwell JT, D'Agostino F, et al. Patterns and predictors of patient and caregiver engagement in heart failure care: A multi-level dyadic study. International Journal of Nursing Studies. 2015;52(2):588-97.

423. Nimmon L, Bates J, Kimel G, Lingard L. Patients with heart failure and their partners with chronic illness: interdependence in multiple dimensions of time. Journal of multidisciplinary healthcare. 2018;11:175.

424. Bidwell JT, Vellone E, Lyons KS, D'Agostino F, Riegel B, Juarez-Vela R, et al. Determinants of Heart Failure Self-Care Maintenance and Management in Patients

and Caregivers: A Dyadic Analysis. Research in Nursing & Health. 2015;38(5):392-402.

425. Bozkurt Zincir S, Sunbul M, Zincir S, Aydin Sunbul E, Oguz M, Feriha Cengiz F, et al. Burden and depressive symptoms associated with adult-child caregiving for individuals with heart failure. The Scientific World Journal. 2014;2014.

426. Hodson AR, Peacock S, Holtslander L. Family caregiving for persons with advanced heart failure: An integrative review. Palliative & Supportive Care. 2019;17(6):720-34.

427. Sayers SL, Riegel B, Pawlowski S, Coyne JC, Samaha FF. Social support and self-care of patients with heart failure. Ann Behav Med. 2008;35(1):70-9.

428. Graven LJ, Grant JS. Social support and self-care behaviors in individuals with heart failure: An integrative review. International Journal of Nursing Studies. 2014;51(2):320-33.

429. Hooker SA, Grigsby ME, Riegel B, Bekelman DB. The impact of relationship quality on health-related outcomes in heart failure patients and informal family caregivers: an integrative review. Journal of Cardiovascular Nursing. 2015;30(4S):S52-S63.

430. Fivecoat HC, Sayers SL, Riegel B. Social support predicts self-care confidence in patients with heart failure. European Journal of Cardiovascular Nursing. 2018;17(7):598-604.

431. Fisher L. Research on the family and chronic disease among adults: Major trends and directions. Families, Systems, & Health. 2006;24(4):373.

432. Swan M. Emerging patient-driven health care models: an examination of health social networks, consumer personalized medicine and quantified self-tracking. International journal of environmental research and public health. 2009;6(2):492-525.

433. Kitko L, Hupcey J. Patient and Caregiver Incongruence in Heart Failure Dyads. Nursing Research. 2014;63(2):E97-E.

434. Dickson VV, Riegel B. Are we teaching what patients need to know? Building skills in heart failure self-care. Heart & Lung. 2009;38(3):253-61.

435. Greenwood N, Smith R. Barriers and facilitators for male carers in accessing formal and informal support: A systematic review. Maturitas. 2015;82(2):162-9.

436. Schwartz AJ, McInnis-Dittrich K. Meeting the Needs of Male Caregivers by Increasing Access to Accountable Care Organizations. Journal of gerontological social work. 2015;58(7-8):655-70.

437. Rohrbaugh MJ, Cranford JA, Shoham V, Nicklas JM, Sonnega JS, Coyne JC. Couples coping with congestive heart failure: Role and gender differences in psychological distress. Journal of Family Psychology. 2002;16(1):3-13.

438. Spendelow JS, Adam LA, Fairhurst BR. Coping and adjustment in informal male carers: A systematic review of qualitative studies. Psychology of Men & Masculinity. 2017;18(2):134-43.

439. Corbin JM, Strauss A. Grounded theory research: Procedures, canons, and evaluative criteria. Qualitative sociology. 1990;13(1):3-21.

440. Smith JA, Osborn M. Interpretative phenomenological analysis as a useful methodology for research on the lived experience of pain. British journal of pain. 2015;9(1):41-2.

441. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006;3(2):77-101.

442. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis: Striving to Meet the Trustworthiness Criteria. International Journal of Qualitative Methods. 2017;16(1):1609406917733847.

443. Attride-Stirling J. Thematic networks: an analytic tool for qualitative research. Qualitative research. 2001;1(3):385-405.

444. Sherif V, editor Evaluating preexisting qualitative research data for secondary analysis. Forum qualitative sozialforschung/forum: Qualitative social research; 2018.

445. Bishop L, Kuula-Luumi A. Revisiting qualitative data reuse: A decade on. Sage Open. 2017;7(1):2158244016685136.

446. Bishop L. Re-using qualitative data: A little evidence, on-going issues and modest reflections. Studia Socjologiczne. 2014;3:167-76.

447. Redfield MM. Heart failure with preserved ejection fraction. New England Journal of Medicine. 2016;375(19):1868-77.

448. Sowden E, Hossain M, Chew-Graham C, Blakeman T, Tierney S, Wellwood I, et al. Understanding the management of heart failure with preserved ejection fraction: a qualitative multiperspective study. British Journal of General Practice. 2020;70(701):e880-e9.

449. Smith K, Lang C, Wingham J, Frost J, Greaves C, Abraham C, et al. Process evaluation of a randomised pilot trial of home-based rehabilitation compared to usual care in patients with heart failure with preserved ejection fraction and their caregiver's. Pilot and Feasibility Studies. 2021;7(1):11.

450. Pharr JR, Dodge Francis C, Terry C, Clark MC. Culture, caregiving, and health: exploring the influence of culture on family caregiver experiences. International Scholarly Research Notices. 2014;2014.

451. Cho J, Ory MG, Stevens AB. Socioecological factors and positive aspects of caregiving: Findings from the REACH II intervention. Aging & mental health. 2016;20(11):1190-201.

452. Liu WT, Kendig H. Critical issues of caregiving: East-West dialogue. Who should care for the elderly. 2000:1-23.

453. Lai DW. Filial piety, caregiving appraisal, and caregiving burden. Research on Aging. 2010;32(2):200-23.

454. Vellone E, Chung ML, Alvaro R, Paturzo M, Dellafiore F. The Influence of Mutuality on Self-Care in Heart Failure Patients and Caregivers: A Dyadic Analysis. Journal of Family Nursing. 2018;24(4):563-84.

455. Samoutis G, Samouti S, Aristodemou PA. Cultivating a Therapeutic Compassionate Relationship: The 3S Approach. J Med Life. 2019;12(4):449-52.

456. Spendelow J, Adam L, Fairhurst B. Coping and Adjustment in Informal Male Carers: A Systematic Review of Qualitative Studies. Psychology of Men & Masculinity. 2016;18.

457. De Maria M, Tagliabue S, Ausili D, Vellone E, Matarese M. Perceived social support and health-related quality of life in older adults who have multiple chronic conditions and their caregivers: a dyadic analysis. Social Science & Medicine. 2020;262:113193.

458. Bozkurt Zincir S, Sunbul M, Zincir S, Aydin Sunbul E, Oguz M, Feriha Cengiz F, et al. Burden and depressive symptoms associated with adult-child caregiving for individuals with heart failure. ScientificWorldJournal. 2014;2014:641817.

459. Tatangelo G, McCabe M, Macleod A, Konis A. I just can't please them all and stay sane: Adult child caregivers’ experiences of family dynamics in care-giving for a parent with dementia in Australia. Health & social care in the community. 2018;26(3):e370-e7.

460. Liu J. Spouse and Adult-Child Dementia Caregivers in Chinese American Families: Who Are More Stressed Out? Journal of the American Medical Directors Association. 2021.

461. Dracup K, Evangelista LS, Doering L, Tullman D, Moser DK, Hamilton M. Emotional well-being in spouses of patients with advanced heart failure. Heart & Lung. 2004;33(6):354-61.

462. Miyawaki CE. Caregiving Practice Patterns of Asian, Hispanic, and Non-Hispanic White American Family Caregivers of Older Adults Across Generations. Journal of Cross-Cultural Gerontology. 2016;31(1):35-55.

463. Ruggiano N, Perry TE. Conducting secondary analysis of qualitative data: Should we, can we, and how? Qualitative Social Work. 2017;18(1):81-97.

464. Waldron EA, Janke EA, Bechtel CF, Ramirez M, Cohen A. A systematic review of psychosocial interventions to improve cancer caregiver quality of life. Psycho-Oncology. 2013;22(6):1200-7.

465. Shepherd-Banigan ME, Shapiro A, McDuffie JR, Brancu M, Sperber NR, Van Houtven CH, et al. Interventions That Support or Involve Caregivers or Families of Patients with Traumatic Injury: a Systematic Review. Journal of General Internal Medicine. 2018;33(7):1177-86.

466. van Dijk M, Vreven J, Deschodt M, Verheyden G, Tournoy J, Flamaing J. Can in-hospital or post discharge caregiver involvement increase functional performance of older patients? A systematic review. BMC Geriatrics. 2020;20(1):362.

467. Van’t Leven N, Prick A-E, Groenewoud JG, Roelofs P, de Lange J, Pot AM. Dyadic interventions for community-dwelling people with dementia and their family caregivers: a systematic review. International Psychogeriatrics. 2013;25(10):1581-603.

468. Arksey H, Jackson K, Croucher K, Weatherly H, Golder S, Hare P, et al. Review of respite services and short-term breaks for carers of people with dementia. 2004.

469. Riegel B, Carlson B, Glaser D. Development and testing of a clinical tool measuring self-management of heart failure. Heart & Lung. 2000;29(1):4-15.

470. Hooker SA, Schmiege SJ, Trivedi RB, Amoyal NR, Bekelman DB. Mutuality and heart failure self-care in patients and their informal caregivers. European Journal of Cardiovascular Nursing. 2017;17(2):102-13.

471. Cohen CA, Colantonio A, Vernich L. Positive aspects of caregiving: rounding out the caregiver experience. International Journal of Geriatric Psychiatry. 2002;17(2):184-8.

472. Lloyd J, Patterson T, Muers J. The positive aspects of caregiving in dementia: A critical review of the qualitative literature. Dementia. 2016;15(6):1534-61.

473. Buck HG, Kitko L, Hupcey JE. Dyadic Heart Failure Care Types Qualitative Evidence for a Novel Typology. Journal of Cardiovascular Nursing. 2013;28(6):E37-E46.

474. Tsai P-C, Yip P-K, Tai JJ, Lou M-F. Needs of family caregivers of stroke patients: a longitudinal study of caregivers' perspectives. Patient Prefer Adherence. 2015;9:449-57.

475. Stawnychy MA, Teitelman AM, Riegel B. Caregiver autonomy support: A systematic review of interventions for adults with chronic illness and their caregivers with narrative synthesis. Journal of Advanced Nursing. 2021;77(4):1667-82.

476. Kayser JW, Cossette S, Alderson M. Autonomy-supportive intervention: An evolutionary concept analysis. Journal of Advanced Nursing. 2014;70(6):1254-66.

477. Niño de Guzmán Quispe E, Martínez García L, Orrego Villagrán C, Heijmans M, Sunol R, Fraile-Navarro D, et al. The Perspectives of Patients with Chronic Diseases and Their Caregivers on Self-Management Interventions: A Scoping Review of Reviews. Patient. 2021.

478. Kline KS, Scott LD, Britton AS. The use of supportive-educative and mutual goal-setting strategies to improve self-management for patients with heart failure. Home Healthcare Now. 2007;25(8):502-10.

479. Meyerson KL, Kline KS. Qualitative analysis of a mutual goal-setting intervention in participants with heart failure. Heart & lung. 2009;38(1):1-9.

480. Doorenbos AZ, Levy WC, Curtis JR, Dougherty CM. An intervention to enhance goals-of-care communication between heart failure patients and heart failure providers. Journal of pain and symptom management. 2016;52(3):353-60.

481. Playford ED, Dawson L, Limbert V, Smith M, Ward CD, Wells R. Goal-setting in rehabilitation: report of a workshop to explore professionals' perceptions of goal-setting. Clinical Rehabilitation. 2000;14(5):491-6.

482. Li Q, Mak YW, Loke A. Spouses' experience of caregiving for cancer patients: a literature review. International Nursing Review. 2013;60(2):178-87.

483. Pressler SJ, Gradus-Pizlo I, Chubinski SD, Smith G, Wheeler S, Wu JW, et al. Family Caregiver Outcomes in Heart Failure. American Journal of Critical Care. 2009;18(2):149-59.

484. Kannan H, Bolge SC, Del Valle M, Alvir J, Petrie CD. The association between Alzheimer's disease symptom severity and caregiver outcomes: a cross-sectional study. Prim Care Companion CNS Disord. 2011;13(3):PCC.10m01043.

485. Pinquart M, Sörensen S. Gender Differences in Caregiver Stressors, Social Resources, and Health: An Updated Meta-Analysis. The Journals of Gerontology: Series B. 2006;61(1):P33-P45.

486. Chappell NL, Dujela C, Smith A. Spouse and adult child differences in caregiving burden. Canadian Journal on Aging/La Revue canadienne du vieillissement. 2014;33(4):462-72.

487. Oldenkamp M, Hagedoorn M, Slaets J, Stolk R, Wittek R, Smidt N. Subjective burden among spousal and adult-child informal caregivers of older adults: results from a longitudinal cohort study. BMC Geriatrics. 2016;16(1):208.

488. Locke EA, Latham GP. New Directions in Goal-Setting Theory. Current Directions in Psychological Science. 2006;15(5):265-8.

489. Dalal HM, Doherty P, Taylor RS. Cardiac rehabilitation. Bmj. 2015;351:h5000.

490. Ades PA, Keteyian SJ, Balady GJ, Houston-Miller N, Kitzman DW, Mancini DM, et al. Cardiac rehabilitation exercise and self-care for chronic heart failure. JACC: Heart failure. 2013;1(6):540-7.

491. Quinn C, Clare L, Woods B. The impact of the quality of relationship on the experiences and wellbeing of caregivers of people with dementia: A systematic review. Aging & Mental Health. 2009;13(2):143-54.

492. Warraich HJ, Kitzman DW, Whellan DJ, Duncan PW, Mentz RJ, Pastva AM, et al. Physical Function, Frailty, Cognition, Depression, and Quality of Life in Hospitalized Adults ≥60 Years With Acute Decompensated Heart Failure With Preserved Versus Reduced Ejection Fraction. Circulation: Heart Failure. 2018;11(11):e005254.

493. Richardson VE, Fields N, Won S, Bradley E, Gibson A, Rivera G, et al. At the intersection of culture: Ethnically diverse dementia caregivers' service use. Dementia. 2017;18(5):1790-809.

494. Dilworth-Anderson P, Williams IC, Gibson BE. Issues of Race, Ethnicity, and Culture in Caregiving Research: A 20-Year Review (1980–2000). The Gerontologist. 2002;42(2):237-72.

495. Riegel B, Dickson VV, Faulkner KM. The Situation-Specific Theory of Heart Failure Self-Care: Revised and Updated. Journal of Cardiovascular Nursing. 2016;31(3):226-35.

496. Teddlie C, Tashakkori A. A general typology of research designs featuring mixed methods. Research in the Schools. 2006;13(1):12-28.

497. Liljeroos M, Ågren S, Jaarsma T, Stromberg A. Dialogues between nurses, patients with heart failure and their partners during a dyadic psychoeducational intervention: a qualitative study. BMJ open. 2017;7(12).

498. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. bmj. 2015;350.

499. Onwuegbuzie AJ, Collins KM. A typology of mixed methods sampling designs in social science research. Qualitative Report. 2007;12(2):281-316.

500. Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative research. 2006;6(1):97-113.

501. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health services research. 2013;48(6 Pt 2):2134-56.

502. Richards DA, Bazeley P, Borglin G, Craig P, Emsley R, Frost J, et al. Integrating quantitative and qualitative data and findings when undertaking randomised controlled trials. BMJ open. 2019;9(11).

503. Guetterman TC, Fetters MD, Creswell JW. Integrating Quantitative and Qualitative Results in Health Science Mixed Methods Research Through Joint Displays. The Annals of Family Medicine. 2015;13(6):554-61.

504. Taylor RS, Hayward C, Eyre V, Austin J, Davies R, Doherty P, et al. Clinical effectiveness and cost-effectiveness of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) facilitated self-care rehabilitation intervention in heart failure patients and caregivers: rationale and protocol for a multicentre randomised controlled trial. BMJ Open. 2015;5(12):e009994.

505. Nabors N, Seacat J, Rosenthal M. Predictors of caregiver burden following traumatic brain injury. Brain Injury. 2002;16(12):1039-50.

506. Kim Y, Given BA. Quality of life of family caregivers of cancer survivors. Cancer. 2008;112(S11):2556-68.

507. Cameron J, Rhodes KL, Ski CF, Thompson DR. Carers' views on patient self-care in chronic heart failure. Journal of Clinical Nursing. 2016;25(1-2):144-52.

508. Ferrell B, Wittenberg E. A review of family caregiving intervention trials in oncology. CA: A Cancer Journal for Clinicians. 2017;67(4):318-25.

509. Morhardt D, Spira M. From Person-Centered Care to Relational-Centered Care. Generations. 2013;37:37-44.

510. Benton D, Meyer K. Healthcare Providers Can Help to Connect Family Caregivers to Resources and Supports: Services cannot truly" wrap around" care recipients unless caregivers are brought into the loop. Generations. 2019.

511. Nolan MR, Davies S, Brown J, Keady J, Nolan J. Beyond 'person-centred'care: a new vision for gerontological nursing. Journal of clinical nursing. 2004;13:45-53.

512. Vellone E, Chung ML, Cocchieri A, Rocco G, Alvaro R, Riegel B. Effects of self-care on quality of life in adults with heart failure and their spousal caregivers: Testing dyadic dynamics using the actor–partner interdependence model. Journal of Family Nursing. 2014;20(1):120-41.

513. Parmar J, Anderson S, Abbasi M, Ahmadinejad S, Brémault-Phillips S, Chan K, et al. Support for family caregivers: A scoping review of family physician's perspectives on their role in supporting family caregivers. Health & Social Care in the Community. 2020;28(3):716-33.

514. Simon C, Kendrick T. Informal carers--the role of general practitioners and district nurses. British Journal of General Practice. 2001;51(469):655-7.

515. Chen Y-M. Differences in Outcomes of Caregiver Support Services for Male and Female Caregivers. SAGE Open. 2014;4(3):2158244014548169.

516. Bos-Touwen I, Jonkman N, Westland H, Schuurmans M, Rutten F, de Wit N, et al. Tailoring of Self-Management Interventions in Patients With Heart Failure. Current Heart Failure Reports. 2015;12(3):223-35.

517. Baker DW, DeWalt DA, Schillinger D, Hawk V, Ruo B, Bibbins-Domingo K, et al. "Teach to goal": theory and design principles of an intervention to improve heart failure self-management skills of patients with low health literacy. Journal of health communication. 2011;16(sup3):73-88.

518. Chung ML, Moser DK, Lennie TA, Rayens MK. The effects of depressive symptoms and anxiety on quality of life in patients with heart failure and their

spouses: Testing dyadic dynamics using Actor-Partner Interdependence Model. Journal of Psychosomatic Research. 2009;67(1):29-35.

519. Lyons KS, Sadowski T, Lee CS. The role of concealment and relationship quality on patient hospitalizations, care strain and depressive symptoms in heart failure dyads. European Journal of Cardiovascular Nursing. 2020;19(2):118-24.

520. Hooker SA, Schmiege SJ, Trivedi RB, Amoyal NR, Bekelman DB. Mutuality and heart failure self-care in patients and their informal caregivers. European Journal of Cardiovascular Nursing. 2018;17(2):102-13.

521. Bidwell JT, Vellone E, Lyons KS, D'Agostino F, Riegel B, Juárez-Vela R, et al. Determinants of Heart Failure Self-Care Maintenance and Management in Patients and Caregivers: A Dyadic Analysis. Research in Nursing & Health. 2015;38(5):392-402.

522. Rosland A-M, Heisler M, Piette JD. The impact of family behaviors and communication patterns on chronic illness outcomes: a systematic review. Journal of Behavioral Medicine. 2012;35(2):221-39.

523. Alonso WW, Kitko LA, Hupcey JE. Intergenerational caregivers of parents with end-stage heart failure. Research and Theory for Nursing Practice. 2018;32(4):413-35.

524. Bidwell J, Higgins M, Abshire M, Dunbar S. Abstract 229: Family Caregiver Stress and Patient Symptom Severity in Heart Failure. Circulation: Cardiovascular Quality and Outcomes. 2020;13.

525. Frost J, Wingham J, Britten N, Greaves C, Abraham C, Warren FC, et al. The value of social practice theory for implementation science: learning from a theory-based mixed methods process evaluation of a randomised controlled trial. BMC Medical Research Methodology. 2020;20(1):1-14.

526. NIHR. 19/13 Support interventions for carers [Internet]. [updated May 2019 9; cited 2020 January 10]. Avialble from https://www.nihr.ac.uk/documents/improving-the-outcomes-of-health-and-social-care-for-frail-people-and-their-carers/11658

527. Buck HG, Mogle J, Riegel B, McMillan S, Bakitas M. Exploring the Relationship of Patient and Informal Caregiver Characteristics with Heart Failure Self-Care Using the Actor-Partner Interdependence Model: Implications for Outpatient Palliative Care. Journal of palliative medicine. 2015;18(12):1026-32.

528. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000;321(7262):694-6.

529. O'Cathain A, Thomas KJ, Drabble SJ, Rudolph A, Goode J, Hewison J. Maximising the value of combining qualitative research and randomised controlled trials in health research: the QUAlitative Research in Trials (QUART) study – a mixed methods study. Health Technol Assess. 2014;18(38).

530. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. Best practices for mixed methods research in the health sciences. Bethesda (Maryland): National Institutes of Health. 2011;2013:541-5.

531. Gitlin LN, Belle SH, Burgio LD, Czaja SJ, Mahoney D, Gallagher-Thompson D, et al. Effect of multicomponent interventions on caregiver burden and depression: the REACH multisite initiative at 6-month follow-up. Psychology and aging. 2003;18(3):361.

532. Laver K, Milte R, Dyer S, Crotty M. A systematic review and meta-analysis comparing carer focused and dyadic multicomponent interventions for carers of people with dementia. Journal of aging and health. 2017;29(8):1308-49.

533. Morton K, Dennison L, May C, Murray E, Little P, McManus RJ, et al. Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. Patient Education and Counseling. 2017;100(4):616-35.