

**Developing a longitudinal profile of the consequences of the
profoundly-affected arm after stroke: a feasibility study**

Submitted by Rhoda Allison to the University of Exeter as a thesis for the
degree of Doctorate in Clinical Research, June 2013.

This thesis is available for Library use on the understanding that it is
copyright material and that no quotation from the thesis may be published
without proper acknowledgement.

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. I have conducted
the work in line with the appropriate professional practice guidelines. I
confirm that all names and identifying information has been changed to
protect confidentiality.

.....Signature

Abstract

Stroke is the principal cause of long-term disability. Hemiplegia affects up to 80% of people with stroke and a significant number will not recover use of the affected arm. People with profoundly-affected arm may experience pain, stiffness and difficulty with care activities. We cannot currently predict who is most at risk of these difficulties, and historically interventions have been designed without understanding the temporal evolution of impairment or disability.

The International Classification of Functioning, Disability and Health (WHO, 2001) was used to develop a model of the consequences of the profoundly-affected arm on impairment, disability, and participation. A systematic review of thirty observational studies was undertaken and identified potential predictors of increased impairment in general populations of people with stroke. However, there was a paucity of evidence directed at people with profoundly-affected arm or regarding impact on passive care.

The aim of this study was to test the feasibility of using an observational study design to develop a longitudinal profile of the profoundly-affected arm. Specific objectives of the feasibility study were to assess the processes of recruitment and follow-up, to review the sample characteristics, and to establish the acceptability and responsiveness of the predictor variables and outcome measures. Key tenets of the project were to involve people with cognitive and communication disability, and to use assessments that could be adopted by therapists working in a patient's own home.

Forty people with stroke and nine carers were recruited and followed up at three and six months post-stroke. Using enhanced communication techniques and personal consultees, it was possible to include people with severe cognitive and communication disability. The baseline demographic characteristics and the rate of loss to follow-up of participants reflect that expected in people more severely affected by stroke.

Qualitative data suggest that participants affirmed the model of impairments and disabilities that had been developed. The predictor variables and outcome measures were considered acceptable to participants, and collected a range of data, generally performing in the manner expected. However, there were a number of exceptions. Cognitive and communication disability impacted on completion of the self-reported assessments, and may have affected performance on measures of mood and sensation/perception. In addition to this, measures of range of movement varied at each time point, in a manner not in accordance with expected change over time.

The evidence from this thesis suggests the research design has potential to be used to develop a longitudinal profile of the profoundly-affected arm. Further work is required to improve carer recruitment, establish the best assessments for those with severest cognitive and communication disability, and review the method of measuring range of movement.

Table of contents

Abstract	2
Table of Contents	3
List of Tables	9
List of Figures	10
List of Appendices	12
Acknowledgements	13
Author's declaration	14
List of abbreviations and symbols	15
Chapter 1: Introduction	17
1.1 The history of stroke	18
1.2 Stroke and the profoundly-affected arm	18
1.3 The purpose of this thesis	19
1.4 Including people with cognitive and communication disability	20
1.5 Clinical practice within the person's own home	21
1.6 Thesis structure	21
Chapter 2: Background	23
2.1 Chapter overview	24
2.2 The International Classification of Functioning, Disability and Health	24
2.3 Applying the ICF to the profoundly-affected arm after stroke	25
2.3.1 Body structures, body functions and their impairments	25
2.3.2 Activity and participation	30
2.3.3 Environmental factors	31
2.3.4 Summary of the ICF application to the profoundly-affected arm	32
2.4 Evidence for management of the profoundly-affected arm	33
2.5 The MRC guidance on complex interventions	35
2.6 Chapter summary	35
Chapter 3: Measuring outcomes in the profoundly-affected arm	37
3.1 Chapter overview	38
3.2 Assessing the measures	38
3.2.1 Content validity	38
3.2.2 Construct validity	39
3.2.3 Inter-rater reliability	39
3.2.4 Intra-rater reliability	39
3.2.5 Responsiveness	39
3.2.6 Use in people with stroke	40
3.3 Measures of impairment	40
3.3.1. Spasticity	41
3.3.2 Contracture and range of movement	43
3.3.3 Joint subluxation	45

3.3.4	Pain	46
3.3.5	Body image	47
3.3.6	Skin integrity	48
3.4	Measures of activity and participation	48
3.4.1	Passive function	48
3.4.2	Active function	50
3.4.3	Quality of life	52
3.5	Measures of environmental factors	53
3.5.1	Services: Health & social care services	53
3.5.2	Support and relationships: Carer burden	53
3.5.3	Products and technology: Splints and equipment	54
3.6	Relationships between measures across domains	54
3.7	Chapter summary	54
Chapter 4:	Impairment and disability in the profoundly-affected arm: a systematic review	57
4.1	Chapter overview	58
4.2	Method	58
4.2.1	Search strategy	58
4.2.2	Criteria for inclusion of studies	58
4.2.3	Study selection	60
4.2.4	Data extraction	61
4.2.5	Assessment of methodological quality	61
4.2.6	Summary measures and synthesis of results	61
4.3	Results	62
4.3.1	Study selection	62
4.3.2	Study characteristics	62
4.3.3	Quality assessment	71
4.3.4	Results of individual studies	73
4.3.5	Synthesis of results	73
4.4	Discussion	80
4.4.1	Limitations of the review	80
4.4.2	Implications for research and practice	81
4.5	Chapter summary	81
Chapter 5:	Method	83
5.1	Chapter overview	84
5.2	Aims and research questions	84
5.3	Recruitment	86
5.3.1	Sample and participants	86
5.3.2	Screening and consent	86
5.4	Selecting and collecting the required data	88
5.4.1	Demographic data	88

5.4.2 Outcome measures	88
5.4.3 Predictors variables	99
5.4.4 Quantitative data concerning cognitive impairment and communication disability	102
5.4.5 Qualitative data	103
5.5 Withdrawals	104
5.6 Adverse event recording	104
5.7 Data management and entry	105
5.8 Data analysis and reporting	105
5.9 Study organisational structure	106
5.10 User consultation	107
5.11 Broader consultation	107
5.12 Ethical issues and approval	107
5.13 Research and development department approvals	108
5.14 Research sponsorship	108
5.15 Chapter summary	108
Chapter 6: Overview of results	109
6.1 Chapter summary	110
6.2 Overview of the recruitment and progress of the participants	110
6.3 Profile of cognitive and communication disability at baseline	110
6.4 Baseline characteristics of the participants	112
6.5 Profile of the predictor measures at baseline	114
6.6 Profile of the outcome measures at three and six months	114
6.7 Data concerning interventions provided	114
6.8 Adverse events	119
6.9 Overview of recruitment and follow-up of carers	120
6.10 Profile of the carer related outcome measure	121
6.11 Characteristics of the interviewees	121
6.12 Chapter summary	122
Chapter 7: The process of recruitment and follow-up	123
7.1 Chapter overview	124
7.2 Eligibility and recruitment of participants	124
7.2.1 Eligibility	124
7.2.2 Recruitment	125
7.2.3 Including people with cognitive and communication disability	126
7.2.4 Consent	127
7.2.5 Summary of participant recruitment	131
7.3 The process of follow-up of participants	132
7.3.1 Overview of follow-up	132
7.3.2 Location of follow-up visits	133

7.3.3 Adverse events	134
7.3.4 Summary of participant follow-up	134
7.4 Eligibility and recruitment of carers	134
7.4.1 Eligibility	134
7.4.2 Recruitment	134
7.4.3 Summary of carer recruitment	135
7.5 Chapter summary	136
Chapter 8: Characteristics of the sample	139
8.1 Chapter overview	140
8.2 Demographic characteristics of the participants	140
8.2.1 Age and gender	140
8.2.2 Stroke classification	141
8.2.3 Length of hospital stay and discharge destination	141
8.2.4 Other factors	142
8.3 The profile of the predictor variables in the study participants	143
8.3.1 Stroke severity	143
8.3.2 Motor control	144
8.3.3 Sensation and perception	145
8.3.4 Mood	148
8.3.5 Spasticity at baseline	150
8.3.6 Pain	151
8.4 Chapter summary	153
Chapter 9: Impairment in the profoundly-affected arm	155
9.1 Chapter Overview	156
9.2 Spasticity	156
9.2.1 Extent of data collected	156
9.2.2 Distribution of data collected	157
9.2.3 Qualitative data concerning the impairment and its measure	159
9.2.4 Summary	161
9.3 Pain	161
9.3.1 Extent of data collected	161
9.3.2 Distribution of data collected	161
9.3.3 Qualitative data concerning the impairment and its measure	162
9.3.4 Summary	163
9.4 Range of movement	164
9.4.1 Extent of data collected	164
9.4.2 Distribution of data collected	164
9.4.3 Qualitative data concerning the impairment and its measure	166
9.4.4 Summary	167
9.5 Skin Integrity	167

9.5.1	Extent of data collected	167
9.5.2	Distribution of data collected	167
9.5.3	Qualitative data concerning the impairment and its measure	167
9.5.4	Summary	168
9.6	Body Image	168
9.6.1	Extent of data collected	168
9.6.2	Distribution of data collected	168
9.6.3	Qualitative data concerning the impairment and its measure	169
9.6.4	Summary	170
9.7	Impairments identified in the original model that were not formally measured	170
9.7.1	Joint subluxation	170
9.8	Impairments that were not identified in the original model	171
9.8.1	Temperature changes	171
9.9	Chapter summary	171
Chapter 10:	Disability and related factors in the profoundly-affected arm	173
10.1	Chapter overview	174
10.2	Passive function	174
10.2.1	Extent of data collected	175
10.2.2	Distribution of data collected	175
10.2.3	Relationship between LASIS scores and related constructs	177
10.2.4	Qualitative data concerning the disability and its measure	179
10.2.5	Summary	181
10.3	Active function	182
10.3.1	Extent of data collected	182
10.3.2	Distribution of data collected	182
10.3.3	Qualitative data concerning the disability and its measure	183
10.3.4	Summary	184
10.4	Quality of life	185
10.4.1	Extent of data collected	185
10.4.2	Distribution of data collected	185
10.4.3	Qualitative data concerning the construct and its measure	186
10.4.4	Summary	187
10.5	Carer burden	187
10.5.1	Extent of data collected	187
10.5.2	Distribution of data collected	187
10.5.3	Qualitative data concerning the construct and its measure	188
10.5.4	Summary	189
10.6	Products and technology	189
10.6.1	Extent of data collected	189
10.6.2	Distribution of data collected	189

10.6.3 Qualitative data concerning the disability and its measure	190
10.6.4 Summary	191
10.7 Health and social services	191
10.7.1 Extent of data collected	191
10.7.2 Distribution of data collected	191
10.7.3 Qualitative data concerning the disability and its measure	194
10.7.4 Summary	195
10.8 Chapter summary	195
Chapter 11: Conclusions	197
11.1 Chapter overview	198
11.2 Recruitment and follow-up processes	198
11.3 Characteristics of the sample	199
11.4 Acceptability and responsiveness of the outcome measures	200
11.4.1 Impairment based measures	200
11.4.2 Activity, participation and related measures	201
11.5 Study limitations	202
11.5.1 Limitations of the selected outcomes	203
11.5.2 Small local study	204
11.5.3 Qualitative data analysis	205
11.6 Study strengths	205
11.6.1 Methodical approach	205
11.6.2 Partnership across clinical practice and academia	205
11.6.3 Patient and public involvement	206
11.7 Thesis conclusions and contributions	206
Appendices	209
References	261

List of tables

Table 1: Outcome measures for assessing impairment in the profoundly-affected arm	40
Table 2: Psychometric properties of the outcome measures of impairment	44
Table 3: Outcome measures for assessing activity, participation and environmental factors in the person with profoundly-affected arm	49
Table 4: Psychometric properties of the outcome measures of activity, participation and environmental factors	51
Table 5: Search terms for systematic review	60
Table 6: Characteristics of participants and studies in the systematic review	66
Table 7: Outcomes and predictor measures used in the studies in the systematic review	68
Table 8: Quality assessment: potential risk of bias in included studies	72
Table 9: Studies of spasticity: Individual results	76
Table 10: Studies of pain: Individual results	77
Table 11: Studies of contracture: Individual results	79
Table 12: Preliminary testing of the reliability of the original Ashworth Scale	92
Table 13: Preliminary testing of the reliability of the MMAS	92
Table 14: Preliminary testing of the reliability of the LASIS	96
Table 15: Summary of outcome measures selected for testing	98
Table 16: Summary of predictor variables selected for testing	102
Table 17: Sites where participants chose to have follow-up appointments	112
Table 18: Summary of participants' cognition and communication disability	112
Table 19: Descriptive data of the participants	113
Table 20: Summary of the profile of the predictor measures taken at baseline	115
Table 21: Summary of the profile of the main outcome measures	116
Table 22: Summary of the profile outcome measures of range of movement	117
Table 23: Interventions reported at three and six months	118
Table 24: Other interventions for the profoundly-affected arm reported	118
Table 25: Results related to carer burden	121
Table 26: Characteristics of participants who were interviewed	121
Table 27: Participant characteristics: Age and gender	141
Table 28: Participant characteristics: Stroke classification, length of stay and discharge destination	142
Table 29: Participant characteristics: Other factors	143
Table 30: Stroke severity	144
Table 31: Distribution of performance on Find the Thumb Test	146
Table 32: Measures of shoulder external rotation and wrist extension	165
Table 33: Summary of recommendations for the conduct of a definitive study	203

List of Figures

Figure 1: Model of application of the ICF to people with profoundly- affected arm after stroke	33
Figure 2: Results of systematic review search	63
Figure 3: Overview of study design	85
Figure 4: Process of the development of the battery of outcome measures	90
Figure 5: Bland Altman plot to show preliminary testing of agreement for measuring range of movement with goniometry	94
Figure 6: Bland Altman plot to show preliminary testing of agreement for measuring range of movement with goniometry with the revised protocol	95
Figure 7: Flow diagram detailing recruitment and progression of participants	111
Figure 8: Adverse events reported by the participants	119
Figure 9: Flow diagram detailing recruitment and progression of carers	120
Figure 10: Distribution of cognitive scores related to assessment of capacity to decide whether to engage with the research study	129
Figure 11: Distribution of ACER language scores related to assessment of capacity to decide whether to engage with the research study, in participants with aphasia	130
Figure 12: Distribution of Fugl-Meyer scores at recruitment	145
Figure 13: Distribution of results of the sensation & perceptual assessment	146
Figure 14: Distribution scores on the SADQH-10 at baseline	148
Figure 15: Distribution of MMAS scores at each muscle group in the arm at baseline	151
Figure 16: Distribution of participants' pain during baseline assessment	153
Figure 17: Profile of the incidence of the highest level of spasticity in any muscle group during the study	157
Figure 18: Profile of spasticity in shoulder adductors	158
Figure 19: Profile of spasticity in shoulder internal rotators	158
Figure 20: Profile of spasticity in elbow flexors	158
Figure 21: Profile of spasticity in wrist flexors	159
Figure 22: Profile of spasticity in finger flexors	159
Figure 23: Profile of pain at each time-point	162
Figure 24: Participants responses to the SIPSO question concerning their perceptions of their appearance	169
Figure 25: Participants ability to complete the LASIS, MAL-14 and SIPSO questionnaires	175
Figure 26: Percentage of participants who considered each LASIS item relevant	176
Figure 27: Distribution of participants LASIS scores at each time point	176
Figure 28: Relationship between LASIS scores and MAL-14 scores at 3 months	177
Figure 29: Relationship between LASIS scores and MAL-14 scores at 6 months	178
Figure 30: Relationship between LASIS scores and summed MMAS scores at 3 months	179

Figure 31: Relationship between LASIS scores and summed MMAS scores at 6 months	179
Figure 32: Distribution of MAL-14 scores	183
Figure 33: Distribution of SIPSO physical Sub-Scale scores	186
Figure 34: Distribution of SIPSO social sub-scale scores	186
Figure 35: Distribution of scores of carer burden	188
Figure 36: Reported times that participants spent wearing splints each day	190
Figure 37: Healthcare interventions received	192
Figure 38: Analgesia taken at each time-point	193

List of appendices

Appendix 1: Systematic review protocol	210
Appendix 2: Data extraction form for systematic review	212
Appendix 3: Quality assessment and risk of bias tool for systematic review	214
Appendix 4: Information leaflet for participants with stroke	216
Appendix 5: Consent form for participants with stroke	220
Appendix 6: Information leaflet for friends and relatives	221
Appendix 7: Consent form for friends and relatives	224
Appendix 8: Example of pictographic resources used to support participants recruitment	225
Appendix 9: Information leaflet for consultees	226
Appendix 10: Consultee declaration form	229
Appendix 11: Information leaflet for participants who regain capacity	230
Appendix 12: Consent form for participants who regain capacity	233
Appendix 13: Letter to inform GPs of participants' involvement in the study	234
Appendix 14: Example of pictographic resources used to support participants- Assessing pain	235
Appendix 15: Final standardised protocol for measuring range of movement	236
Appendix 16: Workbook to record the predictor variables	243
Appendix 17: Workbook to record the outcome measures	247
Appendix 18: Workbook to record the carer outcome	256
Appendix 19: Topic guide for individual and group interviews	257
Appendix 20: Copies of ethical approvals	258

Acknowledgements

With particular thanks to the following:

The Torbay Medical Projects Committee for providing funds for this study to be conducted.

My supervisor Dr Ian Frampton and other staff on the Doctorate of Clinical Research programme at the University of Exeter.

My fieldwork collaborators Dr Cherry Kilbride and Professor Jon Marsden who provided the right combination of encouragement, support and challenge.

Joyce Picken our expert advisor on the consequences of stroke, the members of our Patient and Public Involvement panels and all the people with stroke and their carers who have been part of this project.

Charlotte Bailey for assistance with data collection, Jacky Youngman for her assistance with data entry, and Professor David Richards, Dr Cherry Kilbride, Laura Shenton, and Kathryn Bamforth for their input into the systematic review.

My husband Pete, and children Jack (happy sloth) and Grace (little chicky) for the ongoing support.

Finally, to the many professionals working in the field of rehabilitation who I have met and worked with and who have provided such inspiration.

Author's declaration

The systematic review reported in Chapter 4 was a collaborative piece of work with Professor Dave Richards, Dr Cherry Kilbride, Laura Shenton and Kathryn Bamforth, with all being involved in the development of the study methodology and reviewing manuscripts. However, most of the work was undertaken by Rhoda Allison who conducted all of the searches, screened and extracted data from every article identified and who prepared the manuscript.

Rhoda Allison (RA) was the principal investigator for this feasibility study and was directly involved in developing the study protocol and revisions, was responsible for obtaining ethical and NHS trust approvals and for conduct of the research. She personally recruited all the participants and conducted all of the baseline measures. Some of the follow-up appointments were conducted by another staff member funded by a small study grant but RA entered all data and was responsible for analysis.

List of abbreviations and symbols

ACER	Addenbrookes Cognitive Examination Revised
AMED	Allied and Complementary Medicine Database
CINAHL	Cumulative Index to Nursing and Allied Health
DH	Department of Health
EMBASE	Excerpta Medica Database
FM	Fugl-Meyer Upper Limb Assessment
ICF	International Classification of Functioning, Disability and Health
ISWP	Intercollegiate Stroke Working Party
LASIS	Leeds Arm Spasticity Impact Scale
MAL-14	Motor Activity Log-14
MMAS	Modified Modified Ashworth Scale
MMSE	Mini Mental State Examination
MRC	Medical Research Council
NIHR	National Institute for Health Research
NIHSS	National Institutes of health Stroke Scale
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
pwS	Person/ people with stroke
RA	Rhoda Allison
RCP	Royal College of Physicians
SADQH-10	Stroke Aphasic Depression Questionnaire- Hospital version
SIPSO	Subjective Index of Physical and Social Outcome
WHO	World Health Organisation

Chapter 1: Introduction

1.1 The history of stroke

It is believed that the Greek physician Hippocrates first formally described the syndrome of stroke in approximately 400 BC when he used the Greek word apoplexy (meaning 'struck with violence') to describe the sudden signs of paralysis, aphasia and sensory disturbance, which were recognised as indicators of the condition (Thompson, 1996; Garrison, 1969). However, even before this point there were references in Babylonian tablets thought to refer to the signs and treatment of stroke, and early rehabilitation interventions involved the use of massage, hot poultices, bandaging and incantations (Reynolds & Kinnier Wilson, 2004).

Currently the term stroke refers to 'a focal (or at times global) neurological impairment of sudden onset, and lasting more than 24 hours (or leading to death), and of presumed vascular origin' (WHO, 2005, p1). Stroke is now the second commonest cause of death in adults worldwide (Lopez & Mathers, 2006) and the most significant cause of severe disability in the United Kingdom (DH, 2007). For those who suffer a stroke approximately one-quarter die, and, of the remainder, half will be left with enduring impairments and disabilities (National Audit Office, 2010). There is a need to provide specialist coordinated rehabilitation to both reduce disability (Stroke Unit Trialists' Collaboration, 2007) and to support people with long-term conditions (DH, 2007).

1.2 Stroke and the profoundly-affected arm

Hemiplegia (weakness of one half of the body) affects 80% of people with acute stroke, and, even with a programme of rehabilitation, it is estimated 30-40% of stroke survivors do not recover the use of their affected arm (ISWP, 2012). The term 'non-functional arm' has been used to describe this situation in a number of research publications (Hesse et al, 2012; Bhakta, Cozens, Bamford & Chamberlain 1996). However, for the purposes of this thesis the term 'profoundly-affected arm' is used to describe the situation where a stroke survivor has no movement at all in the affected arm or has slight voluntary muscle activity but the resulting movement is not useful in the sense of active function. This term was developed in consultation with a number of people with stroke (pwS) involved in the project.

Current physical therapies in stroke rehabilitation are based predominantly on exercise and task-specific training (Intercollegiate Stroke Working Party, 2012). However most interventions aimed at improving active function require the presence of some movement within the arm initially, and research has shown that additional physiotherapy and practice of motor tasks does not improve active function in those with most significant arm weakness (Parry, Lincoln & Vass, 1999). For those unlikely to regain active function a different approach focused on reducing the impairments, managing disability and avoiding complications in the arm is required.

Currently there are number of interventions for use with the profoundly-affected arm that have developed historically, some of which are designed to prevent impairments and some of which are intended to improve the ease of providing care. These include the use of passive exercise and positioning (De Jong, Nieuwboer & Aufdemkampe, 2006), splinting (Lannin, Cusick, McCluskey, & Herbert, 2007), stretching (Bovend'Eerd et al, 2008), botulinum toxin (Shaw et al, 2010), and strapping (Griffin & Bernhardt, 2006). However, evidence to support these interventions either individually or in combination is limited. Most of the previous research has focused on relatively small evaluations of existing treatments, and the theoretical underpinnings of the content, and intensity of the interventions are often not described (see Section 2.4). Furthermore, for those presenting with a profoundly-affected arm after stroke there is currently little understanding of the progression of impairments and disabilities so even the timing of potential interventions is unclear. To date, there has been limited application of the Medical Research Council (MRC) work: *Developing and Evaluating Complex Interventions: New Guidance* (Craig et al, 2008) in this area. Greater attention to this framework may give a clearer process for the sound development and appraisal of interventions.

1.3 The purpose of this thesis

The purpose of this thesis is to report a feasibility study that was designed to assess the potential of using a longitudinal research design to develop a greater understanding of the profile of impairment and disability in the profoundly-affected arm after stroke, and to identify if any potential predictors assessed early could distinguish those most at risk of impairments or difficulty caring for

the arm. Improved prediction of disability and knowledge of how the profoundly-affected arm changes over time will enable clinicians to develop appropriately-timed and targeted preventative measures, and will enable pwS to receive care informed by an evidence-based approach. The feasibility study was designed with reference to NIHR guidance (National Institute for Health Research, 2012), and in accordance with other feasibility project designs (Wyatt, Lloyd, Creanor & Logan, 2011). The objectives of the study are to assess (i) the recruitment and follow-up processes (ii) the characteristics of the sample to establish if this was likely to be representative of the target population and (iii) to establish the acceptability and responsiveness of the outcome measures. Key tenets of the study involve being as inclusive of all pwS as possible, and using assessments and outcomes that can be conducted in participants residences in order that care be provided closer to home.

1.4 Including people with cognitive and communication disability

A presentation of profoundly-affected arm post-stroke is correlated with a greater degree of overall disability, reduced cognition and inattention (Kwakkel, Kollen, van der Grond & Prevo, 2003; Feys, de Weerd, Nuyens & van de Wickel, 2000). Therefore stroke survivors with a profoundly-affected arm are more likely to have these additional difficulties and any research design needs to allow for this. Traditionally however, stroke research has a history of excluding people with more severe cognitive impairment and communication disability from research studies (Masuca et al, 2012). For example, considering the previous references related to interventions for the profoundly-affected arm, of the four publications that related to trials of interventions, three of these had specific exclusions related to cognitive ability (Shaw et al, 2010; Lannin et al, 2007; De Jong et al, 2006). Equally, the presence of aphasia has also often been an exclusion to participation in trials (Townend, Brady & McLaughlan, 2007), and even when not directly excluded, studies often do not use specific strategies to enable people with aphasia to participate (Pringle, Hendry & McLafferty, 2008).

Ethical principles of justice in research design require that research participants are treated fairly and that people with more severe impairments should be no more or less likely to be recruited than those with more minor stroke (Rose &

Kasner, 2011). In addition to this ethical dilemma, exclusions in research design then translate into restrictions in applications of treatments clinically and this effectively discounts those who may benefit from receiving interventions (Venables, 2008). A key tenet of this thesis has therefore been to be as inclusive of people with cognitive and communication disability post-stroke as possible.

1.5 Clinical practice within the person's own home

Over the past two decades there has been a shift in providing rehabilitation mostly in hospital to now providing more care at home (RCP, 2012). Indeed home-based interventions such as Early Supported Discharge teams may be more effective than those delivered in hospital settings (Fearon, Langhorne & Early Supported Discharge Trialists, 2012). Healthcare policy demands that this shift continues in order to meet the needs of an ageing population (Institute for Innovation & Improvement, 2013). In keeping with this the second key tenet of this thesis was to utilise assessments and processes that could subsequently be adopted for clinical practice assuming a model of care delivery within the home. Rather than focus on laboratory-based tests and equipment that will not be available to the majority of people receiving care post-stroke this work focuses on the use of assessments that can be conducted within the home environment.

1.6 Thesis structure

Following a brief introduction to the concept of the profoundly-affected arm in this chapter, the thesis moves on to explore the clinical syndrome of profoundly-affected arm and then describe the development and reporting of the feasibility study. Chapter 2 presents the International Classification of Functioning, Disability and Health (WHO, 2001) and uses this framework to explore the problems associated with the profoundly-affected arm after stroke, when a model of the impact on the constructs of impairment, activity and participation is developed. The research evidence to support interventions currently offered for the profoundly-affected arm are reviewed and it is argued that prior to the development and testing of further interventions there first needs to be a greater understanding of the natural history of change in the profoundly-affected arm.

In order to address this question Chapter 3 comprises a review of the outcome measures available for monitoring change associated with the profoundly-affected arm, with an evaluation of their psychometric properties. Chapter 4 contains a systematic review conducted to identify the current knowledge base concerning the natural course of change in the profoundly-affected arm post-stroke and the evidence for any potential predictors of greater risk of developing difficulty caring for the arm or associated impairment. Chapter 5 describes this feasibility study, which recruited 40 participants to test the use of a longitudinal design to identify the profile of change and to test predictors of difficulty caring for the arm. The objectives of the feasibility study are to assess (i) the recruitment and follow-up processes with particular attention to the ability to involve people with cognitive impairment and communication disability; (ii) the characteristics of the sample to establish if this was likely to be representative of the target population and (iii) to establish the acceptability and responsiveness of the outcome measures. Interviews were conducted with a quarter of the participants to establish the acceptability of the design.

Chapter 6 contains an overview of the quantitative results of the study that took place between September 2011 and April 2012. The following four chapters contain the analysis of this quantitative data, and presentation and analysis of qualitative data from the participant interviews. For ease of reading, particularly in relation to the qualitative findings, the analysis and discussion of the results have been combined. Chapter 7 relates to the process of recruitment and follow-up. Chapter 8 concerns the characteristics of the participants including demographic data and results of the predictor assessments. Chapters 9 and 10 describe the results and discussion related to the outcome measures concerned with impairments, and disability and related factors respectively. Finally, Chapter 11 contains the conclusions exploring the strengths and weaknesses of the methods used with a discussion of the recommendations for further work.

Chapter 2: Background

2.1 Chapter overview

This chapter presents definitions of the key concepts within this thesis including the impact of the profoundly-affected arm on health and health-related domains. These domains are presented in a structure according to the International Classification of Functioning, Disability and Health (ICF) (World Health Organisation, 2001). The main potential impairments associated with the profoundly-affected arm are identified and described, and the potential relationship of these with activity and participation, and environmental factors are considered. Although definitions of impairment in the profoundly-affected arm lack clarity, it is argued that these impairments and associated disability can cause significant difficulties for people living with stroke. Therefore, an overview of the current interventions and the evidence to support or refute them are discussed. Examples are used to demonstrate that many evaluations of existing interventions in the profoundly-affected arm have been poorly designed (Section 2.4) and consequently there is limited evidence to guide clinical practice. In line with Medical Research Council guidance: *Developing and evaluating complex interventions* (Craig et al, 2008) it will be suggested that further work is required to establish which people with a profoundly-affected arm are most at risk of developing difficulties and the timing of changes, prior to further work on the development and evaluation of interventions.

2.2 The International Classification of Functioning, Disability and Health

The ICF (WHO, 2001) is a classification of health and health-related domains, which includes reference to both individual and societal views. It covers the concept of disability in its broadest sense and refers to four key areas: body structures, body functions, activity and participation, and environmental factors (WHO, 2001). 'Body structures' within the ICF are anatomical parts of the body such as organs, limbs, and their components. 'Body functions' refers to the physiological functions of these body structures and systems. 'Activity' is defined as the execution of a task or action by an individual, and 'participation' is involvement in a life situation. Finally, environmental factors make up the physical, social, and attitudinal environment. With this variety of factors, the ICF provides a framework to consider the impact of disease and disability at a range of levels, and provides a universal language to describe and measure health and disability (Starrost et al, 2008). The original ICF contains over 1400 items,

so shorter 'core sets' of categories related to particular conditions have been developed to make application of the classification more manageable. However, the core set for stroke still contains a total of 130 categories (Geyh et al, 2004). It is possible to select a smaller number of ICF categories to describe the impact of stroke on a more defined aspect of health and disability, and it has already been used in this way to consider the impact of stroke on motor control of the arm and hence on a person's ability to use the arm for day-to-day tasks (Faria-Fortini, Michaelsen, Cassiano & Teixeira-Salmela, 2011). The ICF framework will now be applied to consider the consequences of living with a profoundly-affected arm after stroke.

2.3 Applying the ICF to the profoundly-affected arm after stroke

2.3.1 Body structure, body functions and their impairments

Body structures that relate to the arm include the relevant bones, muscles, joints, ligaments and the nervous system. The structures and systems themselves are the same for a person with stroke as for a person without, but the stroke lesions lead to changes in the way these structures function.

The ICF (WHO, 2001) terms body functions as the physiological functions of body structures and systems. Within this domain the ICF includes reference to 'neuromusculoskeletal and movement related functions', 'sensory functions and pain', 'functions of the skin' and 'mental functions' all of which may be impaired in the case of the profoundly-affected arm. Each of these functions, and the associated impairments will be considered in turn.

Neuromusculoskeletal and movement related functions

Movement related functions within the ICF include aspects such as 'muscle power functions', 'muscle tone functions' and 'mobility of joint functions'. Muscle power has been shown to be the most significant neuromusculoskeletal element for the recovery of active use of the arm (Patten, Lexell & Brown, 2004). However in people who do not recover active movement spasticity (a disorder of muscle tone) has been shown to be a significant disabling problem (Shaw et al, 2010; Bhakta 2000) and associated with higher costs of healthcare (Lundström, Smits, Borg, & Terént, 2010). Equally, impairments associated with mobility of joint functions are prevalent in people with profoundly affected arm including contracture (Shaw et al, 2010), and joint subluxation (Kumar &

Swinkels, 2009).

Spasticity. Although it is widely recognised that spasticity affects up to one third of people after stroke (RCP, 2009) its definition remains controversial. It was originally defined as “a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex” (Lance, 1980, p. 485). This definition has been criticised as being too narrow and not encompassing the variety of problems seen with spasticity, such as spasm, and reduced co-ordination (Barnes, 1998). However it clearly refers to the phenomenon seen clinically when there is greater resistance when movement occurs at an increased speed. The SPASM (Support Programme for Assembly of database for Spasticity Measurement) defined spasticity as “disordered sensori-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles”, (Pandyan et al, 2005, p.5). Although the pathophysiology of spasticity is not completely understood, it is linked with a loss of inhibitory control from the central nervous system (possibly allied with other peripheral neural changes) leading to an increase in excitation of motor units (Fleuren, 2009). In turn this excitation (along with immobilisation) leads to mechanical change within muscle fibre and other soft tissues, which creates further stiffness (O’Dwyer, Ada & Nielsen, 1996). Some authors advocate that ‘spasticity’ should only be used to describe situations when resistance to movement is exclusively associated with an increase in neural stretch reflex activity (Fleuren et al, 2010), and ‘hypertonia’ should be used to describe other presentations of stiffness. However, in both clinical practice and research the two terms are frequently used interchangeably. Therefore for the purposes of this thesis a more liberal definition of spasticity has been adopted with spasticity describing involuntary muscle stiffness, which occurs following lesions in the central nervous system. Spasticity is more prevalent in stroke survivors with significant weakness (Leathley et al, 2004); and is a common problem in the profoundly-affected arm (ISWP, 2012). Prolonged stiffness from spasticity can lead to subsequent contracture and loss of range of movement (Ada, O’Dwyer & O’Neill, 2006).

Contracture and range of movement. The term contracture is also frequently used but with little consensus regarding its definition (Fergusson, Hutton & Drodge, 2007). Some authors use the term to indicate reduced range of movement from shortened soft tissues (Bakke, 1995) while others use it to describe both a loss of range of movement but also an increased resistance to passive movement (Turton & Britton, 2005). However as previously discussed, resistance to passive movement may be caused by both neural and non-neural changes. It may also reflect the more recent history of movement in that limbs that have not been moved for a period of time are stiffer. Hagbarth, Hägglund, Nordin & Wallin (1985) have termed this resistance as thixotropic changes. Physiologically there is a difference between the neural aspect of muscle stiffness, the loss of soft tissue range of movement and thixotrophy, but clinically this is not always possible to differentiate (Vattanasilp, Ada & Crosbie, 2000). Consequently clinicians often argue over these constructs (Bakheit, Fheodoroff & Molteni, 2011). However, in terms of impact on the person with profoundly-affected arm after stroke, people with stroke (pwS) focus less on diagnostic features of impairment and more on the functional impact (Atkinson et al, 2012). To this end, Kwah, Harvey, Diong & Herbert (2012) defined contracture as the 'functionally significant loss of joint range' (p.46) and this is the definition that is adopted within this thesis. Contractures are a recognised complication in those with weakness post-stroke (ISWP, 2012).

Joint subluxation. Joint subluxation is also a construct where there are variations in the definitions of the term (Kumar & Swinkels, 2009). Generally there is agreement that subluxation occurs when the articular surfaces of joints become mal-aligned in any direction (Shai, Ring, Costeff & Solzi, 1984). It is a well-documented occurrence in the arm after stroke, particularly at the shoulder (Shepherd & Carr, 1998) but also at the wrist. It is associated with more severe weakness (Fotiais, Grouios, Ypsilanti & Hatzinikolaou, 2005) so would be expected to have a high prevalence in people with profoundly-affected arm. Although some authors have suggested that shoulder subluxation contributes to pain after stroke (van Ouwenaller, Laplace & Chantraine, 1986), multiple studies have shown this is not always the case and the relationship between subluxation and pain is not clear (Kumar & Swinkels, 2009).

Sensory functions and pain

Sensory functions and pain within the ICF encompass appreciation of touch, temperature, proprioception and pain. Sensory impairment is common after stroke and is associated with increased weakness and stroke severity (Tyson, Hanley, Chillala, Selley & Tallis, 2008; Connell, 2007). Although reduced sensation has been associated with poorer outcomes in rehabilitation of the arm the full extent of this is difficult to evaluate. This may be due to difficulty completing formal assessments of sensation and in particular the differentiation of sensory and perceptual deficits (Hunter & Crome, 2002). In studies that have included people with profoundly affected arm after stroke there is little reference to the presence or absence of sensory functions such as temperature and proprioception. However there are numerous references to the prevalence of and difficulties caused by pain in the profoundly-affected arm (Lindgren, Jonsson, Norrving & Lindgren, 2007; Langhorne, Stott, Robertson et al, 2000; Bohannon, 1988). For this reason pain was selected for inclusion in the model of the consequences of the profoundly-affected arm.

Pain. Pain has been formally defined as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage’ (International Association for the Study of Pain, 2012, para. 4). However this definition does not indicate that levels of pain do not just reflect the state of biological tissues, and that somatic, psychological and social factors may all have an influence on pain (Moseley, 2007). Alternative definitions are that ‘pain is the unpleasant sensation that has evolved to motivate behaviour which avoids or minimises tissue damage, or promotes recovery’ (Wright, 2012, Section V), and persistent pain is ‘pain without apparent biological value that has persisted beyond the normal tissue healing time’ (International Association for the Study of Pain, 2012, para. 7). Pain after stroke and in the profoundly-affected arm can originate from a number of sources. Musculoskeletal pain may occur in the case of joint degeneration or mal-alignment, or neuropathic symptoms may occur in the case of central nervous system generated pain (Bykov, 2012). In addition many stroke survivors experience a high degree of emotional anguish that may impact on the presence and perception of pain (Gilham & Clark, 2011). Pain may lead to muscle spasm and tension so can overlap with the concept of increased muscle tone. In addition, there are

complex regional pain syndromes including shoulder hand syndrome or Sudek's atrophy where autonomic dysfunction leads to oedema, skin changes, temperature changes and chronic pain although the incidence of this syndrome is unclear (Barnes & Ward, 2000).

Functions of the skin

Skin integrity. The ICF contains reference to the protective functions of the skin. Although there has been no research into the occurrence of skin problems in people with profoundly-affected arm post-stroke, severe hygiene problems of the palmar skin have been reported in association with clenched fist deformity that can accompany spasticity (Pomerance & Keenan, 1996). In some cases orthopaedic surgery can be used to release severe tightness and enable maintenance of better skin condition (Keenan, 1988).

Mental functions

Body image. The ICF classifies body image as a body function and defines it as 'specific mental functions related to the representation and awareness of one's body' (WHO, 2001, Section b1801). Dolan & Birtchnell (1997) present two aspects of body image. The first aspect is the body precept, which refers to the neurological aspects of accumulating and processing sensory information. Body precept can be affected by stroke particularly if a person has visual problems, inattention or agnosia (the loss of the ability to recognise objects and people) (Lindsay, 1997), and these difficulties may accompany a presentation of profoundly-affected arm. The second aspect of body image is the body concept, which refers to the psychological and sociological significance of appearance. This body concept encompasses the consequences of both the appearance of the limbs and body, and adornments to the body. All of these areas may be affected for people with a profoundly-affected arm: spasticity and contracture may alter the shape of the hand and arm; and the use of splints and prosthetics can add further changes to appearance. Although two studies have reported that pwS and arm difficulties have reported an impact on their body image and appearance (Atkinson et al, 2012; Keppel & Crowe, 2000), there has been little formal research in this area.

In all, six potential impairments of the profoundly-affected arm after stroke have been described. The impact of these in the context of living with a profoundly-affected arm on the ICF (WHO, 2001) domains of activities and participation will now be considered.

2.3.2 Activity and participation

Active function and passive function

'Activity' refers to the ability to translate body functions into tasks such as lifting or carrying objects (WHO, 2001). However, the ICF does not just consider 'activity' in terms of performing tasks with a limb (as referenced in the example above). It also covers aspects such as the importance of tasks involving caring for a limb, which is not able to move itself. Chapter 5 of the ICF refers to self-care and includes washing oneself and caring for body parts (such as the skin). This broader view of activity has led to the development of two categories of 'function' within rehabilitation literature (Ashford & Turner-Stokes, 2006). 'Active function' refers to the undertaking of a functional task by the individual themselves (for example being able to pick up an object). 'Passive function' refers to a task such as a care activity, which may be performed by a carer or by the person to a limb they cannot move (for example the process of keeping a hand clean or cutting the finger nails). The importance of passive function activities is becoming increasingly recognised (ISWP, 2012). By definition, people with a profoundly-affected arm will have very little or no active functional use of the arm, but they may experience problems with passive function of the arm (Sheean, 2001). In particular activities such as washing, dressing and positioning the arm have been identified as challenging (Ashford & Turner-Stokes, 2009). In a number of studies there is a clear assumption that difficulty with passive function is related to impairments such as spasticity (Kong, Chua & Lee, 2010; Lundstrom, Terent & Borg, 2008) but this relationship has not been formally tested.

Quality of life

Within the ICF classification the term 'participation' indicates how 'activities' are then applied to daily life such as the ability to work, participate in education and recreation, manage relationships and so on. How individuals feel about their abilities and any restrictions is often referred to as quality of life (Teixeira-

Salmela, Neto, Magalhaes, Lima & Faria, 2009). The areas that individuals consider important for quality of life may be very personal but there is consensus that it may include the ability to achieve personal goals (Wyke et al, 2008), the surrounding environment, the ability to have some security of financial circumstances and to manage psychological stress (Berglund & Ericsson, 2003). Some of these aspects may be related to health status and health-related quality of life is defined as 'optimum levels of mental, physical, role (e.g. work, parent, carer, etc.) and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being' (Bowling, 2001, p.6). Stroke may have a significant impact on the quality of life of those with on-going disability (Choi-Kwon, Choi, Kwon, Kang, & Kim, 2006; Wyller & Kirkevold, 1999). There has, however, been no specific research on the impact on quality of life of those stroke survivors with a profoundly-affected arm.

2.3.3 Environmental factors

Environmental factors within the ICF (WHO, 2001) that relate to the profoundly-affected arm after stroke include 'services', 'support and relationships', and 'products and technology'.

Services

The ICF classification of 'services' refers to the provision of formal health and social care services. This includes access to hospitals, clinics, community services, and social services, including formal packages of care to support people to live at home. Use of both health and social service resources after stroke is high (National Audit Office, 2010) but there has been no work to quantify resource utilisation within the group of people with profoundly-affected arm.

Support and relationships

'Support and relationships' within the ICF refers to interactions with family and others, and support from these people (including the provision of informal caring). It is unclear what proportion of people living with stroke receive support from unpaid caregivers, and the impact of this relationship on the carer may have both positive and negative aspects (Mackenzie & Greenwood, 2012).

However, the majority of studies focus on the burden of care-giving (Vincenta, Desrosierse, Landrevilleb, Demersg, & BRAD group, 2009), which can be high after stroke (Smith, Lawrence, Kerr, Langhorne & Lees, 2004). Levels of carer burden do not necessarily correlate with the degree of physical impairment of the stroke survivor (Thommessen, Wyller, Bautz-Holter & Laake, 2001), and the link between carer burden and supporting a person with profoundly-affected arm after stroke has not been explored.

Products & technology

The ICF includes reference to 'products and technology', which includes any devices aimed at improving functioning such as orthotics, wheelchairs, and environmental controls. For people with profoundly-affected arm after stroke, a number will use splints and supports that are targeted at the prevention of further disability (Lannin et al, 2007). Others will use devices that are designed to increase independence such as equipment to enable tasks that usually require the use of two hands to be completed with one (eg a one-handed tin opener). The use of devices to promote independence in this group has not been studied but there has been a considerable amount of research on splints and arm supports, which will be considered with reference to interventions for the profoundly-affected arm in Section 2.5.

2.3.4 Summary of the ICF application to the profoundly-affected arm

The ICF framework has been applied to the situation of a person living with a profoundly-affected arm after stroke. It has identified six key impairments, with impact on three aspects of activity and participation, and three aspects related to environmental factors. A summary of this model showing the key impairments, difficulties with activity and participation, and environmental factors is shown in Figure 1.

Figure 1: Model of application of the ICF to people with profoundly-affected arm after stroke

Body functions (impairment)		Activity & participation	Environmental factors
Muscle tone functions <i>Spasticity</i>	Mental functions <i>Altered body image</i>	Passive function <i>Self care</i>	Services <i>Health & social services</i>
Mobility of joint functions <i>Contracture</i>	Sensory functions & pain <i>Pain</i>	Active function <i>Lifting & carrying objects</i>	Products and technology <i>Splints & supports</i>
Mobility of joint functions <i>Joint subluxation</i>	Functions of the skin <i>Skin integrity</i>	Health related quality of life	Support & relationships <i>Carer burden</i>

2.4 Evidence for management of the profoundly-affected arm

Currently there are number of interventions for use with the profoundly-affected arm that have developed historically. Interventions aimed at improving active function within the arm such as exercise-based training approaches require the presence of some movement within the arm initially, and research has shown that additional physiotherapy and traditional practice of motor tasks does not improve active function in those with most significant arm weakness (Parry, Lincoln & Vass, 1999). Recently there has been a suggestion that priming the motor system by first providing a burst of sensory stimulation may improve motor outcomes (Sawaki, Wu, Kaelin-Lang & Cohen, 2006). However to date trials have only involved small numbers of participants (for example Sullivan, Hurley, & Hedman, 2012) and larger studies are required. There is also a need to consider sub-categories of participants in trials, for example how those with no volitional movement compare to those with some limited movement.

In the meantime interventions for the profoundly-affected arm are targeted at managing the level of disability. These include the use of passive exercise programmes and positioning (de Jong et al, 2006), splinting (Lannin et al, 2007), stretching (Bovend'Eerd et al, 2008), botulinum toxin (Shaw et al, 2010), and strapping (Griffin & Bernhardt, 2006). Current best practice in rehabilitation is defined as multidisciplinary so pwS may be prescribed any number of these interventions in any amalgamation. However, evidence to support these

interventions either individually or in combination is limited. For example a systematic review of studies of splints concluded that there was no evidence to support or refute their effectiveness (Lannin & Herbert, 2003). However, most of the research examining splinting has focused on relatively small studies of evaluations, and the theoretical underpinnings of the content, intensity, and timing of the intervention are often not described. As an example one study of splinting developed a protocol where the intervention consisted of the application of a thermoplastic wrist splint that was worn overnight (Lannin, et al, 2007). The intervention was started within the first 8 weeks of stroke (at an average of 25 days post-stroke) and was provided for four weeks. The outcomes (extensibility of the wrist and finger flexors) were measured at the end of the four-week intervention and then again two weeks later. The subsequent publication did not refer to any theoretical work to guide why these particular timings were chosen for the provision of the intervention and the outcome measurement, and has been criticised for this (Manigandan & Charles, 2007). In a second example, evidence that supports the use of botulinum toxin to improve ease of care of the hand is drawn from a trial which was designed to assess the effect of treatment on active arm function (Shaw et al, 2010). The intervention included physiotherapy and exercise as well as botulinum toxin and the primary outcome measure was active use of the arm. Ultimately the study included people with no function of the arm to meet recruitment targets, and used secondary outcome measures to record improvements in ease of care of the arm. However given that additional exercise has been shown to be ineffective in this group and would not be used in this way in clinical practice there should be caution in interpretation of these results.

For those presenting with a profoundly-affected arm after stroke there is currently little understanding of the progression of impairments and functional loss so even the timing of potential interventions is unclear. To date, there has been limited application of the MRC work: *Developing and Evaluating Complex Interventions: New Guidance* (Craig et al, 2008) in this area. Greater attention to this framework may give a clearer process for the sound development and appraisal of interventions.

2.5 The MRC guidance on complex interventions

Complex interventions are defined as those that consist of several interacting components (Craig et al, 2008). This complexity may refer to the range of behaviours within the targeted population, and the range of outcomes expected as well as the number of elements in the intervention. The current model of how the ICF classification can be applied to the profoundly-affected arm demonstrates the complexity of the domains of impairment and disability associated with this clinical presentation. The range of interventions adds a further layer to this. The MRC publication (Craig et al, 2008) states that more attention should be given to the development of interventions prior to testing them with randomised controlled trials. The guidance states that:

“Best practice is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory and then a definitive evaluation.”

(Craig et al, 2008, p. 8)

This development of interventions phase includes identifying the existing evidence base for both the problem encountered and the potential intervention, then theoretically modelling the intervention, potential processes and the expected outcome. The MRC guidance pays significant attention to the need to ensure that outcome measures are appropriate and reflect the range of areas that interventions may impact on. To apply the MRC Framework to the development of interventions for the profoundly-affected arm, a greater understanding of the time course of impairments in the arm, potential risk factors, and the relationship between impairment and disability is required. This requirement informed the development of this study.

2.6 Chapter summary

In this chapter the ICF framework has been used to develop a model of the impact of the profoundly-affected arm on impairment, activity, participation, and environmental factors. To date there is limited evidence for the effectiveness of interventions in this area and it has been argued that the MRC framework for the development and evaluation of complex interventions could be used to gain

a better understanding of the natural course of development of impairment and disability in the arm after stroke. As a pre-requisite to review the literature in this area there first needs to be an understanding of how these impairments and disabilities are measured. In the next chapter a review of the outcome measures that can be used to monitor change in impairment, disability and related areas, in the profoundly-affected arm will be presented.

Chapter 3: Measuring outcomes in the profoundly-affected arm

3.1 Chapter overview

In the previous chapter the ICF framework was used to identify (i) the key body functions and their impairments; (ii) consequent impact on activities and participation; and (iii) potential environmental factors related to the profoundly-affected arm. This chapter presents a review of the available outcome measures of these various health and health-related domains. In keeping with one of the key tenets of this thesis, only measures that are reflective of 'real life' situations, and that can be used in all treatment settings including the person's own home were considered. A literature-based evaluation of the psychometric properties of each measure is presented and reference is made to their use with people with stroke (pwS), particularly those with more significant impairment of cognition or communication.

3.2 Assessing the measures

A review of the literature was conducted to identify common outcome measures that could be used to measure impairment, activity, participation or environmental factors in the person with profoundly-affected arm. A large number of outcome measures used to assess these health domains are available, but given this thesis is focused on how impairments and related domains can be assessed in everyday clinical practice, measures that rely on laboratory-based equipment or were not reflective of real-life situations were not considered. The measures identified were subjected to a literature based quality evaluation to assess both their psychometric properties, and the appropriateness of their use with pwS including those with aphasia or cognitive impairment. Quality criteria described by Terwee et al (2007) were utilised to assess the key psychometric properties of each of the measures. These criteria have been used to assess outcome measures used in neurological rehabilitation (Ashford, Slade, Malaprade & Turner-Stokes, 2008) and musculoskeletal medicine (Bot, Terwee, van der Windt, Bouter & deVet, 2004). The quality criteria used are as follows:

3.2.1 Content validity

Content validity refers to the degree that the items of a measure comprehensively assess all aspects of the domain purported to being measured (Ashford et al, 2008). As theoretical definitions of domains are ambiguous this

process can be difficult and it is recognised that one way to ensure content validity is to ask a group of experts their opinion. For this review, content validity was rated as positive if the scientific literature on development of the measure showed that patients, carers, or clinical experts had been involved in item selection or evaluation.

3.2.2 Construct validity

Construct validity reflects the extent to which the measure is able to measure the theoretical concept it was designed to (Bot et al, 2004). Construct validity was rated as positive if there was evidence that scores on the measure chosen were correlated with other tools that were either recognised to measure the same construct, or a related construct in a manner expected in line with an established theory.

3.2.3 Inter-rater reliability

Inter-rater reliability assesses any error in using the instrument when more than one assessor is involved. When scales used dimensionally scaled data a positive rating was given if inter-rater reliability had been assessed and if comparable results such as an intraclass correlation coefficient of greater than 0.70 for total scores had been found (Cicchetti, 1994). In item-by-item analyses and using nominally scaled data, intra and inter-rater agreement was also rated as positive if accepted statistical methods, such as the Kappa coefficient had given satisfactory results, for example kappa scores greater than 0.61 (Cicchetti, 1994; Altman, 1991).

3.2.4 Intra-rater reliability

Intra-rater reliability assesses test-retest accuracy when the same assessor is involved. The same standards for assessing inter-rater reliability were used for this quality assessment.

3.2.5 Responsiveness

Responsiveness reflects the degree to which the measure is capable of identifying change within the target population. Responsiveness was rated as positive if the measure had demonstrated change in conditions where this was expected in line with a specified hypothesis (for example in response to an

intervention, or correlated with other changes expected over time).

3.2.6 Use with people with stroke

This domain was not originally included in the assessment criteria developed by Bot et al (2004) but is included here as a key tenet of this thesis is to be as inclusive of people with more severe cognitive disability or aphasia as possible. Therefore, positive ratings were given if there was evidence that the measure could be successfully used with a significant number of people with these more severe difficulties.

The quality of each of these variables was rated on a four point scale based on findings in the literature: as adequate (+), doubtful (+-), poor quality (-) or as unknown (?) if insufficient information was available (Terwee et al, 2007).

3.3 Measures of Impairment

Table 1 shows the outcome measures that were identified to assess the six impairments in the profoundly-affected arm that were described in Chapter 2. A review of their psychometric properties follows. This is summarised in Table 2.

Table 1: Outcome measures for assessing impairment in the profoundly-affected arm

<p><u>Spasticity</u> Ashworth Scale, Modified Ashworth Scale, Modified Modified Ashworth Scale Tardieu scale Resistance to passive movement scale Tone assessment scale</p>	<p><u>Pain</u> Visual analogue scales Numerical rating scales Faces pain scale Proxy rating by therapist Dichotomous responses</p>
<p><u>Contracture/ range of movement</u> Visual estimation Goniometry (with non standard torque) Goniometry (with standard torque) Composite measures</p>	<p><u>Joint subluxation</u> Finger space measurement Thermoplastic jig</p>
<p><u>Skin integrity</u> No measures identified</p>	<p><u>Body image</u> No measures identified</p>

3.3.1 Spasticity

There has been considerable debate on the methods currently used to measure spasticity (Johnson & Pandyan, 2008). A key difficulty is that while disagreement remains as to what constitutes the construct of spasticity, there will be no agreement as to how the construct can be assessed. Definitions of spasticity refer to increased neural stretch reflex activity so many authors argue against measures that are not capable of detecting changes in electrical muscle activity (Fleuren et al, 2010). However, whilst electromyography (EMG) provides a measure of electrical and reflex activity, and is used in research to measure spasticity, it is not a simple enough measure for use in everyday clinical practice. Clinical practice measures therefore focus on ratings of resistance to passive movement, and consequently, are really measures of 'stiffness' and hypertonia, but consequently align with the definition of spasticity adopted in this thesis (Section 2.3.1). These measures include iterations of the Ashworth Scale (Ashworth, 1964), Tardieu Scale (Decq, Filipetti & Lefaucheur, 2005; Gracies, 2001), Resistance to Passive Movement Scale (Platz et al, 2008), and Tone assessment scale (Barnes et al, 1999). All of the presented measures have been used with pwS, and because they all rely on a therapist conducting the measure without required input from the person being measured, they are equally suited to people with aphasia and cognitive impairment.

Ashworth scale(s)

The original Ashworth Scale (Ashworth, 1964) was a five-point ordinal scale where the assessor rates the resistance to passive movement of a limb. The scale was originally evaluated at the elbow but is widely used at other joints (Watkins et al, 2002). Content validity of all Ashworth Scales as a measure of the neural aspects of spasticity is poor as it is unlikely that a measure of resistance will specifically relate to the neural component in isolation. However if considered as measures of hypertonia rather than the neural aspects of spasticity, the perceived validity of the measure improves (Pandyan et al, 1999). Construct validity was poor in a study comparing Ashworth scores with laboratory-based measures of neural stiffness at the elbow (Fleuren et al, 2010). Studies of inter-rater reliability have shown mixed results (Fleuren et al, 2010; Brashear et al, 2002a), although evaluations of intra-rater reliability have been more promising (Brashear et al, 2002a). The measure has been

responsive in studies of interventions for spasticity in the arm (Stampacchia, Bradaschia, & Rossi, 2004).

The first Modified version of the original measure was developed with an additional level to make a six–point nominal scale (Bohannon & Smith, 1987). This scale still has poor construct validity (Pandyan, Price, Barnes & Johnson, 2003a) and inter-rater reliability has been shown to be worse than the original (Pandyan et al, 1999), although intra-rater reliability has been established (Blackburn, van Vliet, & Mockett, 2002), and the scale is responsive to change (Bakheit et al, 2000). More recently a Modified Modified Ashworth Scale (sic) has been developed (Ansari, Naghdi, Moammeri & Jalaie, 2006). A test of construct validity showed mixed results (Naghdi, et al, 2007) but inter- and intra-rater reliability are better than the Modified Ashworth Scale (Ansari et al, 2009) and it is responsive to change (Keklicek, & Uygur, 2012).

Tardieu scale(s)

The Tardieu scale was constructed to differentiate the aspects of stiffness caused by pure spasticity from contracture by estimating both the amount of resistance but also the point at which this occurs depending on the speed of stretch (Patrick & Ada, 2006). Theoretically this corresponds with the description of spasticity as defined by Lance (1980) leading to a positive rating of content validity, and construct validity when compared with laboratory-based measures is good (Patrick & Ada, 2006). There have been several revisions of the original scale all termed the Modified Tardieu Scale. Studies of intra-rater reliability in stroke have been positive (Singh, Joshua, Ganeshan & Suresh, 2011) but inter-rater reliability is poor (Ansari, Naghdi, Hasson, Azarsa & Azarnia, 2008). Despite some testing in adults the measure is predominantly used in paediatrics and its responsiveness in stroke has not been established.

REPAS (Resistance to passive movement scale)

Platz et al (2008) developed a summary scale to measure spasticity throughout whole limbs rather than within individual muscle groups. The scale (REPAS) uses the same ordinal points as the Ashworth Scale so the rating for content validity is the same as for that. Construct validity has been assessed but only against scales of disability, not with other measures of spasticity. A small study

with 33 people of spasticity indicated positive inter and intra-rater reliability (Platz et al, 2008), and it is responsive to change (Hesse et al, 2012).

Tone assessment scale

The Tone assessment scale was developed to include reference to resistance to passive movement but also resting posture and associated reactions, which, at that time, were believed to be phenomenon related with spasticity (Barnes et al, 1999). However, magnitude of associated reactions is not correlated with increase muscle activity on EMG or spasticity (Stephenson, Edwards & Freeman, 1998) so content validity is rated as poor. This scale requires that participants are sitting upright unaided so it would not be suitable for use with people with greater physical disability. Inter-rater reliability has been established at the items that measure passive movement but not those that measure posture or associated reactions (Gregson et al, 1999). There has been no evaluation of construct validity, intra-rater reliability or responsiveness, and the scale is used very little in practice.

3.3.2 Contracture and range of movement

For the purposes of this thesis, contracture is defined as a loss of functional range of passive movement (Kwah et al, 2012). Methods of measuring passive range of movement including visual estimation, goniometry, both without a standardised force, or measured in the presence of a constant torque, and composite measures of range of movement. For all measures of range of movement there has been some suggestion that measuring the number of degrees of movement about a fixed axis will not reflect articular sliding and rotation so may reduce the validity of the measure, but most clinicians accept this as a fairly minor limitation (Gadjosik & Bohannon, 1987) and accept that content validity of measuring single joints. Construct validity has not been assessed for any of the methods, but as they are conducted by clinicians they are all equally suited for use with people with cognitive or communication impairment.

Table 2: Psychometric properties of the outcome measures of impairment

		Construct	Who completes	Content validity	Construct validity	Inter-rater reliability	Intra-rater reliability	Responsiveness	Evidence for use with PwS
Spasticity	Ashworth Scale	Resistance to passive movement	Clinician	+/-	-	+/-	+	+	+
	Modified Ashworth Scale	Resistance to passive movement	Clinician	+/-	-	-	+	+	+
	Modified Modified Ashworth Scale	Resistance to passive movement	Clinician	+/-	+/-	+	+	+	+
	Modified Tardieu Scale	Resistance & dynamic catch on passive movement	Clinician	+	+	-	+	?	+
	Resistance to passive movement scale (REPAS)	Resistance to passive movement at multiple joints in the arm & leg	Clinician	-	?	+	+	+	+
	Tone assessment scale	Resistance to passive movement, symmetry, associated reactions	Clinician	-	-	+	?	?	+/-
Range of movement	Visual estimation	Passive range of movement	Clinician	+	?	-	-	?	+
	Goniometry with standard guide*	Passive range of movement	Clinician	+	?	+	+	+	+
	Goniometry with standard force*	Passive range of movement & extensibility	Clinician	+	?	?	?	+	+
	Composite measure	Passive range of movement	Clinician	?	?	?	-	?	+
Joint subluxation	Finger space measures	Joint space	Clinician	-	-	+/-	+/-	?	+
	Thermoplastic jig	Joint space	Clinician	+/-	-	-	-	?	+
Pain	Visual analogue scale	Quantity of pain	PwS	?	?	?	?	?	-
	Numerical rating scale	Quantity of pain	PwS	?	?	?	?	+	-
	Faces pain scale	Quantity of pain	PwS	?	?	?	+	?	+/-
	Proxy rating by therapist	Quantity of pain	Clinician	?	?	-	?	?	+
	Dichotomous response	Presence of pain	PwS	?	?	?	?	+	+
Body image	No measures identified								
Skin integrity	No measures identified								

Visual estimation

Visual estimation of the range of movement at joints has been used for a significant period of time, and, has been supported by nationally agreed protocols (for example American Academy of Orthopaedic Surgeons, 1965). However, it has been shown to have very limited intra and inter-rater reliability (Youdas, Bogard, & Suman, 1993), and there has been little assessment of its responsiveness as a measure in research trials.

Goniometry with standardised protocol

Andrews & Bohannon (1989) demonstrated a good degree of intra- and inter-rater reliability when using goniometry to record passive range of movement in the arm after stroke, when the tool was accompanied by a standardised protocol. Measuring range of movement in this way is responsive to changes that occur following rehabilitation interventions (Bhakta et al, 2000).

Goniometry with standardised torque

Some authors argue that range of movement should only be recorded in the presence of a standardised torque to reduce potential bias (Kwah et al, 2012). Turton & Britton (2005) developed a technique using a spring balance to produce a constant torque when measuring shoulder external rotation and wrist extension. Although they demonstrated that this method was acceptable in normal subjects, there has been no evaluation of its reliability with pwS. The measure was however responsive to change over time.

Composite measures

Composite measures of range of movement have been described for use in assessing the hand, where the distance from the finger pulp to the surface of the palm is used to assess flexion of all the finger joints (Boschelnen-Morrin & Conolly, 2001). Inter-rater reliability and responsiveness in stroke have not been assessed but intra-rater reliability is poor compared to goniometry of finger joints (Ellis & Bruton, 2002).

3.3.3 Joint Subluxation

Measures of subluxation rely on estimating the degree of mal-alignment at the joint space for example the space between the acromion and the head of the

humerus in the shoulder. This is generally accepted as an appropriate means of assessing inferior shoulder subluxation but not other forms of subluxation.

Measures using medical imaging have been shown to be reliable in pwS using ultrasound (Kumar, Bradley, Gray & Swinkels, 2011). Techniques that can be used in clinical settings include finger space measurements and thermoplastic jigs. There have been some studies of construct validity and reliability but none of responsiveness.

Thermoplastic jigs

Measures of subluxation using jigs show poor correlation with imaging measures (Hall, Dudgeon & Guthrie, 1995) and poor intra- and inter-rater reliability (Boyd & Torrance, 1992).

Finger space measurements

Finger space measurements have a fair correlation with imaging measures when used with inferior subluxation (Hall et al, 1995) but have not been tested in other forms of subluxation. Intra and inter-rater reliability were positive in a small study of inferior subluxation (Boyd & Torrance, 1992), but, again there is no assessment with other forms of subluxation.

3.3.4 Pain

Methods of measuring pain include numerical rating scales, visual analogue scales, Faces pain scale, therapists' proxy ratings of pain and dichotomous responses (pain was present or absent). All of these measures focus on the quantity of pain rather than frequency or impact. There is little evidence of content or construct validity of these measures.

Visual analogue scales and numerical rating scales

There is evidence that many pwS are not able to accurately complete pain scales including visual analogue scales or numerical rating scales (Gamble et al, 2002; Price, Curlless, & Rodgers, 1999). Although numerical rating scales of pain have been shown to be responsive in published research (Shaw et al, 2010), this particular study excluded people with significant aphasia or cognitive problems.

Faces pain scale

Faces pain scale is a pictographic measure of pain that has been used in stroke (Lord, Langhorne & Quinn, 2010). There have been no studies of inter-rater reliability or responsiveness but test–retest reliability is promising, although people with right hemispheric stroke appear to have difficulty using the scale (Benaim et al, 2007).

Proxy ratings by therapists

In an attempt to address the limitations of self-reporting, Pomeroy et al (2000) investigated the reliability of a system where expert physiotherapists provided pain ratings based on their observations of the person with strokes behaviour. There was no test of validity or responsiveness but results of a review of reliability across three physiotherapists showed a large systematic bias between raters, particularly when the person with stroke experienced pain.

Dichotomous responses

A small number of studies have used a simple yes/ no response to the recording of pain, in order to include more people with aphasia or cognitive deficits (Lord et al, 2010; Paci et al, 2007). To date little work has been conducted to establish the reliability of dichotomous responses to pain, but they are responsive to change within population-based studies (Paci et al, 2007) and have a higher completion rate than numerical scales (Lord et al, 2010).

3.3.5 Body image

There are a number of assessments of body image designed for people with cancer (Holmes et al, 2008), eating disorders (Cash, Fleming, Alindogan, Steadman & Whitehead, 2002) and obesity (Popkess-Vawter & Banks, 1992) but there do not appear to be any developed specifically for pwS. However, there is one measure of health-related quality of life developed for pwS, which includes a reference to self-perceptions of appearance. The Subjective Index of Physical and Social Outcome (Trigg & Wood, 2000) offers five responses to a single question about confidence at being seen in public, but to date no work has been undertaken to consider the validity of this question as a stand alone measure of satisfaction with body image.

3.3.6 Skin integrity

The European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (2009) produced a classification system for use with pressure ulcers, but this system is designed typically for grading skin changes over bony prominences from a combination of pressure and sheer forces. This does not typify the changes with skin maceration that may be seen in the hand after stroke (Pappas, Baldwin & Keenan, 2011). There do not appear to be any classifications of skin condition that any have been developed or evaluated for use in the arm after stroke.

3.4 Measures of activity and participation

Table 3 contains a summary of the outcome measures identified that can be used to assess the degree of disability and health related quality of life with people with profoundly-affected arm after stroke. A review of their psychometric properties follows and is summarised in Table 4.

3.4.1 Passive function

The concept of measuring changes in passive function is relatively recent and specific measures have only developed over the past decade. There are three measures that currently assess passive function of the arm: Disability Assessment Scale (Brashear et al, 2002a), Leeds Arm Spasticity Impact Scale (RCP, 2009), and Arm Activity Measure (RCP, 2009).

Disability Assessment Scale (DAS)

The DAS was developed to assess severity of passive function difficulties in people with arm spasticity (Brashear et al, 2002a). It is a four-point ordinal scale to rate difficulty with hygiene, dressing, limb position and pain, which is completed by a clinician based on interview with the person with spasticity. It is unclear if patients and clinicians were involved in developing the scale and there has been no testing of construct validity. It has been shown to have a good degree of inter-rater and intra-rater reliability in a relatively small study (Brashear et al, 2002a) and has been shown to be sensitive to change (Brashear et al, 2002b) but is not widely used in clinical practice. Its use with people with aphasia and cognitive impairment is not clear.

Table 3: Outcome measures for activity, participation & environmental factors in the profoundly-affected arm

Activity and participation		
<u>Passive function</u> Disability Assessment Scale Leeds Arm Spasticity Impact Scale Arm Activity Measure	<u>Active function</u> ABILHAND Motor Activity Log-14	<u>Health related quality of life</u> Stroke Impact Scale Euro-QoL 5 Short Form 36 Subjective Index of Physical and Social Outcome
Environmental factors		
<u>Support & relationships: Carer burden</u> Self Rated Burden Scale	<u>Services: Health and social care services</u> Client Services Receipt Inventory	<u>Products & technology: Splints</u> No measures identified

Leeds Arm Spasticity Impact Scale (LASIS)

The LASIS (RCP, 2009) was originally published as the Patient disability and carer burden scales (Bhakta, Cozens, Chamberlain & Bamford, 1996). It is an item bank of 12 tasks of caring for the arm including washing the palm, and putting the arm through a sleeve. These tasks were developed from a theoretical review of the impact of spasticity so content validity is positive, but there has been little evaluation of construct validity or reliability (Ashford et al, 2008). It has been shown to be responsive in trials of interventions (Mawson, Datta, Clarke & Harris, 2007), but it has not been tested with people with severe aphasia or cognitive impairment.

Arm Activity Measure (ArMA)

More recently ArMA was developed as a scale of both active and passive function in the arm. There are eight items related to care tasks such as ease of application of splints and positioning the arm, and thirteen items related to active use such as picking up objects. Like the LASIS, it uses a five-point ordinal scale to rate each area. Items in the measure were selected based on a review of goals of treatment so content validity is rated as positive. There has

also been positive evaluation of reliability and responsiveness, but reference to evaluation of construct validity does not name the other measures used to test this (Ashford, Turner-Stokes & Slade, 2010). It has not been used with people with severe cognitive or communication difficulties, and given that more than half the items relate to active function it may be more helpful with people who have some active use of the arm.

3.4.2 Active function

There are multiple measures of active function of the arm. However, many involve scrutiny of a person conducting activities within a clinic setting and do not necessarily reflect real life use of the arm (Ashford et al, 2008). The ABILHAND (Penta, Tesio, Arnould, Zancan & Thonnard, 2001) and Motor Activity Log-14 (Constraint Induced Movement Therapy Research Group, 2004) are both questionnaires where the person affected by stroke reports their use of the arm on a day-to-day basis.

ABILHAND

The ABILHAND is an item bank of 23 activities involving the arm which has been evaluated with stroke (Penta et al, 2001). It includes activities such as peeling vegetables but also fine tasks such as threading a needle. Each area is rated on a three point ordinal scale. The ABILHAND has established content and construct validity and intra and inter-rater reliability (Gustafsson, Sunnerhagen & Dahlin-Ivanoff, 2004), and is sensitive to change (Wang et al, 2011). However, since it focuses on finer control of the hand and arm it is most suitable for use with people with fairly advanced active recovery of the arm, and evaluation to date has excluded people with communication difficulties.

Motor Activity Log (MAL-14)

Motor Activity Logs were developed to assess changes in arm use in response to Constraint Induced Movement Therapy and there have been several iterations of the tool with varying complexity (Constraint Induced Movement Therapy Research Group, 2004). The MAL-14 contains reference to fourteen less complex tasks such as using the arm to steady oneself and picking up a cup, so is suited for use with people with limited recovery. Each item is scored on a six-point ordinal scale that is used to reflect amount and quality of use.

Table 4: Psychometric properties of the outcome measures of activity, participation and environmental factors

		Construct	Who completes	Content validity	Construct validity	Inter-rater reliability	Intra-rater reliability	Responsiveness	Evidence for use with PwS
Passive function	Disability Assessment Scale	2 passive function tasks 1 active or passive function tasks, pain	Clinician	?	?	+	+	+	?
	LASIS	11 passive function tasks 1 active function task	PwS	+	?	?	?	+	?
	ARMA	7 passive function tasks 13 active function tasks	PwS	+	?	+	+	+	?
Active function	ABILHAND	23 active function tasks	pwS	+	+	+	+	+	?
	Motor Activity Log-14	14 active function tasks	pwS	+	+	+	+	+	+
Health related QoL	Stroke Impact Scale	59 questions across eight domains (strength, hand function, ADL, mobility, emotion, memory, communication and social participation) VAS of amount of recovery	pwS	+	+	+	+	?	+/-
	SIPSO	5 questions about physical integration 5 questions about social integration	pwS	+	+	+	+	?	+
	EQ-5D	5 questions (anxiety/depression, mobility, pain, self-care, and usual activities) VAS of wellbeing	pwS	+	+	+	+	?	-
	SF-36	36 questions across eight domains (pain, general health, mental health, physical function, role limitations due to emotional problems, role limitations due to physical problems, social functioning, and vitality)	pwS	+	+	+	+	?	?
Health & social service	Client Services Receipt Inventory	Flexible questionnaire to record number of intensity of services received	pwS	+	?	+/-	+/-	+	?
Carer burden	Self Rated Burden	Visual analogue scale	Carer	+	+	?	?	?	?
Products	No measures identified								

The MAL-14 has demonstrated validity, reliability and sensitivity (Uswatte, Taub, Morris, Vignolo & McCulloch, 2005), and it is widely used. There is no evidence of testing the measure on people with more severe impairments of cognition or communication, but completion by a proxy has been shown to yield similar results to completion by the person with stroke (Uswatte et al, 2005).

3.4.3 Measures of participation and quality of life

There are no measures of quality of life, which have been developed specifically for people with a profoundly-affected arm (Atkinson et al, 2012). However, a number of generic or stroke specific measures of quality of life do include reference to use or care of the arm. These include the Stroke Impact Scale (Duncan et al, 1999), Subjective Index of Physical and Social Outcome (Trigg & Wood, 2000), EuroQoL-5D (EuroQoL Group, 1990) and Short Form 36 (Ware, 1997). Although all these measures have been demonstrated to have some validity and reliability when used after stroke (Patient Reported Health Instruments Group, 2006; Buck, Jacoby, Massey & Ford, 2000), there is no evidence for their use in people with more severe communication or cognitive problems and the two that contain visual analogue scales may be difficult for pwS to complete (Price et al, 1999). It is unclear if any of the measures will be responsive to changes directly related to management of the profoundly-affected arm.

Stroke Impact Scale (SIS)

The SIS contains 59 questions across eight domains regarding quality of life, and a visual analogue scale (VAS) to record the person's perceptions of their recovery. The questions include specific reference to satisfaction with active arm use including gripping and carrying of objects as well as bathing (Duncan et al, 1999). Carer proxy completion is reliable (Duncan et al, 1999).

Subjective Index of Physical and Social Outcome (SIPSO)

The SIPSO contains five items related to physical integration, and five related to social integration (Trigg & Wood, 2000). The physical measures include reference to difficulty with dressing, and the social sub scale includes reference to the persons perceptions of their appearance when out in public, although this is not specifically focused on the arm. Reliable completion by carers has been

established (Trigg & Wood, 2003).

EuroQoL-5D (EQ-5D)

The EQ-5D is a generic quality of life instrument containing five questions and a visual analogue scale to record overall wellbeing (EuroQoL Group, 1990). One of the questions relates to satisfaction with 'self care', which may encompass activities including care of the arm.

Short Form 36 (SF-36)

The SF-36 is also a generic measure involving 36 questions. It refers to satisfaction with dressing among many other aspects of quality of life (Ware, 1997).

3.5 Measures of environmental factors

A summary of the outcome measures identified that can be used to assess use of health and social care services, products and technology, and carer burden is shown in Table 3. The summary of the psychometric properties of these measures is in Table 4.

3.5.1 Services: Health and social care services

Client Services Receipt Inventories (CSRI) have been developed to measure use of health, social care and broader community resources. The CSRI is a self-reported tool, which can be adapted to record inpatient costs, outpatient services, accommodation, medications and local authority services. Different versions have been developed and content validity has been established in the field of mental health (Chisholm et al, 2000). More recently they have been used in research in stroke (Forster, 2007). Studies of the reliability of self reported use of services has shown mixed results (Heinrich et al, 2011), but the CSRI has been shown to be responsive to change (Lam, McCrone, Wright & Kerr, 2005).

3.5.2 Support and relationships: Carer burden

There are numerous measures of burden that have been used with carers of pwS (Visser-Meily, Post, Riphagen & Lindeman, 2004). The majority of these are questionnaires that assess the impact of caring across a range of domains

including physical, emotional, psychological, and social. Studies of reliability, validity and responsiveness have shown that all measures have limitations and none is superior to any other (Visser-Meily et al, 2004). However, Van Exel et al (2004) found that a single question of Self Rated Burden was as valid and sensitive as other, more complicated measures.

3.5.3 Products and technology: Splints and equipment

There does not appear to be any literature concerning methods of recording the use of products and technologies in a systematic way for pwS. In the field of rheumatology questionnaires have been used to explore use of splints (Gunendi, Gogus, Keles & Ture, 2010) but there does not appear to be any evaluation of the reliability of these.

3.6 Relationships between measures across domains of the ICF

To date there have been a few studies that reported relationships between the results of measures across different health domains: Bhakta et al (2000) demonstrated a relationship between measures of spasticity, passive function and carer burden in a study of interventions in the profoundly-affected arm. Doan et al (2012) demonstrated a correlation between measures of passive function and quality of life. These studies would suggest that there may be potential links between aspects of impairment, disability, quality of life and carer burden for people living with profoundly-affected arm, but further work in this area is needed.

3.7 Chapter summary

The review demonstrates that there are a number of measures of spasticity, contracture, and pain for use in the arm after stroke but their psychometric properties are not strong. Measures of subluxation currently only target inferior subluxation and there are no measures of body image or skin condition for use in this group. The small number of measures of disability and health-related quality of life that have been developed with reference to this population have some positive evidence of their validity and reliability. Many have not been tested in people with more significant cognitive or communication disability although proxy responses of carers are reliable for some. Finally there are no universally valid and reliable measures of the environmental factors associated

with the profoundly-affected arm. In the next chapter a systematic review will be presented that was undertaken to identify the natural course of the development of impairment and disability in the profoundly-affected arm, and to identify any potential predictors that can be measured early after stroke to identify those most at risk of developing difficulty caring for the arm.

Chapter 4: Impairment and disability in the profoundly-affected arm: a systematic review

4.1 Chapter overview

The previous two chapters contained definitions of the impairments, disabilities and participation difficulties associated with the profoundly-affected arm, and descriptions of how these can be measured. The evidence for interventions for the profoundly-affected arm are mixed and it has been argued that most existing interventions are designed without considering which people with profoundly-affected arm are most at risk of specific impairment or disability, or what the natural course of these impairments over time would be. This chapter presents a systematic review, which was conducted to examine the current knowledge base in this area. The objective of the review was to identify the incidence and natural course of impairment and disability in the profoundly-affected arm after stroke, and to identify potential predictors which could be used in routine clinical settings in the early stages of care to identify those most at risk of difficulty caring for the arm or related impairments. The chapter contains a description of the methods used, results found, and a discussion of the findings and limitations of the review (Allison, Shenton, Bamforth, Richards & Kilbride, in submission; Allison & Shenton, 2011a,b).

4.2 Method

This review was conducted following the guidance provided by Meta-analysis of Observational Studies in Epidemiology (MOOSE) (Stroup et al, 2000) and reported using PRISMA guidelines (Liberati et al, 2009). The review was conducted by a team involving the researcher (RA) and four collaborators. The systematic review protocol is provided as Appendix 1.

4.2.1 Search strategy

A literature search of the following online databases was undertaken: MEDLINE, EMBASE, CINAHL, AMED, and the Cochrane Library, from the inception date of each database up to May 2012. Relevant papers were also identified by citation tracking, using reference lists from journals. The search terms were a combination of controlled vocabulary (MeSH) and free text terms, and are given in Table 5.

4.2.2 Criteria for inclusion of studies

The review included published research articles that fulfilled the following

PICOS criteria (Liberati et al, 2009):

Participants

The purpose of the review was to identify the knowledge base concerning the incidence and course of impairment and disability in people with profoundly-affected arm after stroke. However there is little research that has been targeted at this specific population and most studies involve populations where people with profoundly-affected arm are included with general populations of people after stroke. Therefore the review included studies where participants were adults aged 18 years and where people with profoundly-affected arm were included as part of a broader population of stroke survivors.

Interventions

The review was not designed to evaluate a specific intervention but did not exclude reports of data from intervention studies that provided data to answer the review questions (for example, if data from control groups identified changes of impairment or disability over time).

Comparators

The studies included did not contain comparators.

Outcomes

The model of impairment, activity and participation factors related to profoundly-affected arm was developed in Chapter 2. This identified six impairments (spasticity, pain, contracture, altered body image, joint subluxation and skin changes) and the impact on disability (passive function). However in Chapter 3 a review of the measures available to monitor these constructs demonstrated that there are currently no clinically based measures that can be used to assess all forms of subluxation, body image or skin changes in the arm after stroke. Therefore for the purposes of this review, studies were included if they examined the impairments where there were established means of assessment: spasticity, pain and contracture. Studies were also included if they considered disability in terms of passive function of the arm.

Table 5: Search terms for systematic review

<p>Stroke related</p> <ol style="list-style-type: none"> 1. stroke 2. hemi* 3. 1 or 2 <p>Predictive</p> <ol style="list-style-type: none"> 4. predict* 5. risk 6. prognos* 7. longitudinal 8. course 9. 4 or 5 or 6 or 7 or 8 <ol style="list-style-type: none"> 23. 3 and 9 and 15 and 22 	<p>Arm-related</p> <ol style="list-style-type: none"> 10. hand 11. arm 12. shoulder 13. wrist 14. upper extremity 15. 10 or 11 or 12 or 13 or 14 or 15 <p>Specific impairments</p> <ol style="list-style-type: none"> 16. passive function 17. spastic* 18. hyperton* 19. contracture 20. range of motion or movement 21. pain <ol style="list-style-type: none"> 22. 16 or 17 or 18 or 19
---	--

Study design

The studies included were of two potential designs: (1) observational studies of the incidence or natural course of events and (2) studies evaluating the ability of identified factors that were assessed within the first eight weeks of stroke to predict impairment and capacity to care for the arm longer term. Studies were excluded if they were not available in English, targeted children, or if laboratory-based tests were used as predictors. Case series and case reports were excluded owing to the high potential for bias in these designs. Studies that considered recovery of active function in the arm only were also omitted as this is not related to the primary outcome of this research.

4.2.3 Study selection

Following completion of the searches, two researchers selected studies independently of each other by first screening titles and then abstracts. RA

assessed all of the studies, and the other collaborators involved divided the studies equally between them. Initially titles were screened, and if both reviewers agreed the study was not relevant it was excluded. If one or both reviewer indicated the study may be relevant the full article was retrieved for review. If both reviewers agreed the study was not relevant after reading the full article it was excluded, and if both rated the study as relevant it was included. If there was disagreement this was resolved through discussion with the wider team.

4.2.4 Data extraction

Two reviewers, working independently undertook the data extraction using a structured format. RA extracted data from all of the studies, and the other collaborators divided the studies equally between them. Key data extraction included the following: general information (title, author, and country of study), study design and characteristics (participant characteristics, potential predictors and outcomes) and findings including length of follow-up. The data extraction form is shown in Appendix 2. Any differences in data extraction were resolved by mutual agreement, and where necessary, referred to a third reviewer.

4.2.5 Assessment of methodological quality

The two reviewers independently rated and recorded the methodological quality of the studies. RA assessed and rated all of the studies, and the collaborators divided the studies equally between them. Methodological quality assessment was appraised using a tool adapted from the Quality Assessment Tool for quantitative studies developed by the Effective Public Health Practice Project at McMaster's University in Canada (EPHPP, 2008). This tool assessed risk of bias in recruitment, blinding of assessors (where predictors and outcomes were evaluated), reliability and validity of data collection methods, recording of withdrawals, integrity, and analysis, and is shown in Appendix 3. In reporting quality, reference was made to individual components of the tool. Agreement between reviewers was calculated using kappa scores, and any differences were resolved through discussion with the wider team.

4.2.6 Summary measures and synthesis of results

The principle summary measures were incidence of each impairment over time,

and risk ratio for predictors of impairment and difficulty with passive function (when this was reported). Data was synthesised via a series of summary tables, which report incidence, change over time and results of any evaluation of predictors.

4.3 Results

4.3.1 Study selection

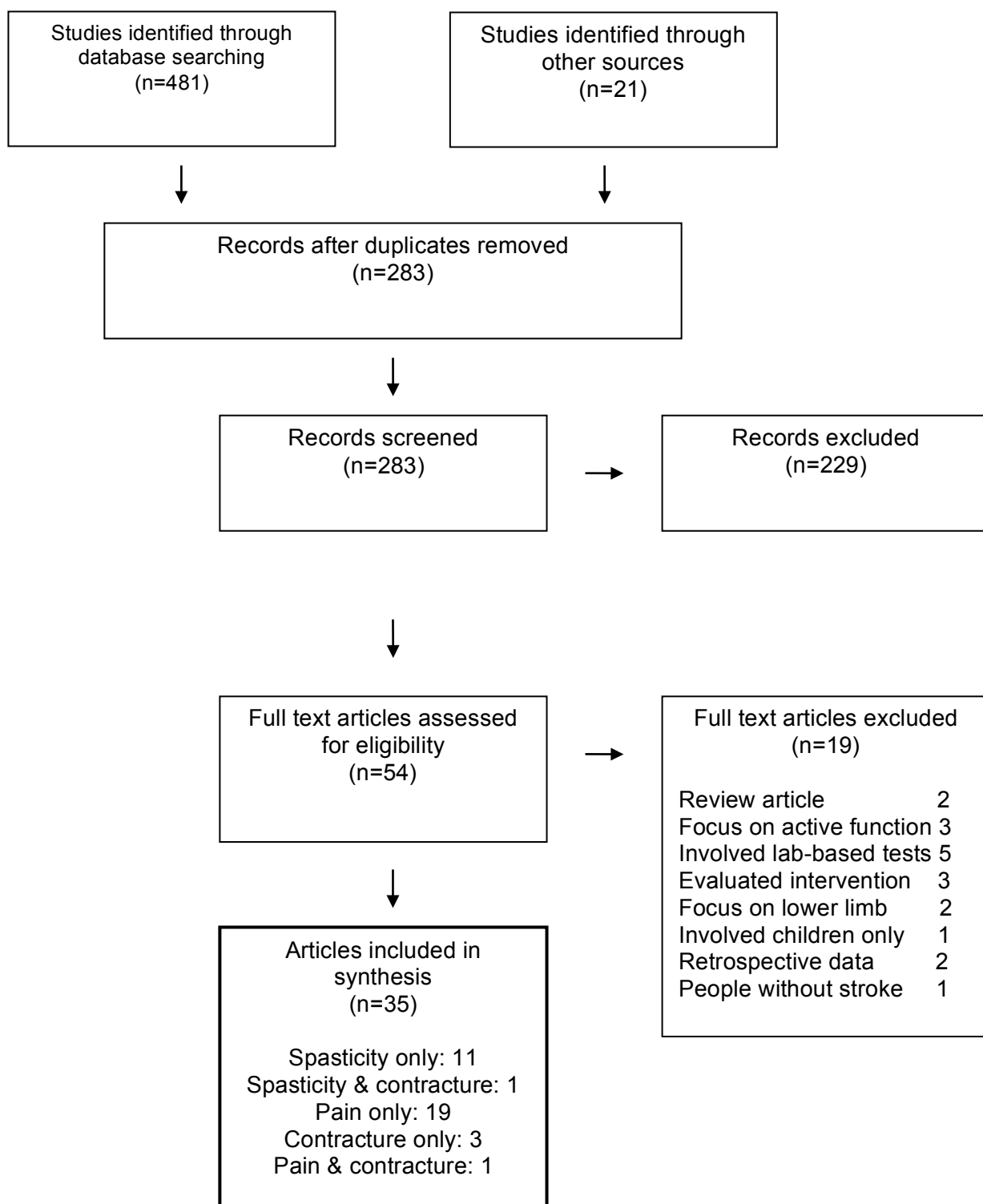
A total of 502 references were initially identified. Figure 2 summarises the search results and reasons for exclusion of studies. There were 219 duplicate references, and a number of other studies focused on predicting recovery of active function in the arm (for example Kwakkel et al, (2003)), which was not within the scope of this review. Fifty-four full articles were retrieved, but a further 19 were excluded because they focused on active function rather than passive, did not include the arm, evaluated laboratory-based tests or included people with arm weakness for other reasons than stroke. In total, 35 publications were suitable for quality assessment. Five pairs of articles (Leathley et al, 2004, and Watkins et al, 2002; Lundstrom, Smits, Terent & Borg, 2010, and Lundstrom et al, 2008; Sommerfeld & Welmer, 2012, and Sommerfeld et al, 2004; Gamble et al, 2002, and Gamble et al, 2000; Lindgren et al, 2012, and Lindgren et al, 2007) presented differing data from the same studies. Therefore to prevent double reporting, this review included thirty-five publications, describing thirty different studies.

4.3.2 Study Characteristics

Participants

The characteristics of study participants are summarised in Table 6. Overall a total of 4474 patients participated in the studies. None of the studies targeted people with a profoundly-affected arm but from the descriptive data available they were included in broader groups. The studies focused on either general populations of people recovering from stroke (including those with a weak arm), or targeted populations such as people with stroke (pwS) and hemiplegia, weakness, or those receiving rehabilitation. One study explicitly included pwS moving to care homes (Sackley et al, 2008). Six studies were from the UK, eleven from Europe, three from North America, and ten from other countries (Table 6).

Figure 2: Results of systematic review search



The average age of study participants was 68.5 years, which is lower than the average age of developing stroke in the UK (75 years) (Rudd, 2009). Participants were recruited at a variety of time points. For two studies the time that recruitment took place was not stated (Kong et al, 2012; Kong et al, 2010), and for one study (Moura et al, 2009) participants were recruited at any point between one and five years post stroke. For the remainder recruitment took place at any point between the onset of stroke and 1 year after.

Interventions and comparators

The search did not specifically target studies that evaluated interventions. However, five articles included data that had been collected as part of larger studies designed to evaluate interventions. This included data from control groups (Pandyan et al, 2003b, and Malhotra et al, 2011), and other supplementary data collected (de Jong et al, 2011, van Kuijk et al, 2007; Wanklyn, Forster & Young, 1996).

Outcomes

Table 7 summarises the outcomes measures and predictor variables used in the studies. Three of the studies briefly referred to passive function of the arm (Kong, Lee & Chua, 2010; Lundstrom et al, 2010; Lundstrom et al, 2008). However none of these studies measured this outcome in a systematic way, although measures of passive function of the arm are available (RCP, 2009). Therefore the included studies all focused on impairment in the arm rather than disability. Twelve of the publications examined spasticity, five considered contracture, and twenty examined pain (Table 7). Spasticity was most frequently measured with the Ashworth Scale, the Modified Ashworth Scale or Tone Assessment Scale. Contracture was measured with a variety of methods. One study used goniometry of the wrist against a standardised force (Pandyan et al, 2003), one study used a standardised force (Malhotra et al, 2011) but did not describe if goniometry was used, and one used a four point scale of restriction (Kwah et al, 2012). Another study measured joint angle from photographs of the arm (Ada et al, 2006), and in the remaining study (Sackley et al, 2008), the method of measurement and joints involved were not described. Of the studies that examined pain, seven used visual analogue or numerical scales (Lindgren et al, 2012 & 2007; Roosink et al, 2011; Lundstrom et al, 2009; Hadianfard et al, 2008; Rajaratnam et al, 2007; Gamble et al 2002; Gamble et al, 2000; Zorowitz et al 1996),

one used a dichotomous variable (Paci et al, 2007), and three developed their own questionnaires or interviews (Sommerfeld et al, 2012; Ratnasabapathy, 2003; Wanklyn et al, 1996). Four studies recorded the presence or absence of pain during clinical examination (Appelros, 2006; Poulin de Courval et al, 1990; Sackley et al 2008; Bohannon, 1988) and three studies did not identify the method by which pain was measured (Suethanapornkul et al, 2008; Aras et al, 2004; Cheng et al, 1995).

Table 6: Characteristics of participants and studies in the systematic review

	Setting	Sample size	Targeted population	Time since stroke at recruitment (days)	Average age (yrs)	Impairment studied	Design	Period of follow-up
Ada et al, 2006	Australia	18	People with stroke & hemiplegia	Fixed: 14	63	Contracture- elbow	Longitudinal	Fixed: 1 year
Appelros, 2006	Sweden	253	People with first stroke	Fixed: 0 (onset)	74	Pain- general	Longitudinal	Fixed: 1 year
Aras et al, 2004	Turkey	85	People with hemiplegia & receiving rehabilitation	Variable: 10-116	60	Pain- shoulder	Cross-sectional	NA
Bohannon, 1988	US	30	People with stroke, hemiplegia & receiving rehabilitation	Variable: 15-45	68	Pain- shoulder	Longitudinal	Variable: at dc (not stated)
Cheng et al, 1995	Taiwan	50	People with stroke & receiving inpatient rehabilitation	Variable: 21-180	62	Pain- shoulder	Cross-sectional	NA
De Jong et al, 2011	Netherlands	50	People with first stroke with arm weakness, receiving TMS	Fixed: onset	70	Spasticity- elbow	Longitudinal	Fixed: 6 months
Gamble et al 2002 Gamble et al, 2000	UK	123	People with stroke	Fixed: 14	71	Pain- shoulder	Longitudinal Cross-sectional	Fixed: 6 months NA
Hadianfard et al, 2008	Iran	152	People with stroke	Variable: 0-60	61	Pain- shoulder	Longitudinal	Fixed: 1 year
Kong et al, 2012	Singapore	148	People with stroke, weakness & receiving rehabilitation	Variable: not reported	63	Spasticity- arm	Longitudinal	Fixed: 1 year
Kong et al, 2010	Singapore	140	People with stroke, weakness & receiving rehabilitation	Variable: not reported	61	Spasticity- arm	Cross-sectional	NA
van Kujik et al, 2007	Holland	40	People with ischaemic stroke & complete arm paralysis	Fixed: Onset	68	Spasticity- arm	Longitudinal	Fixed: 6 months
Kwah et al, 2012	Australia	165	People with stroke	Variable: 0-28	78	Contracture- general	Longitudinal	Fixed: 6 months
Leathley et al, 2004 Watkins et al, 2002	UK	106	People with stroke	Fixed: Onset	70	Spasticity- general	Longitudinal	Fixed: 1 year
Lindgren et al, 2007 Lindgren et al, 2012	Sweden	327 58 (subset)	People with first stroke People with first stroke, motor/sensory deficit & pain	Fixed: Onset	73 71	Pain- shoulder	Longitudinal	Fixed : 16 months
Lundstrom et al, 2010	Sweden	47	People with first stroke and initial weakness	Variable: 2-10	74	Spasticity-arm or leg	Longitudinal	Fixed: 6 months
Lundstrom et al, 2009 Lundstrom et al, 2008	Sweden	140	People with first stroke	Fixed: 12 months	71	Pain- general Spasticity- arm	Cross sectional	NA
Malhotra et al, 2011	UK	30	People with first stroke & no function of arm	Variable: 7-35	70	Contracture- wrist	Longitudinal	Fixed: 9 months
Moura et al 2009	Brazil	146	People with ischaemic stroke	Variable: 1-5 years	64	Spasticity- general	Longitudinal	Not reported
Paci et al, 2007	Italy	107	People with first stroke, hemiplegia & receiving rehabilitation	Variable: 7-27	72	Pain- shoulder	Longitudinal	Variable: not stated
Pandyan et al, 2003	UK	22	People with stroke, & weakness	Variable: 14-28	65	Contracture- wrist Spasticity- wrist	Longitudinal	Fixed: 8 months
Poulin de Courval et al, 1990	Canada	94	People with stroke, hemiplegia & receiving rehabilitation	Variable: 21-35	Not reported	Pain- shoulder	Cross sectional	NA
Rajaratnam et al, 2007	Singapore	135	People with unilateral stroke	Variable: 2-14	64	Pain- shoulder	Cross sectional	NA
Ratnasabapathy, 2003	New Zealand	1201	People with first stroke	Variable: 0-14	Not reported	Pain- shoulder	Longitudinal	Fixed: 6 months

Table 6: Characteristics of participants and studies in the systematic review (continued)

	Setting	Sample size	Targeted population	Time since stroke at recruitment (days)	Average age (yrs)	Impairment studied	Design	Period of follow-up
Roosink et al, 2011	Netherlands	31	People with first stroke, with sensory or motor signs	Fixed: 14	67	Pain- shoulder	Longitudinal	Fixed: 6 months
Sackley et al 2008	UK	73	People with Barthel score of < 10 at 3 months post-stroke	Fixed: 3 months	76	Pain- shoulder Contracture- general	Longitudinal	Fixed: 1 year
Sommerfeld et al, 2004 Sommerfeld et al, 2012	Sweden	95 66 (subset)	People with first stroke	Fixed: Onset	78	Pain- general Spasticity- general	Longitudinal	Fixed: 3 months Fixed: 18 months
Suethanapornkul et al, 2008	Thailand	327	People with stroke who could sit out of bed for 30 minutes	Variable: not reported	62	Pain- shoulder	Longitudinal	Variable: not stated
Urban et al, 2010	Germany	211	People with first stroke & weakness	Variable: 0-5	68	Spasticity- general Spasticity- arm	Longitudinal	Fixed: 6 months
Wanklyn et al, 1996	UK	108	People with stroke & ongoing disability returning home	Variable: not reported	Not reported	Pain- shoulder	Longitudinal	Variable: 6 months post dc
Zorowitz et al 1996	US	20	People with stroke & shoulder subluxation	Variable: 13-40	63	Pain- shoulder	Cross sectional	NA

Table 7: Outcomes and predictor measures used in the studies in the systematic review

	Outcome measures	Predictors of impairment which were assessed			
Studies of spasticity					
De Jong et al, 2011	MAS (elbow flexors)	Motor control (FMMA)			
Kong et al, 2012	AS (shoulder, elbow, wrist, fingers)	Stroke severity (NIHSS)	Global function (mod BI)	Weakness (UEMI)	Sensation (MAND)
Kong et al, 2010	AS (shoulder, elbow, wrist, fingers)	NA			
Leathley et al, 2004 Watkins et al, 2002	Tone assessment scale MAS (wrist, elbow)	Higher cortical dysfunction	Global function (BI) Side of stroke	Weakness (3 pt scale) Gender or Diabetes	Premorbid function (mRS)
Lundstrom et al, 2010	MAS (shoulder, elbow, wrist, fingers)	Stroke severity (NIHSS)	Weakness (ssNIHSS)	Sensation (ssNIHSS)	Global function (mRS)
Lundstrom et al, 2008	MAS (all arm joints)	NA			
Moura et al 2009	MAS (unclear which joint assessed)	Weakness (MST)	Gender or age	Pain (any report)	
Pandyan et al, 2003	MAS (wrist)	Arm function (ARAT)			
Sommerfeld et al, 2004	MAS (all arm joints)	NA			
Urban et al, 2010	MAS (all arm joints)	Sensation (LT-MAND)	Weakness (BMRC)		
Van Kujik et al, 2007	AS (elbow and wrist)	Motor control (FMMA) Apraxia (observation)	Global function (BI)	Sensation (LT & FTT)	Inattention (MAND)
Studies of contracture					
Ada et al 2006	ROM at elbow (measured from photograph- MAND)	NA			
Kwah et al, 2012	Torque-controlled ROM at elbow wrist and ankle; other joints- 4 point scale of restriction	Spasticity (Tardieu) Pain (NRS)	Stroke severity (NIHSS)	Motor control (Mot Ass Scale)	Strength (Manual muscle test)
Malhotra et al, 2011	ROM at wrist with standardised force	Arm function (ARAT)			
Pandyan et al, 2003	ROM wrist (goniometry with standard force)	Weakness (grip dynamometer)			
Sackley et al 2008	30% reduction in ROM (MAND)	NA			

Table 7: Outcomes and predictor measures used in the studies in the systematic review (continued)

Studies of pain					
Appelros, 2006	Pain- reported on examination	Stroke severity (NIHSS)	Sensation (ssNIHSS)	Motor function (ssNIHSS)	
Aras et al, 2004	Pain- MAND	NA			
Bohannon 1988	Pain- reported on examination	NA			
Cheng et al, 1995	Pain- MAND	NA			
Gamble et al 2002 Gamble et al, 2000	Pain- VAS	Mood (HADS) Weakness (ssNIHSS)	Sensation (LT)	Global function (BI)	
Hadianfard et al, 2008	Pain- VAS	Global function (Kenny) Motivation (MAND)	Visual field (MAND) Sensation (NSAS & LT)	Mood (symptom checklist) Aphasia (any problem with speech)	
Lindgren et al, 2012	Pain- VAS	Side of hemiplegia	Stroke severity (NIHSS)		
Lindgren et al, 2007	Pain- VAS	Side of hemiplegia	Stroke severity (NIHSS)		
Lundstrom et al, 2009	Pain- VAS	None			
Paci et al, 2007	Pain- dichotomous response	Motor control (FMMA)	Pain	Shoulder subluxation (palpation)	
Poulin de Courval et al, 1990	Pain- reported on examination	NA			
Rajaratnam et al, 2007	Pain- NRS	NA			
Ratnasabapathy, 2003	Pain- own questionnaire	NA			
Roosink et al, 2011	Pain-NRS	NA			
Sackley et al 2008	Pain- reported on examination	NA			
Sommerfeld et al, 2012	Pain- interview	Sensation light touch (cotton wool)	Motor control (BL) Spasticity (MAS)	Global function (BI)	Proprioception (FTT)
Suethanapornkul et al, 2008	Pain- MAND	Global function (BI) Cognition (Thai mental state exam)	Subluxation (MAND) Proprioception (MAND)	Mood (HADS) Spasticity (MAS)	Motor control (Brunnstrom)
Wanklyn et al, 1996	Pain- own questionnaire	NA			
Zorowitz et al 1996	Pain- VAS	NA			

Abbreviations

ARAT- Action Research Arm Test
AS- Ashworth Scale
BMRC- British Medical Research Council
BI- Barthel Index
BL- Birgitte Lindmark Motor Assessment

FMMA- Fugl-Meyer Motor Assessment
FTT- Find the Thumb
HADS- Hospital Anxiety And Depression Scale
*MAND- method of assessment not described
MAS- Modified Ashworth Scale
Mod BI- Modified Barthel Index

MMSE- Mini Mental State Exam
Mot Ass Scale- Motor assessment scale
mRS- Modified Rankin Score
MST- Muscle Strength Test
NSAS- Nottingham Sensory Assessment Scale

NIHSS- National Institutes for Health Stroke Scale
ROM- range Of Movement
ssNIHSS- sub scale of NIHSS
UEMI- Upper Extremity Motor Index
VAS- Visual Analogue Scale

Predictor measures

The studies examined a wide range of predictor variables related to outcomes in the arm. These included motor and sensory impairment, inattention, cognition, mood, global function, and stroke severity. Some studies used predictor measures, which have well-established validity, and reliability such as the Barthel Index (for example Watkins et al, 2002) while other studies developed their own means of assessing predictors (Urban et al, 2010; Moura et al, 2009; Hadianfard & Hadianfard, 2008), often without reference to psychometric testing.

Study designs

Characteristics of the study designs are summarised in Table 6. Twenty-four of were longitudinal and six were cross-sectional. The longitudinal studies all conducted varying periods of follow up. For some studies this was fixed for all participants, mostly at a time-point between six months and a year post-stroke (Kong et al, 2012; Kwah et al, 2012; Sommerfeld et al, 2012; De Jong et al, 2011; Malhotra et al, 2011; Roosink et al, 2011; Lundstrom et al, 2010; Urban et al, 2010; Hadianfard et al, 2008; Sackley et al 2008; van Kujik et al, 2007; Appelros, 2006; Ada et al, 2006; Leathley et al, 2004; Sommerfeld et al, 2004; Pandyan et al, 2003; Ratnasabapathy, 2003; Gamble et al 2002; Watkins et al, 2002; Gamble et al, 2000). However some studies conducted follow-ups at variable time-points, for example at time of hospital discharge, and one study did not state the follow-up period (Moura et al 2009). All of the studies with the exception of two identified a single primary measure of a specific impairment after stroke and reported its incidence. Pandyan et al (2003) examined both contracture and spasticity; and Sackley et al (2008) examined pain and contracture. Although a number of studies referred to evaluation of *predictors* of impairment, this term was interpreted in two different ways. Some studies followed a process where clinical tests were conducted at an early time point to then look at the accuracy of these early predictors on disability or impairment in the longer-term (for example Leathley et al, 2004 who examined whether Barthel score at 7 days post-stroke predicted longer-term degree of spasticity). The remaining studies looked at the correlation between the selected outcome and related impairment at a single time point (for example whether range of movement at a joint was correlated with pain). As the purpose of this thesis is to

enable the development of targeted interventions after stroke, for this review we included results that related only to early predictors and excluded reference to correlated impairments.

A range of statistical analysis was used in the studies including logistic regression, and dividing participants into groups with specific impairments for comparison. In the synthesis of results, account was taken only of data related to incidence, change over time and evaluation of *early* predictors as these relate to the original research question.

4.3.3 Quality assessment

Inter-rater agreement across reviewers for judging the quality of the studies produced a kappa score of 0.65, indicating good agreement (Altman, 1991). The areas of potential risk of bias identified in each of the studies are presented in Table 8. Methodological details reported in the papers were of variable quality. Most of the studies described selection criteria but many restricted recruitment. The most common shortcomings related to inadequate assessor blinding if comparing outcomes to predictors measures (detection bias), and the use of unreliable or unvalidated data collection tools (performance bias). For example, three of the studies that considered pain did not state a consistent approach to its measurement (Suethanapornkul et al, 2008; Aras et al, 2004; Cheng et al, 1995). Of the studies that did use recognised tools to assess pain, eight used either visual analogue scales or numerical rating scales, which pwS are often unable to accurately complete (Price et al, 1999). Given this, and the lack of formal protocol for assessing pain in the majority of studies, the measurement of this outcome is a potential area of bias in all of the studies, which examined pain. Equally, a significant number of studies assessed predictor variables without the use of validated measurements. For example, sensation was used as a predictor variable in eight of the studies but recognised measures of sensation that could be repeated were used in only two (Hadianfard & Hadianfard, 2008; van Kuijk et al, 2007). The remaining studies either did not fully describe the method of assessment of sensation (Kong et al, 2012; Sommerfeld et al, 2012; Urban et al, 2010; Gamble et al, 2002, or used a sub scale of the NIHSS, which has not been validated for use in this way (Lundstrom et al, 2010; Appelros, 2006).

Table 8: Quality assessment: potential risk of bias in included studies (positive response indicates less risk of bias)

	Is sample representative of target population?	Are assessors blinded?	Are data collection tools reliable and valid?	Are withdrawals reported?	Were participants unlikely to receive an unintended intervention?	Was statistical analysis appropriate?
Appelros, 2006	Yes	No	No	Yes	Yes	Yes
Ada et al, 2006	Yes	No	No	No	Yes	Yes
Aras et al, 2004	No	No	No	Yes	No	Yes
Bohannon 1988	Yes	No	No	Yes	Yes	Yes
Cheng et al, 1995	No	No	No	Yes	Yes	Yes
De Jong et al, 2011	No	No	Yes	Yes	Yes	Yes
Gamble et al 2002	Yes	No	No	Yes	Yes	Yes
Gamble et al, 2000	Yes	No	No	Yes	Yes	Yes
Hadianfard et al, 2008	Yes	No	No	Yes	Yes	No
Kong et al, 2012	No	No	Yes	Yes	No	Yes
Kong et al, 2010	Yes	No	No	Yes	No	Yes
van Kujik et al, 2007	No	No	Yes	Yes	No	Yes
Kwah et al, 2012	Yes	No	Yes	Yes	Yes	Yes
Leathley et al, 2004	Yes	No	Yes	Yes	Yes	Yes
Lindgren et al, 2012	Yes	No	No	Yes	Yes	Yes
Lindgren et al, 2007	Yes	No	No	Yes	Yes	Yes
Lundstrom et al, 2010	Yes	No	Yes	Yes	Yes	Yes
Lundstrom et al, 2009	Yes	No	No	Yes	Yes	Yes
Lundstrom et al, 2008	Yes	No	Yes	Yes	No	Yes
Malhotra et al, 2011	Yes	No	Yes	Yes	Yes	Yes
Moura et al 2009	No	No	No	Yes	No	Yes
Paci et al, 2007	Yes	No	Yes	Yes	No	Yes
Pandyan et al, 2003	No	No	Yes	Yes	Yes	Yes
Poulin de Courval et al, 1990	Yes	Yes	No	Yes	No	Yes
Rajaratnam et al, 2007	No	No	No	Yes	Yes	Yes
Ratnasabapathy, 2003	Yes	No	No	Yes	Yes	Yes
Roosink et al, 2011	Yes	No	No	Yes	Yes	No
Sackley et al 2008	Yes	No	No	No	Yes	Yes
Sommerfeld et al, 2012	Yes	No	Yes	No	Yes	Yes
Sommerfeld et al, 2004	Yes	No	Yes	Yes	No	Yes
Suethanapornkul et al, 2008	Yes	No	No	No	No	Yes
Urban et al, 2010	Yes	No	Yes	Yes	Yes	Yes
Wanklyn et al, 1996	Yes	No	No	Yes	Yes	Yes
Watkins et al, 2002	Yes	No	Yes	Yes	Yes	Yes
Zorowitz et al 1996	No	No	No	Yes	No	Yes

4.3.4 Results of individual studies

Summary results of individual studies are presented in Tables 9, 10, and 11. For ease of interpretation results are presented for distinct impairments, and have been sub-grouped into studies that recruited populations of all pwS, against those who recruited only pwS who also had motor impairment.

4.3.5 Synthesis of results

There were no studies that evaluated the natural course of development or potential predictors of difficulty caring for the arm after stroke in a systematic way. Three studies (Kong et al, 2010; Lundstrom et al, 2010; Lundstrom et al, 2008) made reference to difficulty with passive function but did not measure this so it was not possible to extract this data. Therefore the synthesis only considered studies that had examined the related impairments of pain, spasticity and contracture. Due to the variation in reporting of data (most studies reported p values for predictors in isolation of other statistics), and heterogeneity of the included studies, a decision was made not to attempt meta-analysis of the data. Therefore the synthesis is narrative.

Spasticity

Incidence. In studies that examined general populations of people post-stroke, spasticity in muscles of the arm was present in 18% of participants at three months (Sommerfeld et al, 2004) and 17% at one year (Lundstrom et al, 2008). Populations of people who originally presented with weakness had a higher incidence of spasticity with rates between 63% (van Kuijk et al, 2007) and 78% (Kong et al, 2010).

Time course. Spasticity was evident in some participants as early as 48 hours post-stroke (de Jong et al, 2011). Although the course of spasticity was fairly dynamic, for the majority of cases it was evident in most participants who would experience it by three months (van Kuijk et al, 2007) and appeared to stabilise by 32 weeks (Pandyan et al, 2003). There were some cases where early spasticity resolved.

Risk factors. The most frequent predictors of risk of spasticity were weakness (Lundstrom et al, 2010; Moura et al, 2009; Urban et al, 2006;

Leathley et al, 2004), and reduced motor control (Kong et al, 2012; de Jong et al, 2011; Pandyan et al, 2003). Stroke severity (Kong et al, 2012; Lundstrom et al, 2010) and reduced global function (Kong et al, 2012; Leathley et al, 2004) were also positive predictors of risk in at least 2 studies, and Moura et al (2009) identified early pain as a predictor of risk. The impact of sensory loss on spasticity risk is not clear with one study identifying a positive relationship (Urban et al, 2006) and three discounting this (Kong et al, 2012; Lundstrom et al, 2010; van Kuijk et al, 2007). Higher cerebral dysfunction including apraxia and inattention does not appear to increase risk (van Kuijk et al, 2007; Leathley et al, 2004).

Pain.

Incidence. Pain in any part of the body was reported by 11% (Appelros, 2006) to 21% of participants (Sommerfeld & Welmer, 2012) from a general population of people post-stroke. Incidence of shoulder pain occurred in 19% (Suethanapornkul et al, 2008) to 40% (Gamble et al, 2002) of general populations and up to 90% of people with weakness (Bohannon, 1988).

Time course. Pain was reported as early as 1-week post-stroke (Ratnasabapathy et al, 2003) with new cases of pain still being reported at up to 16 months post-stroke (Lindgren et al, 2007). The highest incidence appeared to be within the first six months post-stroke (Hadianfard & Hadianfard, 2008; Wanklyn et al, 1996). The course of pain was fairly dynamic with some participants reporting resolution of pain at all time points (Lindgren et al, 2007; Wanklyn et al, 1996). However one study found that 72% of people who experience shoulder pain at 4 months still had pain at 16 months (Lindgren et al, 2012).

Risk factors. The most common predictor of increased risk of pain was reduced sensation (Sommerfeld et al, 2012; Hadianfard & Hadianfard, 2008; Gamble et al, 2000; Appelros, 2006). Shoulder subluxation (Suethanapornkul et al, 2008; Paci et al, 2007), weakness (Appelros, 2006; Gamble et al, 2000) and stroke severity (Lindgren et al, 2007; Appelros, 2006) were also identified as consistent risk factors. The significance of depression was not clear with one study identifying a positive link (Hadianfard & Hadianfard, 2008) and one

discounting this (Gamble et al, 2002). Equally, reduced global function was a predictor of pain in one study (Hadianfard & Hadianfard, 2008), but not in two others (Sommerfeld et al, 2012, Gamble et al, 2002). Aphasia and reduced motivation (Hadianfard & Hadianfard, 2008), and reduced mobility (Sommerfeld et al, 2012) had some predictive value in one study each. However, reduced motor control (Sommerfeld et al, 2012; Suethanapornkul et al, 2008), spasticity, proprioception and cognition (Suethanapornkul et al, 2008), and visual field loss (Hadianfard & Hadianfard, 2008) were not associated with increased risk of pain. The role of perception was not assessed.

Contracture.

Incidence. In a single study of a general population of stroke survivors, the incidence of contracture was 52% (Kwah et al, 2012). In those with hemiplegia or severe stroke, reported incidence varied from 43% (Sackley et al, 2008) to 100% (Malhotra et al, 2011).

Time course. Contracture started within 2 weeks of stroke (Ada et al, 2006), and appeared to largely stabilise by 32 weeks (Pandyan et al, 2003).

Risk factors. Contracture was most frequently predicted by weakness (Kwah et al, 2012; Pandyan et al, 2003) and reduced motor function (Kwah et al, 2012; Malhotra et al, 2011), and was linked with increased stroke severity (Kwah et al, 2012). It was not predicted by degree of spasticity or pain (Kwah et al, 2012).

Table 9: Studies of spasticity: Individual results

Study	Incidence of impairment	Reporting of change over time	Value of predictors
Studies which recruited a general population of people post-stroke			
Leathley et al, 2004 Watkins et al, 2002	36 % at 12 months Severe spasticity in 20% at 12 months	Not examined	1. Any degree of spasticity predicted by: ↓ global function (p<0.001) weakness (p<0.001) 2. Severe spasticity predicted by: ↓ global function (p<0.001) Right sided stroke (p<0.02) 3. No relationship with higher cortical dysfunction, gender, diabetes, pre morbid function
Lundstrom et al, 2010	4% at up to 10 days, 27% at 1 month; 23% at 6 months	Not examined	1. Spasticity predicted by: weakness (OR=10: 95% CI: 2.1-48.4) stroke severity (p= 0.002) 2. No relationship with sensation or global disability
Lundstrom et al, 2008	17% at 1 year 6% had 'disabling' spasticity in the arm	Not examined	Not examined
Moura et al, 2009	26% at final timepoint	Not examined	1. Spasticity predicted by: pain (p<0.0001; OR=107.0; 95% CI: 13.5-847.3), weakness (p<0.0001; OR=91.9; 95% CI: 12.0-699.4) 2. No relationship with gender or age
Sommerfeld et al, 2004	20% at 1 week, 18% at 3 months	Prevalence decreased over time	Not examined
Studies which recruited a population of people post-stroke with hemiplegia or weakness			
De Jong et al, 2011	10% at 48 hours, 20% at 10 days, 42% at 3 months & 42% at 6 months	Some cases resolved at each time point with 1 new case at 6 months	Spasticity predicted by: ↓ motor control (p<0.001)
Kong et al, 2012	33% at 3 months, 43% at 6 months and 47% at 1 year Severe spasticity in 17%	Some cases resolved at 12 months with some new cases at 6 and 12 months	1. Moderate to severe spasticity predicted by: ↓ global function (p<0.001) ↓ motor control (p<0.001) stroke severity (p<0.001) 2. No relationship with sensation
Kong et al, 2010	78%, severe in 38%	Not examined	Not examined
van Kujik et al, 2007	63% at any time point 55% at 26 weeks	Spasticity evident in 1 week, some cases resolved over all timepoints, few new cases at 26 weeks	No relationship between spasticity & arm control, global function, sensation, apraxia or Inattention
Pandyan et al, 2003	Not reported	Spasticity evident in 1 week, and plateaued by 20 weeks	Spasticity predicted by: ↓ arm function (p<0.01)
Urban et al, 2010	43% 16% had severe spasticity	Not examined	Spasticity predicted by: weakness (p<0.001) ↓ sensation (p<0.001)

Table 10: Studies of pain: Individual results

Study	Incidence of impairment	Reporting of change over time	Value of predictors
Studies which recruited a general population of people post-stroke			
Appelros, 2006	11% reported any pain at 1 year	Not examined	Pain predicted by: stroke severity (OR=1.24 95% CI: 1.11-1.39) weakness (OR 1.8 95% CI: 1.3-2.7) ↓ sensation (OR 3.2 (95% CI: 1.5-6.5))
Gamble et al 2002 Gamble et al, 2000	25% developed shoulder pain at 2 weeks; 40% developed shoulder pain within 6 months	80% of cases had resolved at 6 months	Shoulder pain predicted by: ↓ sensation (p<0.001) weakness (p<0.001) No relationship with depression or global function
Hadianfard et al, 2008	32% reported shoulder pain within first year	6% reported shoulder pain in first 2 months, 12% within 4 months and 11% within 6 months Occasional case reported after 6 months	Shoulder pain predicted by: ↓ sensation (p<0.0001) aphasia (p<0.0001) ↓ global function (p<0.0001) depression (p<0.001) ↓ motivation (p<0.0001) No relationship with visual field deficit
Lindgren et al, 2012 Lindgren et al, 2007	22% reported shoulder pain within 4 months; 72% of these still had pain at 16 months	Few new cases at 16 months but resolved cases at all timepoints	Shoulder pain predicted by: stroke severity (P=0.008) left hemiplegia (p=0.01)
Lundstrom et al, 2009	21% report stroke pain at 1 year	Not examined	Not examined
Rajaratnam et al, 2007	22% reported shoulder pain within 1 week	Not examined	Not examined
Ratnasabapathy, 2003	17% at 1 week, 20% at one month , 23% reported shoulder pain at 6 months	Pain presented within 1 week, 72% of cases had resolved at 6 months	Not examined
Sommerfeld et al, 2012	17% initially, 21% at 3 months, 17% at 18 months		Pain predicted by: ↓ sensation (p<0.05) ↓ mobility (p<0.05) No relationship with spasticity, motor control or global function
Suethanapornkul et al, 2008	19% developed shoulder pain	Pain resolved in 77% of cases	Pain predicted by: Shoulder subluxation (OR 2.06 95%CI: 1.08-3.95) No relationship with motor control, spasticity, proprioception, cognition, global function or mood

Table 10: Studies of pain: Individual results (continued)

Study	Incidence of impairment	Reporting change over time	Value of predictors
Studies which recruited a population of people post-stroke with hemiplegia or weakness			
Aras et al, 2004	63% reported shoulder pain	Not examined	Not examined
Bohannon, 1988	80% reported shoulder pain at first assessment (approx 30 days) and 90% at discharge from rehab	Not examined	Not examined
Cheng et al, 1995	64% reported shoulder pain at 3-6 months	Not examined	Not examined
Paci et al, 2007	54% report shoulder pain at 1 month post hospital discharge	Not examined	Pain predicted by: shoulder subluxation (p<0.001) early pain (p<0.001) No relationship with motor control
Poulin de Courval et al, 1990	48% reported shoulder pain within 1 month	Not examined	Not examined
Roosink et al, 2011	22% reported shoulder pain at 2 weeks, 32% at 3 months, 26% at 6 months	Not examined	Not examined
Sackley et al, 2008	36% reported shoulder pain at 3 months, 42% at 6 months, 47% at 12 months	Not examined	Not examined
Wanklyn et al, 1996	36% reported shoulder pain at hospital discharge, 50% 2 months later, 33% 8 months later	26% of cases had resolved at 6 months. Less than 5% of new cases at 6 months	Not examined
Zorowitz et al, 1996	45% reported shoulder pain within 6 weeks	Not examined	Not examined

Table 11: Studies of contracture: Individual results

Study	Incidence of impairment	Reporting change over time	Value of predictors
Studies which recruited a population of people post-stroke with hemiplegia or severe stroke			
Ada et al, 2006	51% of those with hemiplegia developed contracture	Contracture evident by 2 weeks and plateaued by 9 weeks	Not examined
Kwah et al, 2012	52% develop contracture	Not examined	Contracture predicted by stroke severity (p<0.01) weakness (p<0.01) ↓ motor function (p<0.01) No relationship with pain or spasticity
Malhotra et al, 2011	100% of those without function develop contracture	Contracture evident by 6 weeks and plateaued by 24 weeks	Contracture predicted by: ↓ function (p<0.01)
Pandyan et al, 2003	Not reported	Contracture evident by 6-8 weeks and plateaued by 32 weeks	Contracture predicted by: Weakness (p<0.01)
Sackley et al, 2008	43% had contracture at 3 months, 56% at 6 months, 67% at 12 months	Not examined	Not examined

4.4 Discussion

This review has highlighted that to date there appear to be no studies that examine the construct of difficulty caring for arm after stroke, and no studies that specifically target people with profoundly-affected arm. Although three of the studies identified did refer to passive function of the arm (Kong et al, 2010; Lundstrom et al, 2010; Lundstrom et al, 2008) none used formal measures of this. Therefore all of the studies included in this review focused on the impairments of spasticity, pain and contracture. There were higher incidences of these impairments in people who originally presented with hemiplegia when compared to general populations of people recovering from stroke. In the former the incidence of arm spasticity ranged from 36% to 78%, shoulder pain affected 22% to 90%, and contracture was present in 43% to 100%. Spasticity and pain were detected from as early as one week after stroke, with contracture apparent by 2 weeks. Although some cases were dynamic in presentation, spasticity and contracture appeared to largely plateau over the first 32 weeks and the majority of new cases of pain were identified within the first six months after stroke.

The most consistent risk factor for developing spasticity and contracture were weakness and reduced motor control, with reduced global function, stroke severity and pain also associated with spasticity. Risk of pain is predicted by reduced sensation, shoulder subluxation, weakness and stroke severity. It is less clear if there is a link between these impairments and each other, and the relationship with higher cerebral functions and depression. In those studies that have been included there are large variations within the populations of pwS studied, making synthesis of the results limited. Many of the studies themselves used data collection tools that may either not have been subjected to psychometric testing, or, if they had, may still not be reliable in pwS with particular difficulties such as aphasia or inattention, adding further potential bias.

4.4.1 Limitations of the review

A comprehensive literature search was undertaken as part of this review but may be subject to retrieval bias. Notable omissions include the grey literature, and articles not published in English.

4.4.2 Implications for research and practice

There is not sufficient evidence for clinicians to develop targeted interventions at this stage. However the research available suggests that with respect to impairments, clinicians may need to intervene early post-stroke but also be prepared to act over a longer time period. Further research is required to establish the relationship between impairments and difficulty caring for the arm, and to investigate if predictors of impairment can be used to identify those at risk of developing difficulty caring for the arm or if other mediators of the relationship are involved.

4.5 Chapter summary

A systematic review of literature concerning impairment and disability in the arm after stroke was conducted. There is currently no evidence to predict the risk of developing difficulty caring for the profoundly-affected arm. However related impairments such as spasticity, pain and contracture are prevalent and may be predicted by stroke severity, weakness/ decreased motor control; with reduced sensation and subluxation predictors of pain and pain a predictor of spasticity in general populations of stroke survivors. Further work is needed to establish if these predictors can be used in a targeted population of people with profoundly-affected arm. These findings will now be used to design a longitudinal study to develop a profile of impairment and disability and test the most promising predictors of difficulty caring for the arm.

Chapter 5: Methods

5.1 Chapter overview

A systematic review has demonstrated there is currently no evidence to inform the profile of impairment or risk of difficulty caring for the arm in people with profoundly-affected arm (Allison et al, in submission; Allison & Shenton, 2011a,b). Further work is needed to examine this group as a targeted population. This feasibility study was developed to test the use of an observational research design to achieve this. This chapter reports the methods used including process of recruitment, selecting the variables and qualitative data, collecting and analyzing the data.

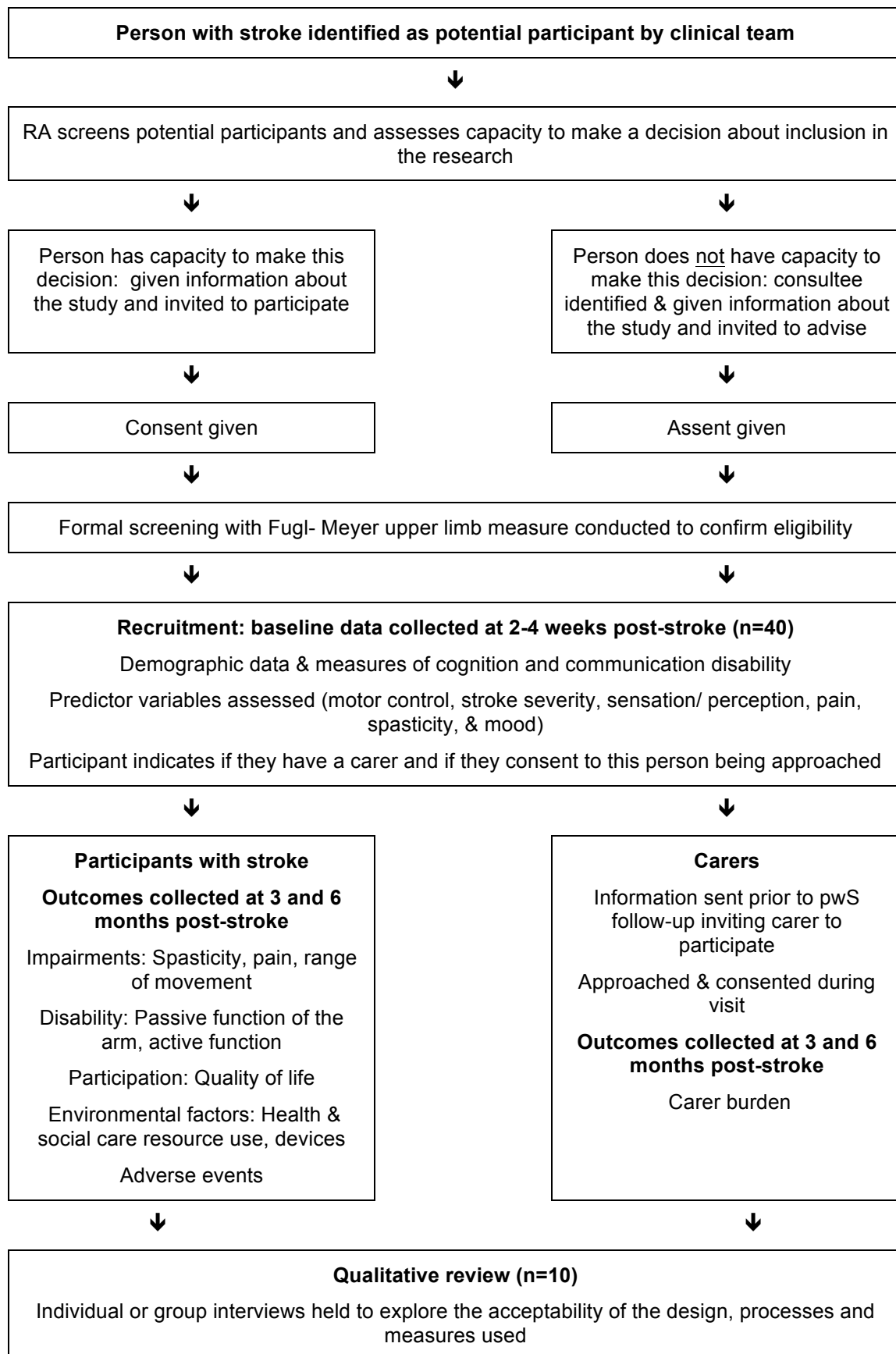
5.2 Aims, research questions and objectives

The aim of this study is to test the feasibility of using a proposed study design to conduct a definitive study to (i) develop a longitudinal profile of impairment and disability in the profoundly-affected arm and (ii) test a number of potential predictors of difficulty caring for the arm. The MRC recommends that prior to conducting larger investigations the feasibility of projects is demonstrated (Craig et al, 2008). The NIHR defines feasibility studies as ‘pieces of research done before a main study in order to answer the question “Can this study be done?”’ (NIHR, 2012, Para 4). Their purpose is to test procedures, estimate recruitment and retention, and consider the characteristics and responsiveness of outcome measures. Therefore the research question that this feasibility study was designed to answer is: ‘is an observational research design a feasible and acceptable way of developing a longitudinal profile of the profoundly-affected arm and testing predictors of difficulty caring for the arm’. There were three objectives:

- (i) to assess recruitment and follow-up processes with particular attention to the ability to involve people with cognitive impairment and communication disability
- (ii) to review the characteristics of the sample to establish if this was likely to be representative of the target population
- (iii) to establish the acceptability and responsiveness of the outcome measures.

An overview of the study design is shown in Figure 3.

Figure 3: Overview of feasibility study



5.3 Recruitment

5.3.1 Sample and participants

A key tenet of this research was to be maximally inclusive of all people with stroke (pwS). Therefore inclusion criteria were based purely on the predicted use of the arm using Fugl-Meyer upper limb assessment scores in the first month post-stroke (Kwakkel et al, 2003). There were no exclusions on the grounds of communication or cognitive ability.

Inclusion criteria

1. Diagnosis of stroke within the past 2-4 weeks.
2. Fugl-Meyer upper extremity score of equal to or less than 11 points at 2 weeks, 15 points at 3 weeks or 19 points at 4 weeks post-stroke (these scores are associated with a high chance of not regaining use of the arm (Kwakkel et al, 2003)).
3. Age over 18.

Exclusion criteria

1. Person was unable to use the affected arm at all before the stroke.
2. Person lives outside of the area where follow-up is provided.

For the purposes of testing feasibility, the aim was to recruit a sample of 40 pwS. This sample size was selected on the basis of a previous audit of numbers of people within the service who were unable to use their arm and was expected to be achievable over the study period.

5.3.2 Screening and consent

Participants were recruited from the Stroke Services in South Devon, between September 2011 and April 2012. In this geographical area there is an acute stroke unit at Torbay Hospital and a stroke rehabilitation unit at Newton Abbot Hospital. Members of the clinical team identified if inpatients on either of these units potentially met the eligibility criteria, and RA then screened them and assessed whether the individual had mental capacity to make a decision about engagement in the research (DH, 2005). For each pwS referred to RA an anonymised record was made of whether they were eligible for the study, and if not what the reasons for this were.

If the potential participant was assessed as having capacity, the study was explained to them and they were provided with a written information leaflet (Appendix 4). Following a period of at least 24 hours the researcher returned to the potential participant and, if they indicated a wish to participate in the study, the researcher obtained either written consent or verbal consent with an independent witness countersignature (Appendix 5). If a person with stroke agreed to participate in the study they were asked to identify if they had a carer or spouse, and if they would consent to the researcher approaching this person. If so, the carer was subsequently approached at the time of the first follow-up visit (at three months post-stroke) and asked if they would like to participate in the recording of the carer-related outcomes. There was a separate information leaflet and consent form for friends and family for this purpose (Appendices 6 and 7). Consent from a carer was not required for the person with stroke's continued inclusion in the study.

As a specific aim was to include as many pwS as possible special consideration was given as to how people with cognitive impairment and communication disability could be supported through the process of consent. Dunn et al (2001) and Wirshing et al (1998) demonstrated that repeated provision of information and use of alternative formats including computerised presentations and bullet points enabled a larger number of people with mental health illness to understand and retain information about research trials and thus develop informed consent. Pringle, Hendry, McLafferty & Drummond (2010) developed guidance for enabling people with aphasia to participate in research. These include provision of information in differing formats including pictographic, the importance of approaching people in quiet environments and being prepared to return on more than one occasion if the person becomes fatigued. For this feasibility study RA attended a workshop on engaging with people with aphasia in research run by CONNECT (the communication disability charity), in addition to attending Good Clinical Practice and Mental Capacity Act training. There was access to speech and language therapy, and to a range of pictographic resources (for example Appendix 8) to assist potential participants.

If the person with stroke was assessed as not having capacity to make a decision about involvement in the study, the views of a consultee were sought

on their behalf. The Department of Health (2008) states that in the first instance researchers should take reasonable steps to identify a person who 'who knows the person who lacks capacity well but is not acting in a professional or paid capacity' (Department of Health, 2008, p.4). This person is termed a 'personal consultee'. If there is no-one available it is possible to use a 'nominated consultee' who is an independent advocate or professional who is not associated with the research. For this feasibility study personal consultees were approached and utilised but a system for nominated consultees was not arranged. The personal consultee was asked to consider the person's beliefs and interests and any advance decisions. A separate information sheet and consultee declaration form was used for this purpose (Appendices 9 and 10). If a participant with a consultee assent regained capacity during the course of the study, they were asked for their consent at that point. Again there was a specific information leaflet and consent form for this purpose (Appendices 11 and 12). All participants were asked for their consent for their GP to be informed of their inclusion in the study, and a standard letter was developed (Appendix 13).

5.4 Selecting and collecting the required data

5.4.1 Demographic data

Demographic data included age, sex, time post-stroke at recruitment, co-morbidities that affected the arm prior to stroke, and the side of hemiplegia. Length of stay (Andrews & Bohannon, 2001) and discharge destination (Sapkota, Chaudhry, Rodriguez, Suri & Qureshi, 2012) were also collected as proxies of level of disability.

5.4.2 Outcome measures

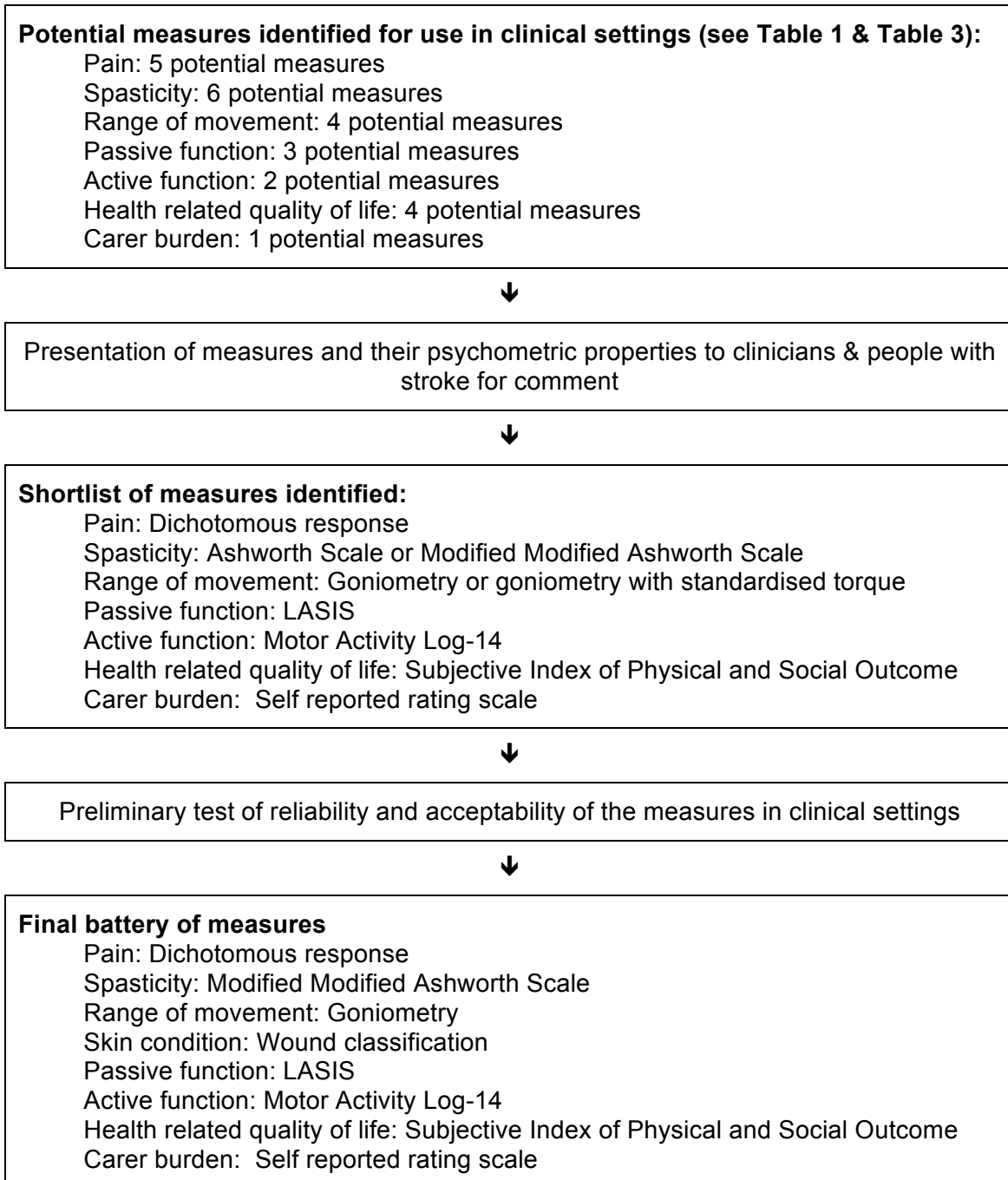
Six impairments, three aspects of activity and participation, and three factors related to the environment were identified when the ICF model was applied to the profoundly-affected arm (Chapter 2). These are summarised in Figure 1. A review of the measures used to record these aspects was presented in Chapter 3. As part of the preliminary work for this feasibility study, two engagement events were conducted within the local health community to seek consensus on how the outcomes for the study were measured. These events involved the presentation of the findings of the review of the measures of impairment, disability and participation (Chapter 3) to a group of clinicians and pwS who

then developed a shortlist of which measures appeared the most promising. The potential measures were entered into a draft battery and were tested in assessments conducted by ten staff (six physiotherapists and four occupational therapists) and ten pwS. Therapists worked in pairs where the first therapist independently applied the relevant aspects of the outcome battery to a person with stroke and the second therapist repeated the measures within an hour. The pwS all presented with profoundly-affected arm, and agreed to be involved as part of their contribution to Patient and Public Involvement. Staff and pwS tested the impairments that they felt were most relevant to them. Quantitative data from the assessments were captured to provide a preliminary indication of inter-rater reliability and qualitative data were collected as the staff and pwS commented on the acceptability of the measures and made any further suggestions for changes or additions to the battery of measures (Allison et al, in submission; Allison et al, 2012). A summary of the process is shown in Figure 4.

Pain

From the review of measures in Chapter 3, many pwS are unable to accurately complete visual or numerical scales (Price et al, 1999) and proxy measures of pain completed by staff are not accurate (Pomeroy et al, 2000). Clinicians and pwS who were consulted about the measures voted unanimously that presence of pain should be measured with a simple yes/ no response during a physical examination supported with pictographic resources for those with aphasia (see Appendix 14 for an example). Each participant was asked to indicate if they had any pain in the arm prior to physical movement at the start of the assessment, and if they had experienced any pain during the examination. As a measure there were four nominal classifications of pain: whether the participant was pain free at all times, if they experienced pain only at rest, if they experienced pain only on movement, or if they experienced pain on movement and at rest.

Figure 4: Process of the development of the battery of outcome measures



Pain was assessed as part of the consultation in six of the pwS (two of whom had aphasia and one of whom had a level of inattention) as the other four did not feel its measurement was relevant to them. All of the pwS asked were able to indicate a response. Using this method there was perfect agreement between assessors for recording the presence or absence of pain expressed by the person with stroke both at rest, and on movement. All staff and pwS involved agreed that this was an acceptable method of recording although they recognised that the amount of pain being experienced would not be recorded:

“People’s pain levels are different. I am lucky my pain levels are very good.”

Person with stroke involved in the consultation

Spasticity

Six measures of spasticity were reviewed in Chapter 3. When these were presented to clinicians and pwS the original Ashworth Scale (Ashworth, 1964) and the Modified Modified Ashworth Scale (Ansari et al, 2006) were shortlisted for testing. This decision was primarily based on reviews of the reliability of the measures, and perceived ease of their use. Urban et al (2010) identified the arm muscles most commonly affected by spasticity. These were shoulder adductors and internal rotators, elbow flexors, wrist flexors and finger flexors. Written guidance on using the measures in these groups was produced, including always measuring with the participant seated and standardising the number of repeated movements prior to the measure being conducted (Johnson & Pandyan, 2008).

Independent reviewers rated spasticity at a total of 14 muscles groups in six pwS using the original Ashworth Scale; and 29 muscle groups across seven different pwS using the Modified Modified Ashworth Scale. Results are shown in Table 12 and Table 13. Percentage agreement using the original Ashworth Scale was 50%, with Kappa scores of 0.33, indicating only fair agreement (Altman, 1991). Using the Modified Modified Ashworth Scale percentage agreement was much improved at 86%. Kappa scores of 0.82 indicated very good agreement, although the numbers assessed were still small.

Table 12: Preliminary testing of the reliability of the original Ashworth Scale

		Reviewer 2				
		0	1	2	3	4
Reviewer 1	0					
	1		2			
	2		1	2	1	
	3			3	2	2
	4					1

Table 13: Preliminary testing of the reliability of the Modified Modified Ashworth Scale

		Reviewer 2				
		0	1	2	3	4
Reviewer 1	0	6				
	1	0	4	1		
	2		1	3	1	
	3				9	1
	4					3

The majority of staff indicated that they felt the revised wording of the Modified Modified Ashworth Scale assisted them:

“I found the extra words useful as it showed a clear classification.”

Physiotherapist involved in the consultation

Following the preliminary testing it was agreed that the Modified Modified Ashworth Scale should be adopted as the measure of spasticity for the feasibility study.

Range of movement (contracture).

Four methods of measuring range of movement were identified in Chapter 3. When the results of the review of the properties of the measures were presented to clinicians and pwS they indicated that they favoured measurement of range of movement with goniometry, in either the presence or absence of a standardised torque. Clinicians identified which joints and movements they felt

were most at risk of developing contracture. These were shoulder flexion, abduction and external rotation; elbow flexion and extension; wrist extension, first & fourth finger extension at each finger joint (metacarpo-phalangeal, and each inter-phalangeal); and thumb extension at each joint (metacarpo-phalangeal and inter-phalangeal). As part of the preliminary work for this study, a Standard Operating Procedure for measuring range of movement throughout the arm including a pictographic guide was developed.

Turton & Britton (2005) developed a technique for the measurement of shoulder external rotation and wrist extension using a standardised torque applied via a spring balance. These authors kindly agreed to loan their equipment to the principle researcher for the preliminary testing. Although a protocol was developed for the use of a spring balance to standardise the torque applied, this proved problematic during testing. Both staff and pwS reported that it was difficult to standardise the exact direction of pull, leading to variability in the torque applied; and that they found the appearance of the apparatus quite threatening. Staff and pwS indicated that they did not find the procedure acceptable in a clinical setting and virtually no data using the spring balance was collected.

“I did not like (the) spring balance- there was a lot of margin for error.”

Physiotherapist involved in the consultation

“I can not go up to someone with this-it looks like an instrument of torture.”

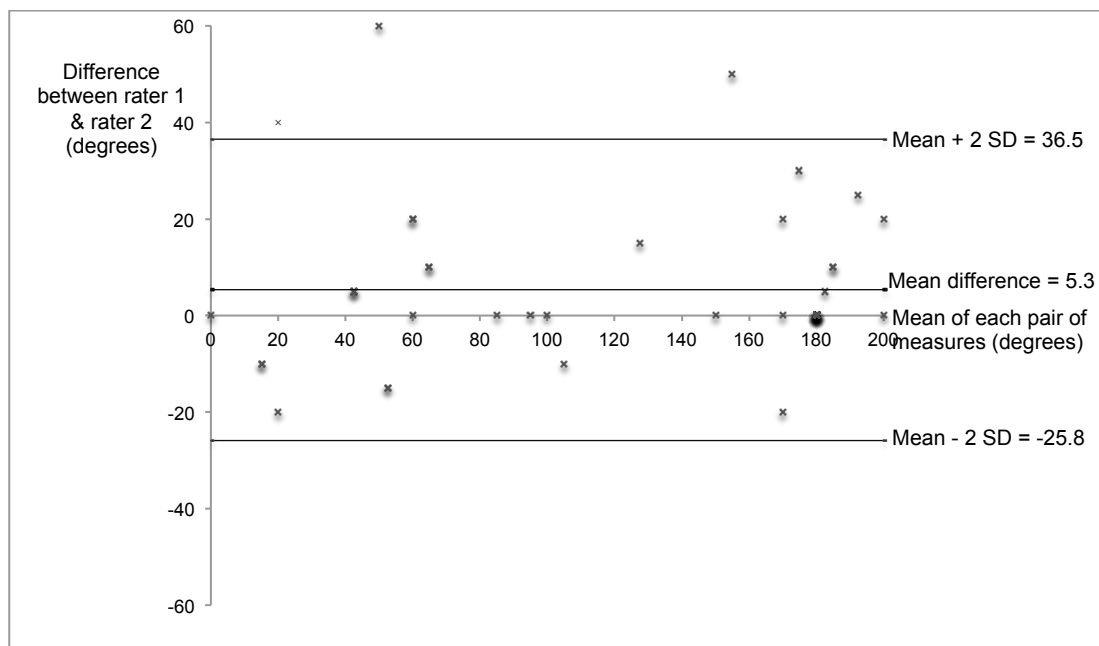
Occupational therapist involved in the consultation

Therefore the majority of data collected during preliminary testing related to recording range of movement using a standardised protocol without a standardised torque. Results are shown in Figure 5. The plot contains data referring to all joints that were measured (shoulder, elbow, wrist and fingers). As a rule there was a high degree of agreement with an intraclass correlation coefficient of 0.96. However on examination of the data, there were particular outliers. The greatest agreement appears to have occurred on particular joints. For example there is a cluster of measures where there was a high degree of

agreement around the 180 degrees measurement mark. This refers to measuring extension of the finger joints where there was little disagreement. Measures resulting in outliers where there was a greater degree of disagreement noted referred more frequently to measurement of shoulder external rotation and wrist extension or those taken when the person being measured experienced pain.

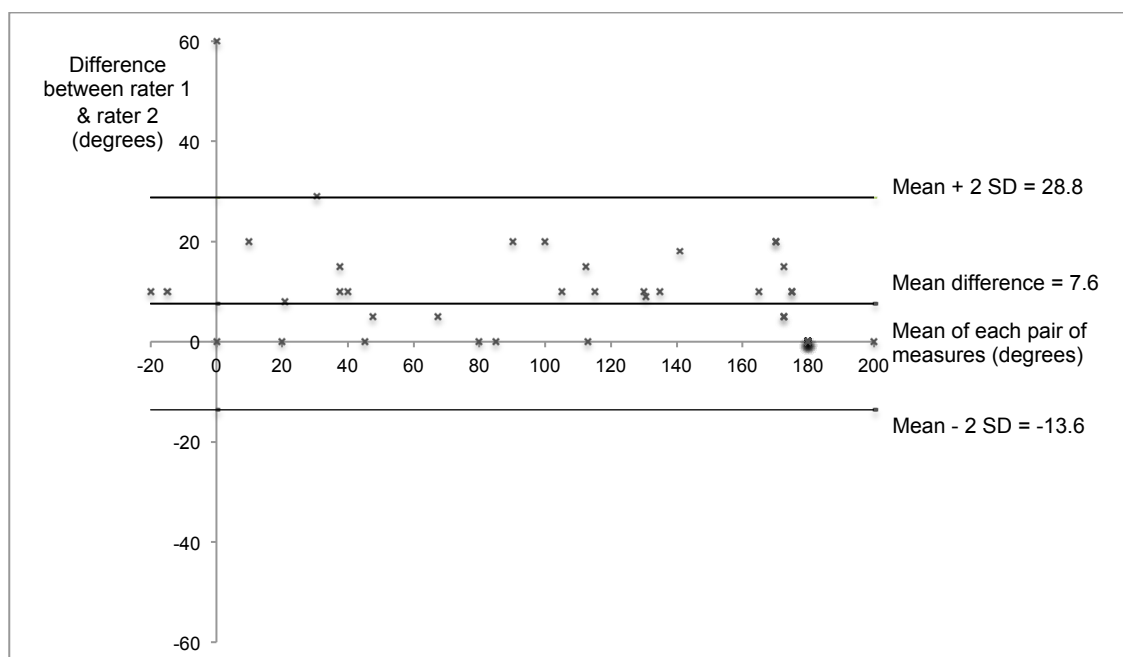
The standardised protocol was amended to make it clear that wrist extension should be measured while the fingers were flexed, and to introduce a large protractor, which could be positioned under the forearm to improve measurement of shoulder external rotation. Results for assessment using the revised protocol are shown in Figure 6. Intraclass correlation co-efficient increased to 0.98 indicating a further improvement in reliability.

Figure 5: Bland Altman plot to show preliminary testing of agreement for measuring range of movement with goniometry and the original protocol



The clinicians and pWS agreed that goniometry used with the standardised protocol for measurement was the optimum way of assessing range of movement. The measurement produced is a continuous variable from minus 60 up to 180 degrees of movement, depending on the specific joint being measured. The final protocol for measuring range of movement at the relevant joints is shown in Appendix 15.

Figure 6: Bland Altman plot to show preliminary testing of agreement for measuring range of movement with goniometry with the revised protocol



Skin condition

No specific measures of skin condition were identified during the review of outcome measures (Chapter 3). However during the preliminary testing of the other outcome measures a number of clinicians reported that they felt strongly that changes in skin condition were a relatively rare but important consequence of the profoundly-affected arm. It was therefore agreed to adopt the descriptions used in the Best Practice Statement on the Care of Older Person's Skin (Wound UK, 2006) and test the feasibility of using an ordinal scale where skin condition was classified as either clean and dry, macerated, or broken (pressure area or tear).

Passive function

The review of outcome measures identified three measures that particularly targeted passive function. Although ArMA was the measure of passive function with the most robust evaluation of psychometric properties (Ashford et al, 2010) it also contains 13 questions related to active function of the arm including quite sophisticated functions such as managing to fasten buttons and turn a key. Consequently the clinicians and pwS consulted did not consider it appropriate for use with this particular population of pwS. They preferred the LASIS, which

is targeted at people with little active function of the arm. In assessing reliability the LASIS was completed with four pws, with two independent reviewers. Reliability was considered at individual item level, where responses could be 0,1,2,3,4, or not applicable. Results for the 46 items measured are shown in Table 14. Agreement between raters scoring was 87% with a Kappa score of 0.8 indicating very good agreement.

Table 14: Preliminary testing of the reliability of the Leeds Arm Spasticity Impact Scale

		Reviewer 2					
		0	1	2	3	4	NA
Reviewer 1	0	24	0	0	3	0	0
	1	0	3	0	2	0	0
	2	0	0	4	1	0	0
	3	0	0	0	2	0	0
	4	0	0	0	0	2	0
	NA	0	0	0	0	0	5

All the staff and pws felt the LASIS provided a structured approach to recording difficulty with care of the arm but which was also then useful for goal setting.

“It’s indicative of difficulties found whilst providing care, like hand and axilla care.”

Occupational therapist involved in the consultation

‘it relates to quality of life.’

Person with stroke involved in the consultation

LASIS was selected for inclusion in the feasibility study on this basis. It is recommended in the National guidelines for spasticity management with botulinum toxin (Royal College Physicians, 2009); although it’s psychometric properties have not been fully evaluated.

Active function

It was recognised that, although unlikely, some participants may go on to recover active function of the arm. Two outcome measures of active function

that were reflective of real life were identified in Chapter 3. Of these, ABILHAND is focused at quite dexterous use of the arm and hand including activities like threading a needle, whilst the MAL-14 contains reference to less demanding functional tasks such as holding larger items. The clinicians and pwS consulted voted unanimously that the MAL-14 was the preferred measure for recording any changes in active use of the arm during the study. The MAL-14 was currently in use in the local community as an outcome measure and staff involved in this project had previously undergone training in its use. Therefore it was not included in the draft battery of measures assessed but was adopted outright. It produces data on a continuous scale from zero to five.

Health-related quality of life

Four measures of health-related quality of life were identified in Chapter 3. In the local health community there has previously been considerable consultation on their use as part of other research projects and findings have indicated that individuals with stroke have their own preferences of which scales they feel are most relevant to them. The clinicians and staff that were consulted about this project favoured a scale that was not too detailed in order to facilitate its use with people with communication disability and cognitive impairment. The SIPSO (Trigg & Wood, 2000) was selected for this purpose. It contains 10 items giving an overall score as well as physical and social component scores on continuous scales from 0 to 20 each. There is one question related to the persons perception of their appearance. As SIPSO is a self reported measure and internal reliability and validity have been established (Patient Reported Health Instruments Group, 2006), it was not tested for reliability in the preliminary evaluation. However the pwS were consulted about it's acceptability and indicated that they felt it was appropriate to use in the first 6 months after stroke.

Environmental factors

Health and social care services, and products and technology. A simple client service receipt inventory was developed to capture the use of social care packages, therapies and home programmes targeted at the arm, medications, splints and other interventions.

Carer burden. As discussed in Chapter 3, there are a large number of measures of carer burden. However, van Exel et al (2004) found that a single question of self-rated burden was as feasible and sensitive as other, more complicated measures. Carers are asked to rate how 'burdensome' it was to care for their friend or partner on a continuous scale divided into 100 units. Clinicians and pws who were consulted felt this was an acceptable approach to take but the measure was not subjected to preliminary testing as this would have required a group of carers, which was beyond the remit of the members of the patient and public involvement group.

Summary

A summary of the outcome measures that were selected for inclusion in the feasibility study are shown in Table 15.

Table 15: Summary of outcome measures selected for testing

Domain of ICF	Dependent variable	Outcome measure	Data collected
Body structure	Spasticity	Modified Modified Ashworth Scale	Ordinal (5 fields)
	Pain	Dichotomous response re pain at rest or on movement	Nominal (4 fields)
	Range of movement	Goniometry	Continuous scale from -60 to 180
	Skin condition	Wound classification	Nominal (3 fields)
Activities	Passive function of the arm	LASIS	Continuous scale from 0 to 4
	Active use of the arm	MAL-14	Continuous scale from 0 to 70
Participation	Quality of life	SIPSO	Continuous scale from 0 to 40
Environmental factors	Health & social care service and products & technology	Client services receipt inventory	Nominal (8 fields)
	Carer burden	Self rated scale	Continuous scale from 0 to 100

The assessment of outcome measures was ordered to ensure each participant undertook the same process. The workbook to collect the participant's outcomes data and any adverse events (Section 5.6) can be seen in Appendix 17. The workbook to collect the carer data is in Appendix 18. The combined outcome measures took approximately 60 minutes to complete. For a definitive study outcomes data would need to be collected for a minimum of one year. However, for the purposes of testing the feasibility of the project it was agreed to collect data at three and six months only. Participants were offered the choice of where they wanted their follow-up assessments to be conducted and this information was recorded.

5.4.3 Predictor variables

Seven predictors of spasticity, pain and contracture in the weak arm were identified following the systematic review. They were weakness, reduced motor control, stroke severity, reduced global function, subluxation, pain and reduced sensation. The impact of depression, and other higher cortical function on arm impairment is unclear. Arm weakness and motor control are closely associated (Rabadi & Rabadi, 2006), as are stroke severity and level of global function (Tseng & Chang, 2006) so only one of each of these related constructs was included. Equally, there are no reliable, valid clinically based measures of different aspects of subluxation (Section 3.3.3). Therefore the predictors chosen for testing in this feasibility study were degree of motor control, stroke severity, sensation/ perception, depression, pain and spasticity. The measures selected to record these predictors are as follows:

Motor control

The degree of motor control of the arm was quantified using the Fugl-Meyer test. This tool assesses a progression of motor recovery including reflex muscle activity, synergic movements, and progressing to finer movement in all parts of the arm. The scale has good validity, reliability and responsiveness (Hsieh et al, 2009; Lin, et al, 2009), and a standardized manual for its completion has been developed (Deakin, Hill & Pomeroy, 2003). It was selected as the screening tool for eligibility, as well as a baseline predictive measure. It produces data on a scale between 0 and 66, and, although there are some sub-categories it is a continuous measure.

Stroke severity

Stroke severity was recorded using the Oxfordshire Community Stroke Project Classification (Bamford, Sandercock, Dennis, Burn & Warlow, 1991). It is a nominal classification, which is predictive of outcome at 90 days post-stroke (Spriggs, et al, 2007). It was originally designed for ischaemic stroke only but has been expanded to include reference to cerebral haemorrhage (McNaughton, Weatherall, Taylor & McPherson, 2001).

Sensation/ perception

Altered sensation was identified as a potential predictor of pain in the arm post-stroke. However sensation involves many different aspects such as tactile sensation, heat, and proprioception; and Connell, Lincoln & Radford (2008) demonstrated that different sensory impairments after stroke are discrete and recommended that assessment target them individually. Consequently comprehensive sensory assessments can be lengthy (Connell, 2007) and use complicated language that may not be accessible to people with aphasia. Korner-Bitensky et al (2006) demonstrated that some people with aphasia could record sensation of heat using visual analogue scales, but, given the difficulties for other stroke survivors in using analogue scales (Price et al, 1999) this is clearly not a universal solution. Therefore for this study sensation was combined with perception and quantified using 'Find the Thumb' test. This is a simple measure where the person is asked to grasp the thumb of the hand on the stroke-affected arm with their other hand. It was originally developed as a measure of sensation and proprioception (Prescott, Garraway, & Akhtar, 1982), but it is also sensitive to perceptual difficulties locating the arm caused by personal inattention (Kalra, Perez, Gupta, & Wittink, 1997), and is directly relevant to care of the arm. It was chosen as it is a better predictor of recovery of active use of the hand after stroke than other measures of sensory impairment (Welmer, Holmqvist & Sommerfeld, 2008), and it was successfully utilised as a predictor in some of the studies included in the systematic review (Chapter 4).

Originally 'Find the thumb' was developed as an ordinal scale of four categories but in some studies these have been collapsed to produce scales of two (van

Kuijk et al, 2007; Hirayama, Fukutake, & Kawamura, 1999) or three categories (Bohannon, 2003). The original test involves the assessor asking the person being tested to close their eyes, the assessor then passively raises the hemiplegic arm above the head of the person being tested before asking them to locate their thumb. However, Bisiach, Perani, Vallar, & Berti (1986) adapted the procedure so the participant is asked to reach to the affected hand while it rests by their side. For the purposes of this study this adapted procedure was used as it was felt that the original procedure may be likely to cause pain. A three-point ordinal scale was used to record abilities: the participant was able to locate their thumb, the participant was able to locate they arm but not their thumb, or the participant was unable to locate their arm.

Mood

Depression was assessed using the Stroke Aphasic Depression Questionnaire Hospital-10 (SADQH-10). The full Stroke Aphasic Depression Questionnaire was originally a 21-item questionnaire where the scoring was based on behaviour observed by staff (Sutcliffe & Lincoln, 1998) The SADQH-10 is a reduced version, which has been validated against the Geriatric Depression Scale (Leeds, Meera & Hobson, 2004). It was selected to measure depression in this study because it has been shown to be appropriate for all people with stroke, including those with aphasia or cognitive difficulties (Bennett & Lincoln, 2006). Although there are sub-categories of assessment, it is treated as a continuous scale from 0 to 30. The score is calculated in consultation with at least two members of the rehabilitation team based on observation of the participant during the previous 48 hours.

Spasticity

Spasticity was tested as a predictor variable as well as an outcome. It was measured using the Modified Modified Ashworth Scale following the preliminary testing (Section 5.4.2).

Pain

Pain was also included as a predictor variable as well as an outcome. It was assessed using the dichotomous (yes/no) response which was considered during preliminary testing (Section 5.4.2).

Summary

A summary of the predictor variables is shown in Table 16. The assessment of predictor variables was ordered to provide a consistent approach. A workbook for recording was developed and is included in Appendix 16. The combined measures took approximately 30 to 60 minutes to complete.

Table 16: Summary of predictor variables selected for testing

Predictor variable	Measure used	Type of data
Motor control	Fugl-Meyer	Continuous scale (0-66)
Stroke severity	Oxfordshire Community Stroke Project Classification	Nominal data (5 fields)
Sensation/ perception	Find the Thumb test	Ordinal data (3 fields)
Pain	Participant indicated if there was no pain at rest or on movement, if there was pain only on movement, or pain at rest and on movement	Nominal data (4 fields)
Spasticity	Modified Modified Ashworth Scale	Ordinal data (5 fields)
Depression	Stroke Aphasic Depression Questionnaire- 10	Continuous scale (0- 30)

5.4.4 Quantitative data concerning cognitive impairment and communication disability

As a key tenet of this project was to be maximally inclusive of all pwS, additional data was collected to monitor the process of consent and use of consultees, as well as the degree of communication disability and cognitive impairment of participants. In order to reduce the burden of assessment this data was collected from assessments that had already been conducted as part of the person's multi-disciplinary rehabilitation assessment. Communication disability (aphasia or dysarthria) was established from speech and language therapy assessment. If the participant was identified as having aphasia, the score on the language section of the Addenbrooke's Cognitive Examination Revised (ACER) assessment was recorded. The ACER is a test originally developed to assess cognition which contains a section on language with assessment of

naming, comprehension, repetition, reading and writing, scored from a total of 26 points. In a study of 86 people, Gaber, Parsons & Gautam (2011) found that a cut off score of 20/26 had a high degree of specificity and sensitivity in detecting aphasia when compared with speech and language therapy assessment. Although formal speech and language therapy assessments were used to identify communication disability, the ACER language score was also captured in order to give an indication of the degree of impairment. This approach has been used in other studies as a means of monitoring the levels of communication disability of participants (Dalemans et al, 2009).

Cognition was assessed using the Mini Mental State Examination (MMSE), although it is recognised that it also reflects communication impairment to some extent (Gigliacca et al, 2012). There is a total score of 30 points, and scores of 23/24 or less have been shown to be sensitive and specific to demonstration of cognitive impairment (Galasko et al, 1990; Tombaugh & McIntyre, 1992). Although there is some evidence that the ACER may be a superior measure of cognitive impairment (Pendlebury et al, 2012) and both tests are conducted within the stroke service in question, the MMSE was selected to monitor cognitive impairment due to the presence of other research related to MMSE scores and their link with capacity to make decisions (Whelan, Oleszek, MacDonald & Gaughran, 2009).

5.4.5 Qualitative data

Qualitative data was collected to ascertain the views of participants and their carers of the acceptability of the research processes and the measures used. Ten of the participants and their carers (where relevant) were invited to attend either an individual or group to feedback their experience of participating in the study. Previous research within the stroke service has found that offering this choice allows individual needs to be incorporated (Allison, Evans, Kilbride & Campbell, 2008). Participants were purposively sampled to ensure the cohort interviewed contained people with communication disability and cognitive impairment, as well as presenting with a range of the impairments associated with the profoundly-affected arm. A topic guide for these sessions (Appendix 19) was developed based on open questions around individual experiences of living with a profoundly-affected arm after stroke and the experiences of

participating in the research study. It enabled semi-structured discussions whilst still allowing participants to raise issues of personal importance. The guide was developed with and approved by the service user representative on the study steering group.

Additional consideration was given to supporting people with communication disability and cognitive impairment to participate in the interviews. This included ensuring interviews were conducted in a quiet place of the choice of the participant, supplementing verbal questions with bullet points and pictographic resources, allowing plenty of time for people to respond, clarifying people's views either verbally or in writing or with drawing, and inviting participants to give input to the interview in ways that suited them (for example one person brought some pre-developed notes and pictures with her). A speech and language therapist was available to give specific advice on techniques to assist the interviews when needed. These techniques have previously been utilised to enable people with aphasia to participate in research (Pringle et al, 2010; Dalemans et al, 2009).

5.5 Withdrawals

Participants were informed that they were free at any time to withdraw their consent to participate in the study without giving reason, and without it affecting their relationship with the clinical team, or their future care. Participants were asked to identify their reason for withdrawing from the study, but were informed that they are under no obligation to do so. Withdrawal from the study (and the reason for withdrawing consent if it was provided), were clearly documented in the participants' medical records and study documentation.

5.6 Adverse event recording

An adverse event was defined as any unfavourable and unintended sign, symptom or illness that developed or worsened during the period of the study, whether or not it was considered to be related to the study process. At each participant contact, any adverse events reported by the participant were recorded in the participants file (and in the hospital notes as appropriate), by the researcher. The researcher considered whether any adverse event was likely to have a reasonable suspected causal relationship to the study. If this occurred

the event was recorded as an adverse reaction. Data on adverse events and adverse reactions were presented to steering group meetings, to the sponsor and to the funding committee.

5.7 Data management and entry

Participants were allocated a unique study number. A separate record of names and addresses linked to participants' study numbers was maintained in a locked cabinet at the research office. Persons authorised to collect, record, and enter study data at each site were listed on the study Delegation Log.

Quantitative data

Quantitative data was coded and entered onto a password-protected database on Excel designed by the researcher with input from a statistician. Data was independently entered into spreadsheets by the researcher and a clerical staff member assigned to the research team. Spreadsheets were then compared with each other to identify errors and any discrepant data verified using the original paper data sheets.

Qualitative data

Data from the individual or group interviews were audio-taped and transcribed verbatim. Typed transcripts were stored on a password-protected computer.

Archiving

Following completion of data analysis, data and essential documentation have been archived in a secure location for at least 5 years after the end of the study, in accordance with the Sponsors standard operating procedure.

5.8 Data analysis and reporting

Quantitative data

Data were analysed and reported in line with the guidance contained within the NIHR definition of feasibility studies (NIHR, 2012). Quantitative analysis included calculating the proportions of eligible participants and carers and their willingness to be recruited, follow-up rates and locations selected by participants for visits. Descriptive data were presented for all of the predictor and outcome data, to identify the amount of data collected and distributions.

There was no attempt to analyse the value of predictors or to develop a longitudinal profile of impairment and disability as the feasibility study was not adequately powered for this and this was not the purpose of the study (Thalbane et al, 2010).

Qualitative data

Qualitative data from interviews was analysed using content analysis (Green & Thorogood, 2004) with a framework approach (Lathlean, 2006). Content analysis is a research method, which historically developed for the analysis of textual material (Harwood & Garry, 2003). It is now used widely in the field of healthcare to systematically describe and quantify phenomena, and to distil large amounts of narrative into fewer content related categories (Elo & Kyngas, 2008). The analysis used in this study followed a step-wise method including familiarisation of data, generation of codes to label transcript passages, and development and revision of themes. The first phase of the analysis consisted of the researcher reading and rereading the transcripts and listening to the tapes of the interviews prior to commencing coding. The second phase involved the researcher freely assigning open codes to narrative within the text. Following the open coding, the lists of sub- categories produced from the codes were grouped under higher order headings with the aim of developing broader categories (Graneheim & Lundman, 2004). Abstraction was the process used to formulate general themes from these codes and categories (Elo & Kyngas, 2008). Although this description indicates a linear approach, the steps overlapped somewhat reflecting a more iterative approach. A framework was used to assist with organisation and management of the data.

5.9 Study organisational structure

The researcher and her supervisor, met regularly (usually six weekly) during the period of the study, to monitor progress, oversee recruitment and discuss analysis, results, draft reports and dissemination. A Steering Group was convened with the researcher, her supervisor, two fieldwork collaborators and a service user representative. This group met at six monthly intervals during the study to oversee progress.

5.10 User consultation

The user involvement has followed a number of key stages:

1. The Stroke Service held a meeting with pwS in October 2009. This was used to explore people's experience of rehabilitation, and any outstanding needs. Six people with a profoundly-affected arm identified the following as being particularly important:
 - a. Understanding what to expect in terms of potential recovery in the arm
 - b. Knowing what to expect when caring for the arm became more difficult
 - c. Knowing when to use splints, stretching and other interventions
 - d. Knowing how to avoid and manage pain in the arm
 - e. Feeling that therapists often did not know how to advise them or gave them conflicting advice.
2. A participant with stroke from this original event then helped to develop a draft study outline. The draft outline was presented to and discussed at the South Devon Stroke Conference in June 2010, attended by 60 pwS and their carers, and their further comments were incorporated.
3. The person with stroke identified in step 2 above joined the study steering group, became a co-applicant on a bid for a small grant and assisted with design of the study. The researcher met with the service user prior to group meetings to ensure they had sufficient background information to participate, in line with guidelines for involving members of the public (Hanley, Bradburn, Barnes, Evans et al, 2003), and expenses were paid in line with National guidance (Involve, 2010).

5.11 Broader consultation

Members of the Rehabilitation Clinical Study Group of the Stroke Research Network, and the South West Research Design Service commented on earlier drafts of the research proposal.

5.12 Ethical issues and approval

A favourable ethical opinion to conduct this study was granted by the National Research Ethics Service Committee South West on 21st July 2011 (Reference 11/SW/0149) and the University of Exeter Psychology Research Ethics Committee on 9th August 2011 (Reference 2010/26) (see Appendix 20). The researcher maintained current certification in International Conference on

Harmonisation Good Clinical Practice (GCP) training throughout the study period, and annual reports on the study were submitted to the National Research Ethics Service Committee South West.

There were potential sensitivities in approaching participants at an early stage after stroke, particularly when the study protocol was to recruit people who are unlikely to regain much recovery of their affected arm. The service user representative on the study had herself survived a stroke and not regained any use of her arm. With her assistance the information leaflets were drafted to broach this subject in a sensitive manner.

5.13 Research and development department approvals

Research and development department approval to conduct this study was granted by the South Devon Healthcare NHS Foundation Trust R & D Department on 22nd August 2011 (Reference number 11/08/037) and by the Torbay and Southern Devon Care Trust R & D Department on 12th September 2011 (Reference TOR019).

5.14 Research sponsorship

The sponsor of the study was NHS Devon. The sponsor was responsible for implementing and maintaining quality assurance and quality control systems to ensure that the study was conducted and data are generated, and reported in compliance with the study protocol, GCP, and the applicable regulatory requirement.

5.15 Chapter summary

This chapter contains a description of the methods used in this feasibility study including recruitment processes, selection and preliminary testing of the predictors variables and outcome measures. It also details the consultation with service users and research groups, and the processes for ethical and research department approvals. The next chapter contains an overview of the results.

Chapter 6: Overview of results

6.1 Chapter summary

This chapter contains an overview of the results of this feasibility study. It includes a summary of the process of recruitment and follow-up of the participants, and their baseline characteristics including demographic data and diagnosis. Descriptive data are presented to demonstrate the participants' level of physical disability and their degree of cognitive impairment and communication disability. There is a summary of the predictor measures collected at baseline, the outcome measures at three and six months, and any adverse events reported by the participants. With respect to recruitment and follow-up of carers, this process is also described. Finally descriptive data related to the selection of the ten participants who were interviewed are included. A more in-depth review of these results, along with qualitative data collected at interviews are presented alongside discussion in the subsequent chapters.

6.2 Overview of the recruitment and progress of the participants

A total of 40 people with stroke (pwS) were recruited to the study between 12th September 2011 and 10th April 2012 (a period of 30 weeks). Figure 7 is a flow diagram based on the CONSORT format that illustrates the process of recruitment and progress of participants throughout the study. Table 17 contains data concerning where participants chose to be assessed for their follow-up appointments. A discussion of these results will be given in Chapter 7.

6.3 Profile of communication disability and cognitive impairment within the participants at baseline

Table 18 contains a summary of data describing the degree of cognitive impairment and communication disability of participants. These data are generally routinely collected as part of a person's stay within the stroke units or under the care of the community stroke team. However cognitive assessments were not conducted on two individuals and Addenbrookes Cognitive Examination Revised-Language assessments were not completed on one person with aphasia. A full discussion of these results is given in Chapter 7.

Figure 7: Flow diagram detailing recruitment and progression of participants through the study

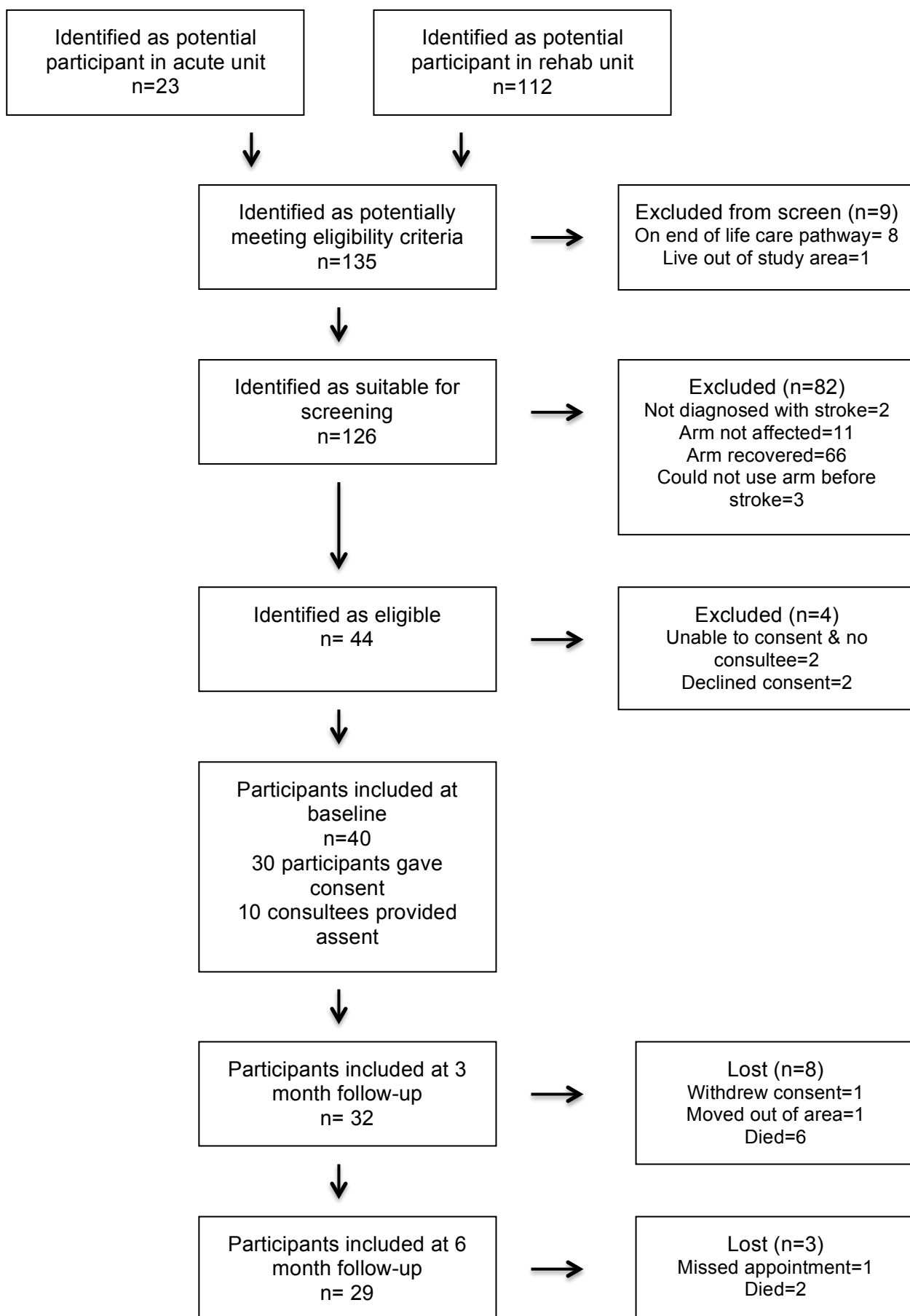


Table 17: Sites where participants chose to have follow-up appointments

Place of appointment	3 month follow-up (n=32)	6 month follow-up (n=29)
Own home	18 (56%)	19 (66%)
Care home	7 (22%)	6 (21%)
Outpatient department	5 (16%)	3 (10%)
Hospital ward (inpatient)	2 (6%)	1 (3%)

Table 18: Summary of participants' cognition and communication disability

Characteristic		Value for study sample (n=40)
Cognitive impairment (n= 38)	MMSE score	Median: 21 IQR: 15
	Impaired (scored 23 or less)	22 (55%)
	Unimpaired (Scored 24 or more on MMSE)	18 (45%)
Dysarthria*	Affected	16 (40%)
	Unaffected	24 (60%)
Aphasia*	Affected	14 (35%)
	Unaffected	26 (65%)
Degree of aphasia (n=13)	ACER-L of participants with aphasia	Median: 6 IQR: 13

MMSE- Mini mental state examination

ACER-L- Addenbrookes Cognitive Examination Revised Language Section

* As assessed by speech and language therapist

6.4 Demographic characteristics of the participants

Table 19 contains data of the demographic details of the participants including age, gender, type of stroke, previous co-morbidities, presence of carer, hospital length of stay and discharge destination. A discussion of these participant characteristics is given in Chapter 8.

Table 19: Descriptive data of the participants

Characteristic		Value
Age	Years	Median: 77.5 IQR: 17.75
Time since stroke	Days	Median: 15 IQR: 7.0
Gender:	Male	15 (37.5%)
	Female	25 (62.5%)
Type of stroke	Infarct	36 (90%)
	Haemorrhage	4 (10%)
Side of hemiplegia	Left	25 (62.5%)
	Right	15 (37.5%)
Presence of carer	Has a carer	29 (72.5%)
	Did not have a carer	11 (27.5%)
Presence of co-morbidities that affected use of arm prior to stroke	Rheumatoid arthritis	2 (5%)
	Previous stroke	1 (2.5%)
	Previous spinal cord compression	1 (2.5%)
	Concurrent spinal cord compression	1 (2.5%)
Total length of stay in hospital	Days	Median: 43 IQR: 35.5
Place of discharge from hospital	Own home	22 (55%)
	Relative's home	1 (2.5%)
	Intermediate care unit	2 (5%)
	Residential home	4 (10%)
	Nursing home	9 (22.5%)
	Died	2 (5%)

6.5 Profile of the predictor measures at baseline

Table 20 contains a summary of the predictor measures taken of the participants at the time of recruitment for the study with reference to degree of motor control, spasticity, pain, sensation/perception, stroke severity and mood. A discussion of these results will be given in Chapter 8.

6.6 Profile of the outcome measures at three and six months

Table 21 and 22 contain summaries of the outcome measures recorded during assessments of the participants at the three and six month follow-ups. Table 21 contains details of outcomes related to pain, spasticity, skin condition, recovery of active movement, difficulty with passive function, and quality of life. Table 22 contains a summary of the passive range of movement available at each joint that was assessed. A discussion of these outcome measures taken is provided in Chapters 9 and 10.

6.7 Data concerning interventions provided

Data was collected on the interventions provided to the participants during the period of the study. In keeping with the model of application of the ICF to people with the profoundly-affected arm (see Section 2.3) this included health and social care services, products and technology; and any other intervention that the person with stroke felt was relevant. Table 23 summarises the data concerning the provision of these interventions at three and six months post stroke. Table 24 contains details of additional interventions that were named by participants. These results are discussed in Chapter 10.

Table 20: Summary of the profile of the predictor measures taken at baseline

Predictor variable		Value
Motor control (Fugl- Meyer upper limb score)	Fugl-Meyer score	Median: 3.0 IQR: 8.25
	Participants with no movement or only reflex activity on FM score	22 (55%)
	Participants with some volitional movement on FM score	18 (45%)
Greatest degree of spasticity in any of the assessed muscle groups in the arm (MMAS)	0	4 (10%)
	1	15 (38%)
	2	14 (35%)
	3	7 (17%)
	4	0
Pain	No pain at any time	33 (82.5%)
	Pain only at rest	0
	Pain only on movement	6 (15%)
	Pain at rest & on movement	1 (2.5%)
Sensation and perception (Find the Thumb test)	Able to locate affected thumb	28 (70%)
	Able to locate affected arm only	5 (12.5%)
	Unable to locate affected arm	7 (17.5%)
Mood (Stroke Aphasic Depression Questionnaire H-10)	SADQH-10 score	Median: 9.0 IQR: 5.25
Classification of stroke (Oxfordshire Community Stroke Project)	Total anterior circulation stroke	18 (45%)
	Partial anterior circulation stroke	9 (22.5%)
	Lacunar stroke	7 (17.5%)
	Posterior circulation stroke	2 (5%)
	Haemorrhage	4 (10%)

**Table 21: Summary of the profile of the main outcome measures
(excluding range of movement)**

Outcome variable		Value at 3 months (n=32*)	Value at 6 months (n=29)
Greatest degree of spasticity in any of the assessed muscle groups in the arm (MMAS)	0	2 (6%)	2 (7%)
	1	5 (16%)	6 (21%)
	2	20 (65%)	13 (44%)
	3	4 (13%)	8 (28%)
	4	0	0
Pain	No pain at any time	5 (16%)	9 (31%)
	Pain only at rest	0	1 (3%)
	Pain only on movement	17 (53%)	14 (49%)
	Pain at rest & on movement	10 (31%)	5 (17%)
Skin condition	Clean & dry	32 (100%)	29 (100%)
	Macerated	0	0
	Pressure area	0	0
Passive function of arm	Leeds Arm Spasticity Impact Scale	Median: 1.2 IQR: 0.9	Median: 1.0 IQR: 1.0
Active function of the arm	Motor Activity Log-14	Median: 0 IQR: 1.4	Median: 0 IQR: 1.2
Quality of life	SIPSO- Physical scale	Median: 2.9 IQR: 7.0	Median: 1.0 IQR: 10.0
	SIPSO- Social scale	Median: 10.0 IQR: 6.5	Median: 11.0 IQR: 5.0
	SIPSO- Total	Median: 15 IQR: 12.0	Median: 14 IQR: 9.0

* Some data on spasticity, LASIS, SIPSO missing for one participant at this data point

Table 22: Summary of the profile outcome measures of range of movement

Passive range of movement	Value at 3 months	Value at 6 months
Shoulder flexion	Median: 90 IQR: 47.5	Median: 90 IQR: 20
Shoulder abduction	Median: 80 IQR: 31.25	Median: 80 IQR: 20
Shoulder external rotation	Median: 30 IQR: 20	Median: 25 IQR: 20
Elbow extension	Median: 170 IQR: 20	Median: 180 IQR: 30
Elbow flexion	Median: 140 IQR: 10	Median: 130 IQR: 10
Wrist extension	Median: 40 IQR: 30	Median: 40 IQR: 20
Index finger MCP extension	Median: 180 IQR: 0	Median: 180 IQR: 0
Index finger PIP extension	Median: 180 IQR: 0	Median: 180 IQR: 10
Index finger DIP extension	Median: 180 IQR: 0	Median: 180 IQR: 0
Little finger MCP extension	Median: 180 IQR: 0	Median: 180 IQR: 0
Little finger PIP extension	Median: 180 IQR: 0	Median: 180 IQR: 20
Little finger DIP extension	Median: 180 IQR: 0	Median: 180 IQR: 0
Thumb MCP extension	Median: 180 IQR: 0	Median: 180 IQR: 0
Thumb PIP extension	Median: 180 IQR: 0	Median: 180 IQR: 0

Table 23: Interventions reported at three and six months

		3 month follow-up n= 32	6 month follow-up n= 29
Social packages of care	Nursing care	5 (15%)	6 (21%)
	Residential care	4 (13%)	2 (7%)
	Hospital care	2 (6%)	1 (3%)
	Home based package	13 (41%)	12 (41%)
	No care	8 (25%)	8 (28%)
Medications	Analgesia	11 (34%)	11 (38%)
	Oral muscle relaxants	3 (9%)	3 (10%)
	Botulinum toxin injection	1 (3%)	1 (3%)
Splints	Participants using splints	10 (31%)	13 (45%)
	Amount of time splints used (hours/ day)	Median: 3.5 IQR: 2	Median: 4.0 IQR: 2.25
Therapy	Physiotherapy	24 (75%)	13 (45%)
	Occupational therapy	14 (44%)	9 (31%)
Home programmes		19 (59%)	18 (62%)

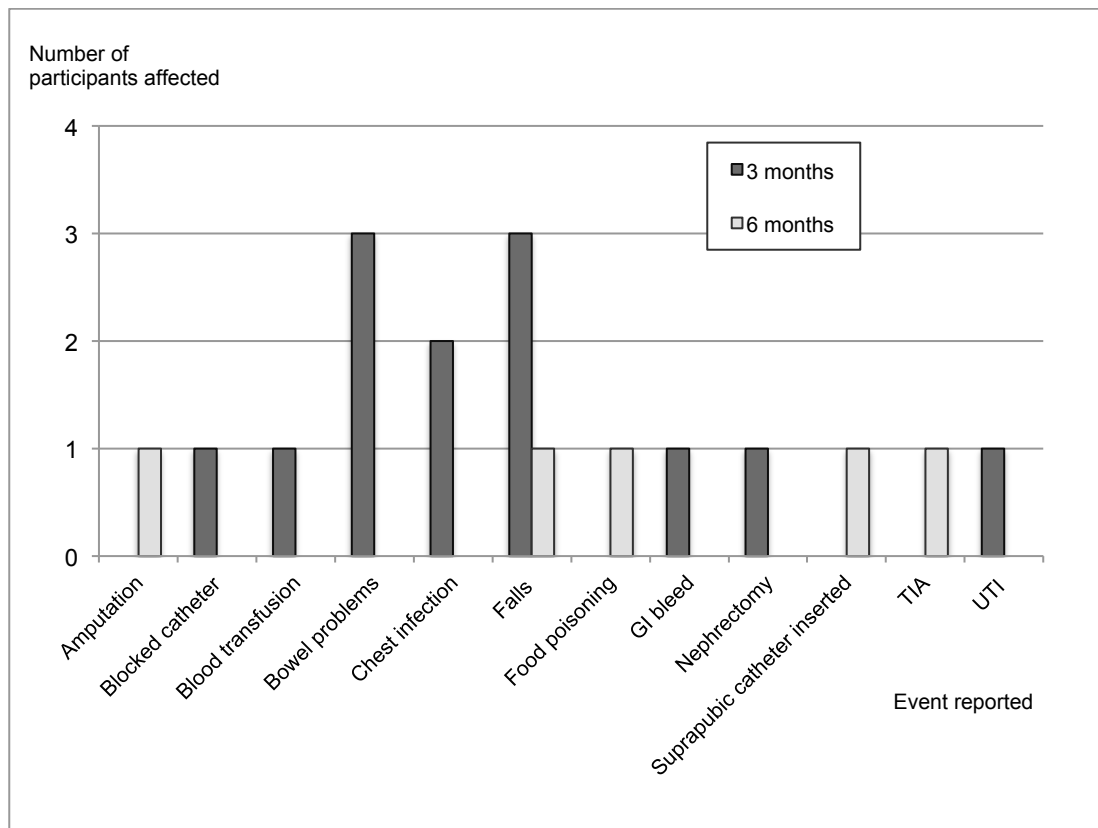
Table 24: Other reported interventions for the profoundly-affected arm

	3 month follow-up (n=3)	6 month follow-up (n=4)
Swimming	2	2
Massage	1	0
Acupuncture	0	1
Nintendo Wii	0	1

6.8 Adverse events

Figure 8 contains a summary of the adverse events that were reported by the participants at follow-up assessment. Thirteen participants (41%) reported adverse events at three months and five (17%) reported them at six months post-stroke.

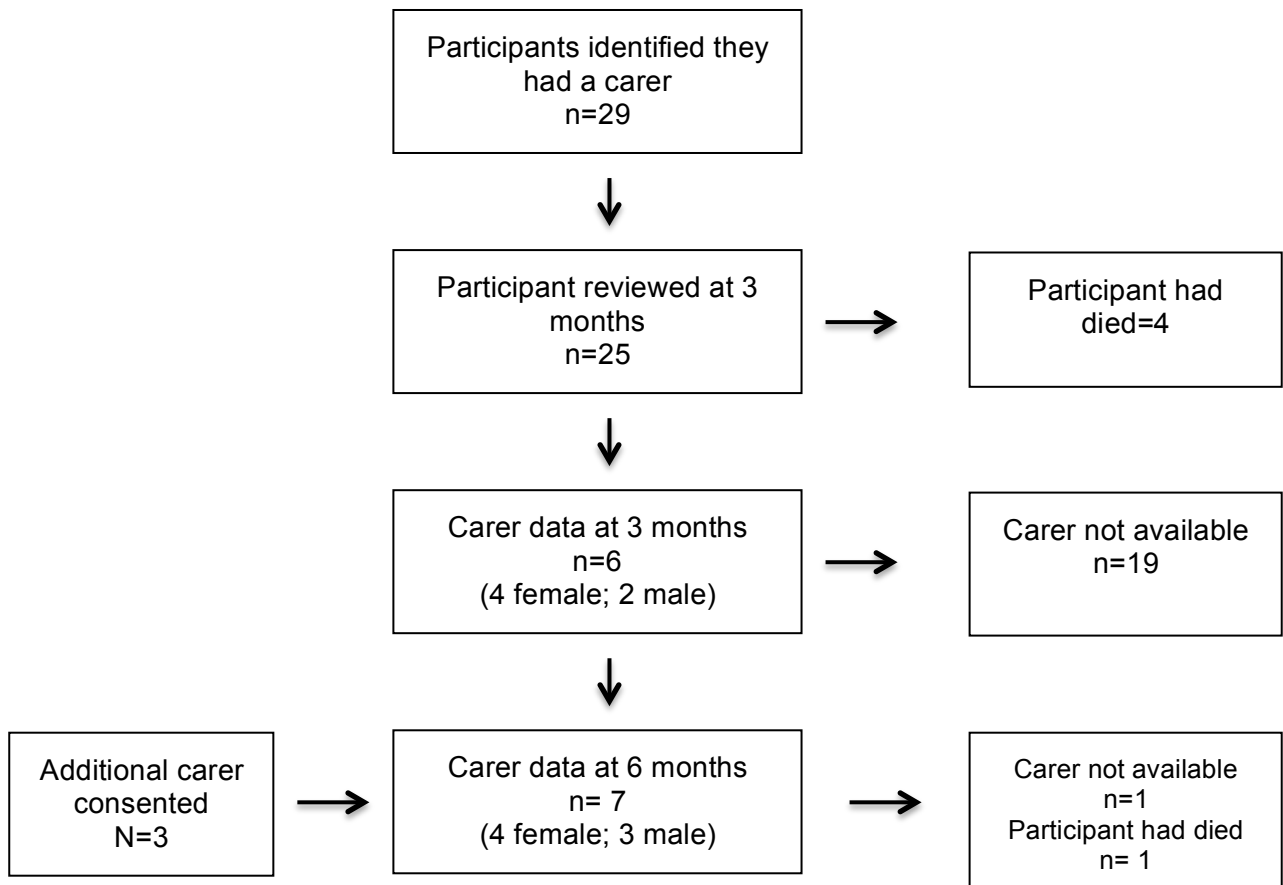
Figure 8: Adverse events reported by the participants



6.9 Overview of the recruitment of carers

Figure 9 demonstrates the process of recruitment and follow-up of carers during the study. A discussion of these results will be given in Chapter 7.

Figure 9: Flow diagram detailing recruitment and progression of carers through the study



6.10 Profile of the carer related outcome measure

Table 25 contains the summary of the data collected on carer burden.

Table 25: Results related to carer burden

	Value at 3 months (n= 6)	Value at 6 months (n=7)
Self rated carer burden (Score from 100)	Median: 44.5 IQR: 55.6	Median: 24 IQR: 40.5

6.11 Characteristics of the interviewees

Following completion of the outcome measures at 6 months, ten of the participants and their carers were invited to participate in an interview. Interviewees were purposively sampled to try to ensure the process was inclusive of people with a range of age, and severity of physical disability including the impairments measured, and to ensure that people with communication disability and cognitive impairment were included. All participants chose to undergo an individual rather than group interview. This may reflect their levels of physical disability when leaving the home to attend a group may be considered more challenging than being visited at home. Descriptive data on the participants interviewed are included in Table 26.

Table 26: Characteristics of participants who were interviewed

	Side of hemiplegia	Age / years	MMSE score at recruitment	Aphasia (ACER-L score)	Carer present	Other relevant factors
Interviewee 1	L	83	23	No	Yes	
Interviewee 2	R	67	16	Yes (6)	Yes	Regained use of arm
Interviewee 3	L	65	22	No	No	
Interviewee 4	R	38	28	Yes (23)	Yes	Younger person
Interviewee 5	L	69	24	No	Yes	
Interviewee 6	R	70	3	No	No	Regained capacity
Interviewee 7	R	80	9	Yes (3)	Yes	
Interviewee 8	L	59	25	No	Yes	
Interviewee 9	R	73	12	Yes (9)	Yes	
Interviewee 10	L	72	25	No	No	

6.12 Chapter summary

This chapter contains an overview of the quantitative results of this feasibility study. In the following four chapters these results, and the qualitative data obtained will be analysed and presented with respect to the three objectives of the feasibility study: (i) assessing the processes of recruitment and follow-up, (ii) reviewing the characteristics of the sample and (iii) considering the properties of the outcome measures.⁸

Chapter 7: The process of recruitment and follow-up

7.1 Chapter overview

This chapter relates to the first objective of the feasibility study to assess recruitment and follow-up processes in the study and particularly to assess the ability to involve people with cognitive impairment and communication disability. It contains an analysis of the number of people who were considered eligible for the study and the proportion of these who were recruited. The results of assessments of cognition and communication ability of the participants are analysed in order to assess the potential to involve people with more severe impairments in these areas. Given the potential challenges that these disabilities may pose in assessing mental capacity to make a decision about the research, there is also a review of the process of assessing capacity, and the use of consultee assent. There is a review of the follow-up process including reasons that participants were lost to follow-up, locations where they chose to have visits conducted and any adverse events reported. Finally, the recruitment of carers is reviewed and suggestions are made for how this could be improved. Throughout the chapter qualitative data from the interviews are used to provide insight into the participants and carers experiences of the recruitment process and engagement with the study.

7.2 Eligibility and recruitment of participants

The results of screening for eligibility and the process of recruitment are shown in Figure 7 (p.107).

7.2.1 Eligibility

Over the recruitment period of 30 weeks 363 people were admitted to the recruiting hospitals and 135 of them were identified as presenting with a weak arm on their admission to the stroke unit by the research team. Nine of these people were not screened for inclusion in the study because one lived outside the study area and eight were receiving care on end of life pathways. When the remaining 126 people were screened it was found that two of them had not sustained a stroke, eleven of them had not experienced any arm weakness, and three of them were unable to use the arm prior to the stroke. Therefore there were a total of 110 people (30% of those admitted) identified with a new presentation of weak arm immediately post-stroke, who survived to be admitted to the stroke unit. This incidence appears relatively low when typical estimates

are that 80% of people with stroke present with hemiplegia (ICSWP, 2012). However Truelsen, Bonita & Jamrozik (2001) have highlighted the difficulty in obtaining accurate epidemiological data when some signs of stroke may be transient and there may not be strict definitions.

When assessed at two to four weeks post-stroke, 66 of the 110 people identified had regained enough control of the arm to be considered likely to regain functional use of the arm (Kwakkel et al, 2003), leaving 44 people who were profoundly weak who were eligible. This suggests that approximately 12% of people admitted to the recruiting hospitals with stroke were eligible for inclusion in the study. In a previous study, Heller et al (1987) suggested that 30% of the people with stroke (pwS) in a sample they studied did not regain the use of their arm. However on examination, their sample excluded those who died, were lost to follow-up or had other difficulties with the arm prior to the stroke. When these factors are included it appears that in their study approximately 15% of all people admitted to hospital with a stroke did not recover use of their arm. This would suggest that the proportion of pwS found to be eligible for inclusion in this feasibility study is in line with that expected from other work in this area. However, without strict protocols for screening and following all patients admitted acutely it is not possible to understand the true extent of incidence of the profoundly-affected arm.

7.2.2 Recruitment

Of the 44 pwS who were identified as meeting the eligibility criteria, 40 were ultimately recruited into the study. They were all identified in the stroke units but four had their recruitment finalised when they had left hospital under the care of the community team. Of the forty participants, thirty were able to provide consent themselves, and for ten of the participants recruited, assent was obtained from a consultee. Of the four people who met the inclusion criteria who were not recruited, 2 declined to give consent, and 2 potential participants were unable to consent for themselves and did not have a personal consultee available. The two people who declined to give consent were asked if they would like to give a reason for not participating, although they were both informed that they were not obliged to do this. One did not wish to comment and the other indicated that they could not consider being involved in research when

they felt they had too much to concentrate on in terms of their recovery. However, the majority of pwS and their carers who were subsequently interviewed were very positive about being included in the research, even when they were approached fairly early after the stroke. Alexander (2010) identified that altruism in aiming to help others affected by ill health or disability could be a key reason for participation in research, and this was confirmed in participants' comments about the process:

"It was fine- if other people benefit it's fine"

Interviewee 4, age 38

One carer indicated that the offer of some structured follow-up was a motivating factor in his wife choosing to be involved in the research:

"Personally we were just very pleased that there was a follow-up and you were taking the care or the bother to do it – to just follow-up and find out- to be interested in that person to want to know how they were progressing..."

Carer of Interviewee 2, age 67

This reflects findings in cancer research where increased access to healthcare specialists is seen as a motivating factor for research recruitment (National Institutes of Health National Cancer Institute Office of Communications, 1996). Stroke survivors in the UK frequently cite feelings of isolation post hospital discharge (Kilbride, Allison & Evans, 2011), so it is understandable that they may seek other means of follow-up.

7.2.3 Including people with cognitive and communication disability

The incidence of cognitive impairment of participants was assessed by Mini-Mental State Examination (MMSE). The presence of aphasia or dysarthria was assessed by the speech and language therapist working on the stroke units. If the participant was identified as having aphasia, their score on the Language section of the Addenbrookes Cognitive Examination Revised (ACER-L) was recorded. These assessments are undertaken as part of patients' routine stay on the stroke units. Table 18 (p.108) contains data related to the results of these assessments.

Cognitive impairment

Two of the participants did not complete MMSE assessments due to staff shortages on the wards. Of the remaining 38, scores achieved ranged from 0 to 30. Twenty-one of the participants (55%) scored less than 23 points, indicating some degree of cognitive impairment (Galasko et al, 1990; Tombaugh & McIntyre, 1992). Population based studies using the MMSE to estimate cognitive impairment in general populations of people post-stroke have shown incidences of 42% acutely (Pedersen, Jorgensen, Nakayama, Raaschou & Olsen, 1996) and 22% at 3 months post-stroke (Douai, Rudd & Wolfe, 2013). The sample of this feasibility study contains a higher proportion of people with cognitive impairment than this. This may be expected as this study has recruited a higher proportion of people with a diagnosis of total anterior circulation stroke, which is associated with greater physical disability and higher cognitive impairment (Bamford et al, 1991).

Communication disability

Of the 40 participants recruited, seventeen (43%) were identified as having dysarthria, and fourteen (35%) were identified as having aphasia. This largely reflects the expected level of these disabilities in a general population of people post-stroke where incidences of 44% of people with dysarthria and 38% with aphasia have been found (RCP, 2011). One participant with aphasia did not complete the ACER-language assessment but for the remaining thirteen people scores ranged from 0 to 23, indicating a wide range of severity of communication disability.

Summary

This descriptive data demonstrates that the participants recruited to the feasibility study did have a wide range of both cognitive ability and communication disability. However, this produces potential challenges around the process of gaining consent (Stein & Wagner, 2006), which will now be considered.

7.2.4 Consent

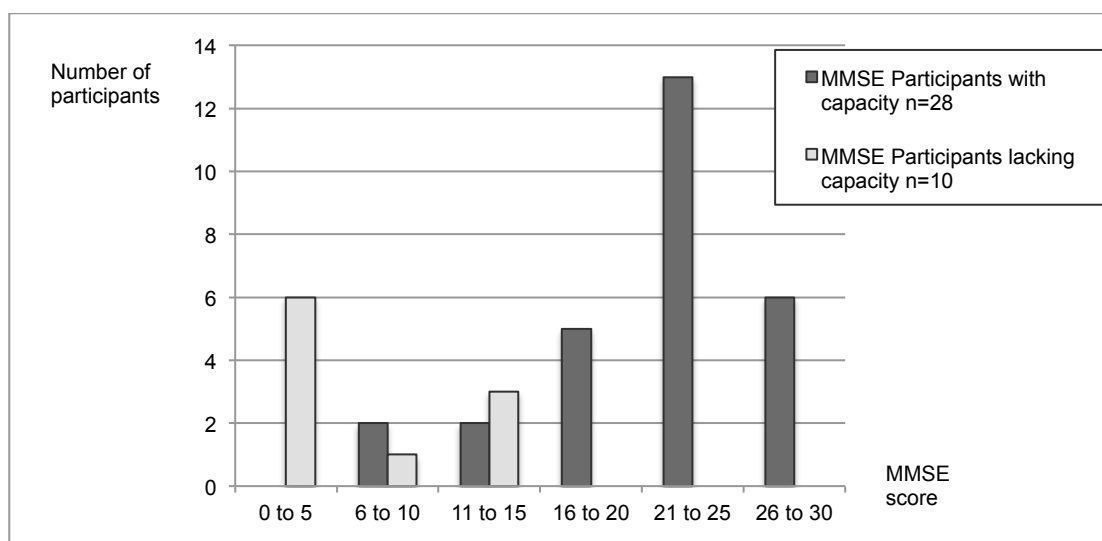
Assessment of mental capacity to make decisions is described in Section 3 of the Mental Capacity Act (DH, 2005) and includes four steps: ensuring that the

person can understand the information related to the decision, that they can retain it; that they can weigh up the information, and that they can communicate their decision. Enhanced communication techniques and a range of pictographic resources were developed to support the formal study information leaflets (see Appendix 8 for an example). Of the 44 people who were eligible for recruitment, 32 were assessed as having the mental capacity to make a decision regarding their inclusion in the research. Results of cognitive and communication disability testing related to assessments of participants capacity to make a decision about the research were reviewed to establish if they were in keeping with other data available.

Impact of cognitive impairment on capacity

Results related to cognition assessment are presented in Figure 10. There appears to be a relationship between MMSE scores and the ability to consent with a trend for higher scores to indicate greater likelihood of the participant being judged to have capacity. However, there was not a clear MMSE score that indicated if a participant would have capacity to make this decision. One participant with a score of 9 on the MMSE, and two with scores of 10 were judged to have capacity to make the decision whereas two people with scores of 12 and one with a score of 13 were judged not to have capacity. In comparison with other research, Whelan et al (2009) established that a score of 13 or more points on the MMSE had a positive predictive value of capacity to agree to inclusion in a randomized controlled trial of an additional booster of the influenza vaccine. This contrasts with findings by Gregory, Roked, Jones, & Patel (2007) where a score of 18 points on the MMSE was identified as a threshold to predict capacity to make a decision regarding nomination of enduring power of attorney. Whelan et al (2009) suggested that the gravity of the decision to be taken might influence the degree of cognitive ability required. However, both studies still found there were a significant number of participants wrongly labelled as either having or lacking capacity when using this cut-off alone, so suggested that MMSE scores did not replace full capacity assessments.

Figure 10: Distribution of cognitive scores related to assessment of capacity to decide whether to engage with the research study



At interview one participant with cognitive impairment commented that he did not subsequently remember of the process of consent:

“To be honest with you although I got the gist of it but it didn’t make sense to be honest with you- it was a bit too early.”

Interviewee 3, age 65

The Mental Capacity Act (DH, 2005) states that during assessment of capacity the person needs to be able to retain information about the decision they are making for as long as it takes them to weigh up the information and communicate the decision and does not necessarily need to recall it subsequently:

“The fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision.”

(DH, 2005, page 2)

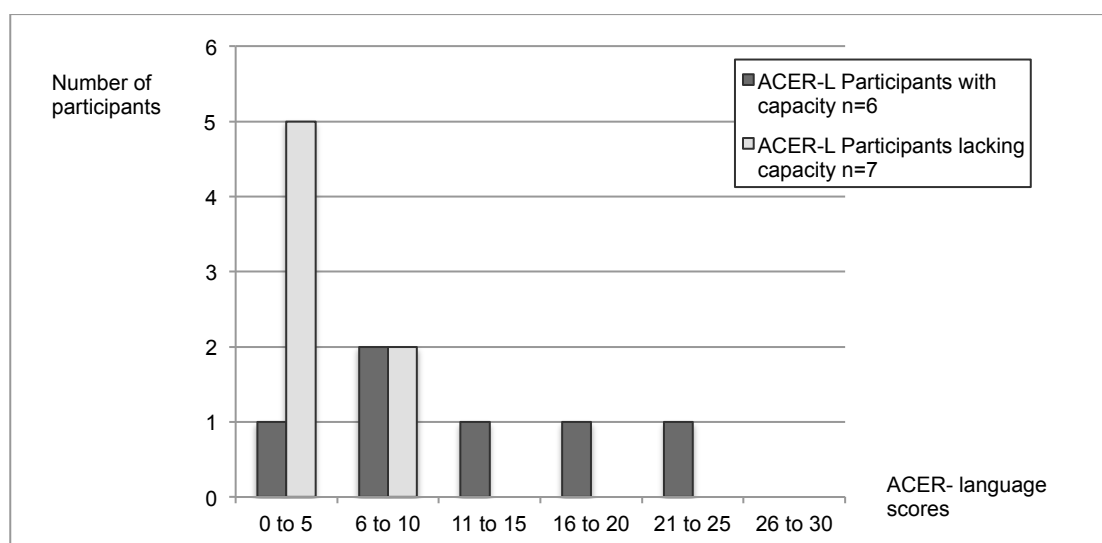
Consequently it is possible that a person who is judged to have capacity at the time of assessment will subsequently not remember the assessment process or their decision. Throughout the study welcome letters were sent to participants following recruitment, but findings from other studies show that pwS express concern about their ability to take on board information in the early stages

(Allison et al, 2008). This illustrates the need to ensure that research participants have their consent checked at each follow-up visit (General Medical Council, 2010).

Impact of communication disability on capacity

Results related to communication disability assessment are presented in Figure 11. There appears to be a trend that those with the lowest scores on the ACER-L assessment were more likely to lack capacity to make a decision about inclusion in the research study but this finding is not absolute. With the assistance of the pictographic resources one person with an ACER-L score of only 3 was able to demonstrate capacity to give consent.

Figure 11: Distribution of ACER language scores related to assessment of capacity to decide whether to engage with the research study, in participants with aphasia



Although much has been written about the impact of aphasia on peoples' ability to consent to inclusion in research (Brady, Fredrick & Williams, 2013) there has been little research in comparing scores on formal language assessments with capacity. Daleman et al (2009) demonstrated that it was possible to involve people with scores as low as 10/30 on the Frenchay Aphasia Screening Test (FAST) in research. Although this is recognised as indicative of severe aphasia there is no research available to indicate how the FAST assessment correlates with ACER-L. Results of assessments from this feasibility study have been

shared (Allison, Kilbride, Frampton, Picken & Marsden, 2013) in order to start building on knowledge in this area.

Consultee assent

Following screening, twelve pwS were identified as eligible to participate in the research but they did not have capacity to make a decision themselves. Of these twelve, the researcher identified personal consultees for ten, all of whom gave assent for inclusion of the person in the research. Masuca et al (2012) found that using legal authorised representatives to provide consent tended to delay the provision of consent but that was not the experience of this study. For the remaining two pwS, personal consultees could not be identified. For this feasibility study no attempt was made to identify a person independent of the research to act as a nominated consultee, and hence these two potential participants were not involved. It has been suggested that the role of nominated consultee could involve Independent Mental Capacity Advocates or healthcare professions not involved in the research. For a larger study it would be worth exploring how this process could be utilised to increase the opportunities for those without personal consultees to be included. During the course of the study one of the participants for whom consultee assent was given was judged to have regained capacity to make a decision for herself. She was re-consented using the process developed for this. At interview this participant stated that she was satisfied with the process of being re-consented when she had regained capacity.

7.2.5 Summary of participant recruitment

In this feasibility study 90% of the eligible participants who could consent and 100% of consultees approached gave assent for participation in the research process. This is higher than other observational studies in stroke rehabilitation, where recruitment rates were 79% of those who were able to give consent and 53% of those for whom a consultee was approached (Pickering et al, 2010). The higher recruitment rate in this study may in part be explained by the method of recruitment where members of the clinical team approached potential participants and their families. Direct approaches from clinical staff are one of the most successful strategies for research recruitment (Markgraf et al, 2009; National Institutes of Health National Cancer Institute, 2004). However

recruitment rates have also been shown to be higher in studies involving single centres with recruitment rates reducing as the total number of study sites increases (Elkins, Khatabi, Fung, Rootenberg, & Claiborne Johnston, 2006). Therefore, the relatively high rate of recruitment achieved in this feasibility study should not be assumed if a larger study involving multiple centres was undertaken.

7.3 The process of follow-up

The overall process of follow-up is shown in Figure 7 (p.107).

7.3.1 Overview of follow-up

Eight (20%) of the participants were lost to follow-up at the 3-month time point and three (7.5%) at the 6-month time point. Therefore the total 'lost to follow-up' rate over the 6 months was 27.5%. Reasons for loss included eight deaths (20%), one participant moving out of the study area (2.5%), one withdrawing consent (2.5%) and one who was out when the researcher visited at the two pre-arranged times (2.5%). In other longitudinal studies of older people with new stroke over 6 months, total lost-to-follow-up rates have been between 33% (Sackley et al, 2008) and 39% (Gregson et al, 1997). The predominant reason for loss in both these others studies was death. Our findings are in agreement with these studies.

Participants who remained in the study were general positive about the experience of this:

"It was fine by me- I don't mind at all... there have been very good follow-ups."

Interviewee 5, age 69

One carer saw involvement in the study as a way of accessing a follow-up review after leaving hospital care

(other follow-up) "is negligible really in my view but then you think well- you read the state the national health is in- the cost of it and you think I can understand if they are not following up too much because they have enough new patients to contend with.... we had no follow-up" (from other services)

Carer of Interviewee 2, aged 67

One participant commented that he had found it difficult to differentiate between staff who were visiting him to provide his ongoing therapy and rehabilitation, those providing personal care visits, and the research staff:

“All these names I can’t remember- I’ve got so many carers”

Interviewee 3, age 65

These comments concerning motivation for continuing with research studies and difficulty differentiating research staff from clinicians illustrate the potential vulnerabilities of research participants in this area. Careful consideration needs to be given to how participants are protected. This includes practical steps such as rechecking informed consent at each follow-up visit (General Medical Council, 2010). However it also underlines the importance of clarifying roles and avoiding coercion by attending to subtle cues that indicate hesitancy to continue (Kavanaugh, Moro, Savage & Mehendale, 2006).

7.3.2 Location of follow-up visits

Table 17 (p.108) presents data on the location of follow-up visits. Two of the participants were still in hospital at the time of the 3-month follow-up and one at the time of the 6-month review. The remaining participants had left hospital and were given the choice to receive the follow-up appointment in their own home or in an outpatient department. The majority (78% of those seen at 3 months and 87% at 6 months) of participants chose to be seen in the place of their residence (either their own home or their care home). For some this reflected difficulty leaving the house:

“I’m finding it an ordeal to go places really.... I mean the first time I came to see you I didn’t have any pain so it was completely different- I was more my normal self in a way when I came over but now the pain, coupled with the amitriptyline is making it hard...”

Interviewee 6, age 70

The distances travelled in order to conduct home visits were very variable from 1 mile to 84 miles (the average return distance travelled was 15 miles).

7.3.3 Adverse events

At each follow-up visit participants were asked if they had experienced any admissions to hospital, other symptoms or illnesses since they were last seen. Thirteen participants (41%) reported an adverse event at the three-month time-point and five participants (17%) at six months (see Figure 8, p.115). The most frequent adverse events related to falls, chest infections and bowel problems. Nationally it is recognised that stroke survivors are at high risk of falls (Forster & Young, 1995) and chest infections (RCP, 2011) and our findings concur. The study steering group reviewed all the events reported and none were identified as being related to the study.

7.3.4 Summary of participant follow-up

Our sample is not large enough to make predictions of attrition rates but this appears to be in keeping with other studies of people more severely affected post-stroke and, given the high level of disability in participants recruited, any larger study would need to be powered to allow for a relatively high rate of lost to follow-up from mortality. The majority of participants chose to be seen in their place of residence and at interview some commented that this was a factor in ensuring their ongoing involvement. There were a range of reported adverse events but none related to the research study.

7.4 Eligibility and recruitment of carers

The results for recruitment of carers is shown in Figure 9 (p.116).

7.4.1 Eligibility

In this study, participants were asked to identify if they had a carer (at the time of their recruitment into the study), but no specific definition of this was used to inform eligibility. Of the initial 40 participants, 29 identified that they had a carer and gave consent for this person to be approached for their views.

7.4.2 Recruitment

Twenty-five of the participants who had identified that they had a carer were seen at 3 months post-stroke and twenty-two at 6 months. During the feasibility study the process of carer recruitment and consent was conducted as an adjunct to the participants' follow-up visits. When the appointment for the

participant's visit was confirmed by letter the Information leaflet for carers and friends was included along with an invitation to ask them to attend. At the appointment itself the participant was reminded that they had given consent for their carer to be approached, and the carer was then asked if they would like to be involved in the research. If the carer gave consent to be included, the measure of carer burden was conducted at the end of the participants assessment. At the three-month data collection point, 6 carers were present and all consented to being involved in the study. At the six-month point, one of the participants related to one of these carers had died, and one carer was out during the follow-up visit. However an additional three carers of participants consented to be involved at this time point. Therefore a total of nine carers consented to give data during the study. Five of them were female, and four were male. The greatest reason for other potential carers not being recruited is that they were not present during the participant's assessment. It is not possible to know if this was because the potential caring role identified by the participant at the start of study had not come to be, or if the carer did not want to be involved with the research, or if the carer was prepared to be involved but was simply not available at the time agreed with the participant. With hindsight, this method of recruiting carers as an addition to the participant assessment has not been very successful.

At interview carers appeared to consider their involvement most important in terms of supporting the engagement of the person with stroke, rather than providing input in their own right:

"I was perfectly happy (to be approached)- if it helped D and if it helped other people in future... no problems at all"

Carer of Interviewee 1, age 83

This may reflect the development of the study, which is mostly focused on the person with stroke.

7.4.3 Summary of carer recruitment

Ultimately data on carer burden was collected from nine of the twenty-five potential carers identified at the start of the study (for whom participants were followed up). This indicates a recruitment rate of 36% of potential carers. In

other research studies, Mastwyk et al (2002) achieved an 81% response rate when recruiting carers of people with dementia by questionnaire, while Monaghan et al (2009) recruited only 40% of eligible carers of people recently diagnosed with stroke.

Carers who engaged in this project indicated that they found the process positive. However, there was no definition as to what constitutes a 'carer', and this is an area that could be developed. In a recent study of education of carers of pwS (Training of Caregivers after Stroke- TRACS), caregivers were defined as 'the main person, other than health, social or voluntary care provider, helping with activities of daily living and advocating on behalf of the patient' (Forster et al, 2006, p.10). Adopting a formal definition may help add clarity, although it may also bring challenges. There is concern that using language such as 'care' carries connotations about 'caring for' (and a sense of ongoing work) as well as 'caring about' (Open University, 2012). Therefore labeling spouses as 'carers' at an early stage post-stroke and including reference to assistance with activities of daily living may alarm some carers. In the TRACS trial 60% of eligible carers who were approached while their spouse was still an inpatient declined to participate (Monaghan et al, 2009).

An alternative recruitment strategy would be to approach potential carers for consent during the participants inpatient stay and then arrange the carer follow-up appointments in their own right. Generally, recruitment rates from other trials suggest that direct approaches rather than postal invitations give higher recruitment rates (Markgraf et al, 2009). Telephone reminders have also been shown to improve recruitment rates of patients for research (Nystuen & Hagen, 2004) so it would be worth considering whether a telephone call to carers prior to the participants follow-up may increase recruitment.

7.5. Chapter summary

A relatively high rate of recruitment was achieved for participants with stroke who were eligible for this study suggesting that the design is acceptable. Data collected concerning cognitive impairment and communication disability demonstrate that it has been possible to involve people with fairly severe disabilities in these areas. A quarter of people who were eligible were assessed

as not having the mental capacity to make a decision about involvement in the research themselves. Therefore, ten of the participants recruited had a personal consultee who gave assent on their behalf, but developing a robust process of the use of a nominated consultee would enable participants without a close friend or relative to also have the opportunity to engage. The process of follow-up and loss of participants is broadly in line with other studies that have recruited those with the most severe physical disability post-stroke. Conducting home visits was valued by participants and needs to be considered as a means of ensuring future studies in this area achieve the greatest rates of follow-up available. However recruitment of carers was less successful and a number of suggestions for improving engagement with carers for future studies have been made. Qualitative data from both pwS and carers suggests that those who were involved valued the experience of engagement in the research study. In the next chapter, the characteristics of the participants will be considered.

Chapter 8: Characteristics of the sample

8.1 Chapter overview

This chapter relates to the second objective of the feasibility study to review the characteristics of the sample to establish if participants were likely to be representative of the target population. These characteristics include reference to demographic data including age, gender, length of hospital stay, discharge destination and type of stroke. Participants were selected on the basis of being a restricted cohort of people identified as unlikely to regain the use of their arm after stroke. Consequently the characteristics of the sample are not expected to reflect a general population of people after stroke. However data on characteristics in the general population of people after stroke are provided as a reference to highlight the differences in the characteristics of the sample. The chapter also contains a summary of the predictor variables including stroke severity, motor control, spasticity, pain, mood and sensation/perception. A key purpose of feasibility studies is to test procedures, and consider the characteristics and responsiveness of measures (NIHR, 2012). Therefore each predictor recorded is considered with reference to how data was collected, the range of data collected and what participants and carers opinions were of both the process used and perceived personal importance of the predictor.

8.2 Demographic characteristics of the participants

8.2.1 Age, sex and time since stroke

The age and sex of the participants along with comparator data are given in Table 27. Participants in the sample had a similar mean age (73.8 years) to that expected in the broader population of people after stroke (RCP, 2011).

However, the sample contained a greater proportion of women than men (62.5% compared to 37.5%). In the UK fairly equal numbers of men and women are admitted to hospital following stroke (RCP, 2011), but in European studies a greater number of women are affected by stroke than men with rates of 58% compared to 42% found (Kolominsky-Rabas et al, 2001). Gender is not a predictor of poor functional recovery of the arm after stroke (Kwakkel et al, 2003), so the greater proportion of women in the study sample is likely to have occurred by chance.

Participants were recruited to the study at any point between 14 and 32 days post stroke, with a mean of 18.2 days and median of 15 days (Table 19, p.109).

Table 27: Participant characteristics: Age and gender

Characteristic		Value for study sample (n=40)	National benchmarks
Age	(years)	Median: 77.5 Range: 17.75	Mean: 74.8 ^(RCP, 2011)
Sex:	Male	15 (37.5%)	49% ^(RCP, 2011)
	Female	25 (62.5%)	51% ^(RCP, 2011)

8.2.2 Stroke classification

Stroke was classified in two ways: as infarction or haemorrhage; and in relation to the side of the body affected by hemiplegia. Details of the sample characteristics are given in Table 28. Within the study sample 90% of participants had sustained a cerebral infarct and 10% a haemorrhage. This is broadly in line with that expected in a general population of pwS (Rudd, 2009). However, a larger proportion of participants in the sample had a left hemiplegia (62.5%) with only 37.5% presenting with right hemiplegia. This may not be unexpected as people with left-sided signs are less likely to recover functional use of the arm (Malhotra et al, 2011; Kwakkel et al, 2003).

8.2.3 Length of hospital stay and discharge destination

The length of hospital stay of participants and their discharge destination is shown in Table 28. The median length of stay was 43 days, which is significantly longer than that of the general population of people hospitalised after stroke (RCP, 2011). This is not unexpected given that length of hospital stay is correlated with increased stroke severity (Reynolds et al, 2001), and the high degree of disability seen within the sample. The discharge destinations of people leaving hospital showed a similar proportion of people returning home but fewer deaths and a greater number of people transferred to care homes than is found in national data (Portelli et al, 2005). In this feasibility study people who may have been eligible at two weeks post-stroke but who were then receiving care on end of life pathways were not approached, and consequently this may explain the relatively low proportion of people in the study dying while in hospital. Equally, the high proportion of participants moving to nursing homes again reflects the higher level of physical disability of those within the sample.

Higher levels of disability are predictors of the need for institutionalisation (Portelli et al, 2005).

Table 28: Participant characteristics: Stroke classification, length of stay & discharge destination

Characteristic		Value for study sample (n=40)	National benchmarks
Type of stroke	Infarct	36 (90%)	87% (Rudd, 2009)
	Haemorrhage	4 (10%)	13% (Rudd, 2009)
Side of hemiplegia	Left	25 (62.5%)	44% (Foerch et al, 2005)
	Right	15 (37.5%)	56% (Foerch et al, 2005)
Total length of stay in hospital post-stroke	Days	Mean: 49.9 days Median: 43 days Range: 2-200 days	Median: 10 days (RCP, 2011)
Place of discharge from hospital	Own home	23 (57.5%)	55% (RCP, 2011)
	Intermediate unit	2 (5%)	18%
	Residential home	4 (10%)	10% (RCP, 2011)
	Nursing home	9 (22.5%)	
	Died	2 (5%)	17% (RCP, 2011)

8.2.4 Other factors

Twenty-nine of the participants (72.5%) identified that they had a person who they considered to be their carer at the time of their recruitment to the study (Table 29). There is very little data on how many stroke survivors from a general population would be expected to have an informal carer, and definitions of what this constitutes are difficult to ascertain. However in other studies in rehabilitation, Rodgers et al (1999) identified that 86% of pwS in hospital identified that they had an informal carer, and Brocklehurst, Morris & Andrews (1981) found that 55% of people living at home post-stroke were supported by an informal carer. The indications from our sample fit within these potential ranges.

Table 29: Participant characteristics: Other factors

Characteristic		Value for study sample (n=40)	National benchmarks
Presence of carer	Has a carer	29 (72.5%)	Unknown
	Did not have a carer	11 (27.5%)	Unknown
Presence of co-morbidities that affected use of arm prior to stroke	Rheumatoid arthritis	2 (5%)	Unknown
	Previous stroke	1 (2.5%)	Unknown
	Previous spinal cord compression	1 (2.5%)	Unknown
	Concurrent spinal cord compression	1 (2.5%)	Unknown

Ten per cent of the participants stated that they had some reduced function of their affected arm prior to the stroke (from rheumatoid arthritis for 2 people, for spinal cord compression for 1 and from previous stroke for the fourth). In addition, 1 participant was diagnosed with spinal cord stenosis at the time of the stroke.

8.3 The profile of the predictor variables in the study participants

Data on six potential predictors of difficulty caring for the arm after stroke were collected at 2-4 weeks post-stroke. These included stroke severity, motor control, spasticity, pain, sensation/perception and mood. The summary of the profile of predictor variables across the participants is shown in Table 20 (p.110).

8.3.1 Stroke severity

Stroke severity is shown in Table 30. Using the Oxfordshire Community Stroke Project Classification, 45% of the sample participants had been diagnosed with total anterior circulation stroke (TACS) and 10% with cerebral haemorrhage (the most severe diagnoses of stroke), with 22.5% having partial anterior circulation stroke (PACS), 17.5% with lacunar stroke (LACS) and 5% with posterior circulation stroke (POCS). Our sample contains a higher proportion of people with TACS and a reduced number of those with POCS when compared to a general population of people with stroke (pwS) (Bamford, et al, 1991). However

it bears similarities to other studies where those with weak or profoundly-affected arm were recruited (Malhotra et al, 2011, Kwakkel et al, 2003). This is not unexpected given that those presenting with a profoundly-affected arm are more likely to be within the group of people more severely affected by stroke.

Table 30: Stroke severity

Characteristic		Value for study sample (n=40)	National benchmarks
Classification of stroke (Oxfordshire Community Stroke Project)	Total anterior circulation stroke	22 (55%)	15% ^(Bamford et al, 1991*)
	Partial anterior circulation stroke	9 (22.5%)	30% ^(Bamford et al, 1991*)
	Lacunar stroke	7 (17.5%)	22% ^(Bamford et al, 1991*)
	Posterior circulation stroke	2 (5%)	20% ^(Bamford et al, 1991*)
	Cerebra haemorrhage	4 (10%)	13% ^(Rudd, 2009)

* adjusted to account for addition of those with cerebral haemorrhage

8.3.2 Motor control

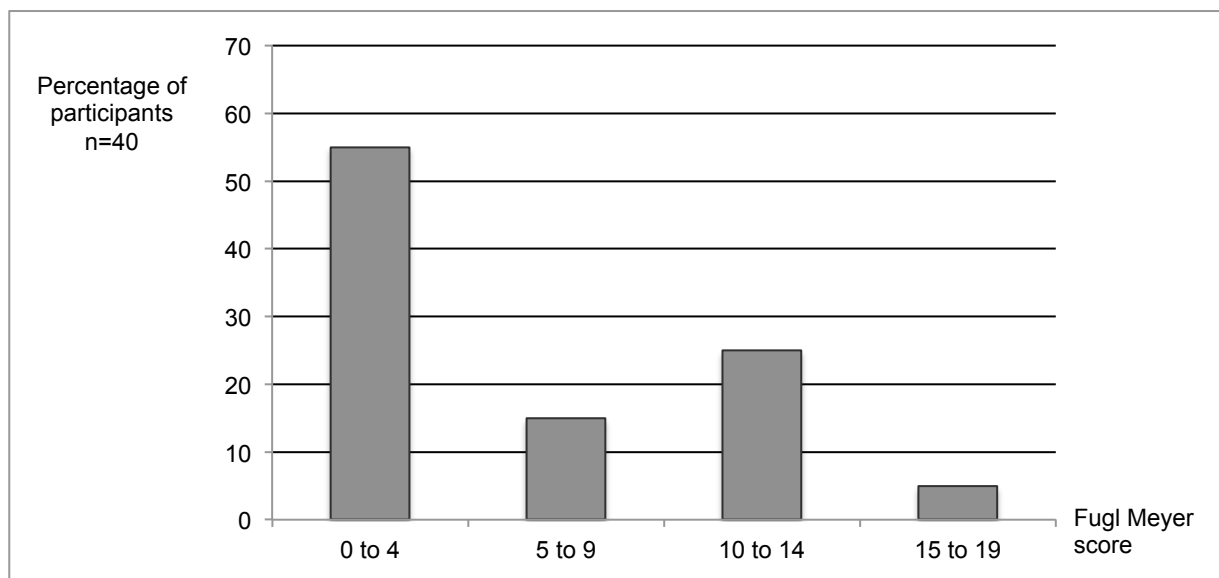
Motor control of the arm was measured using the Fugl-Meyer upper limb assessment. Full data was collected from each participant at baseline. A histogram of the distribution of scores is presented in Figure 12. Participants presented with varying degrees of movement in the arm. Those who scored 4 or lower generally presented with reflex activity only and no volitional movement. Twenty-two of the participants (55%) presented with a score of 4 or less. The remaining 45% of participants had some volitional movement of the arm, although for many this was within synergistic patterns, with little selective control of movement.

At interview participants who had some motor control of the arm commented that this had an impact of daily life:

“It does come out (demonstrates opening the hand)- in the water it comes out and when it’s drying it comes out and the carer can dry it.”

Interviewee 4, age 38

Figure 12: Distribution of Fugl-Meyer scores at recruitment



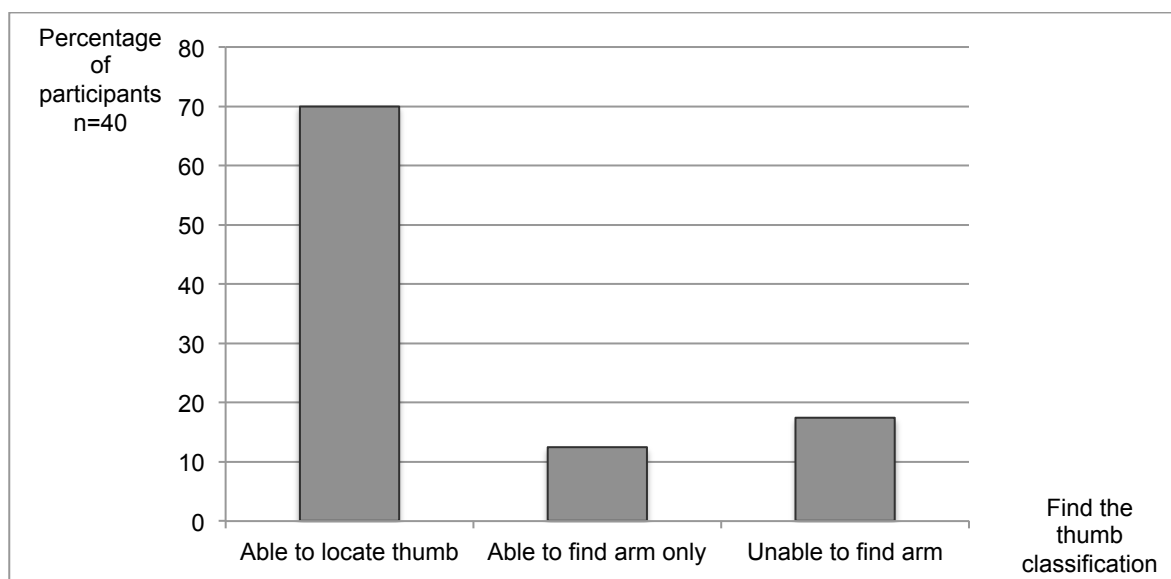
Comments of this nature indicate that participants felt that some degree of motor control influenced the ease of care of the arm, and therefore support the use of a measure of control of movement as a potential predictor of difficulty caring for the arm.

8.3.3 Sensation and perception

Sensation and perception was assessed with the 'Find the Thumb' test, which is sensitive to changes in proprioception (Prescott, Garraway, & Akhtar, 1982) and inattention (Kalra et al, 1997). A summary of the results is in Table 20 (p.110) and a histogram of the distribution of the results is shown in Figure 13. Twenty-eight of the participants (70%) were able to locate the thumb of their affected arm correctly when placed by the side of the body; five participants were able to locate their arm (12.5%) but not their thumb, and seven (17.5%) were unable to locate their arm at all.

There have been relatively few studies that have identified the prevalence of sensory and perceptual loss using this assessment. In studies of proprioception where the affected arm was raised above the head in order to conduct the test 8% of participants were unable to locate their thumb (Prescott, Garraway & Akhtar, 1982). In a study evaluating perception, 6% of a sample of people with left hemiplegia could not find their hand when using the assessment (Bisiach et al, 1986).

Figure 13: Distribution of results of the sensation & perceptual assessment



However in this feasibility study twelve participants (30%) could not find their thumb. The relatively high proportion of participants having difficulty with the assessment may have occurred by chance given the small sample size, or reflect the increased level of physical disability within the cohort but may also be associated with their other disabilities. Table 31 shows the relationship between participants performance on Find the Thumb test and the side of their hemiplegia.

Table 31: Distribution of performance on Find the Thumb Test related to side of hemiplegia

	Participants with right hemiplegia (n=15)	Participants with left hemiplegia (n=25)
Able to locate thumb	7 (17.5%)	21 (52.5%)
Able to locate arm only	4 (10%)	1 (2.5%)
Unable to locate arm	4 (10%)	3 (7.5%)

Of the twelve participants who were unable to locate the thumb accurately, eight presented with right-sided weakness and four with left hemiplegia. If the Find the Thumb test is viewed primarily as a sensory and perceptual assessment there may be expected to be a greater incidence of reduced ability in those with left-sided signs, who are more likely to present with inattention (Bowen, McKenna & Tallis, 1999). However in this sample a larger number of people

with right hemiplegia could not successfully complete the test. The participants with right-sided hemiplegia who were unable to Find the Thumb following the instruction all had aphasia. It is possible that difficulty locating the thumb could be a reflection of difficulty following the instruction given as much as a problem with sensation or perception.

During interviews participants with inattention commented on difficulties at times with perceptual changes:

“The other day I lost it in the van- it went down the side and I couldn’t find it again. I lost it in hospital at lunch when it fell down the chair and everyone was laughing and said lets find G’s arm. I have to hold my sleeve to find it again.”

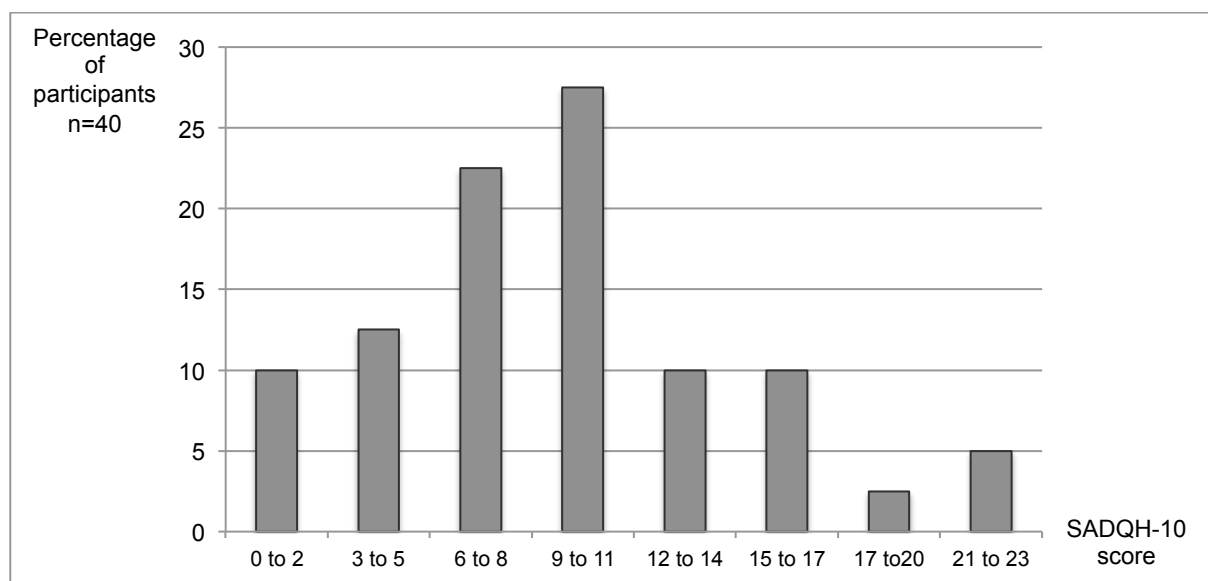
Interviewee 10, age 72

The qualitative data would appear to indicate that sensory and perceptual difficulties can present challenges in caring for the arm and therefore it appears appropriate to include sensation/ perception as a predictor within the study design. However it is unclear if the Find the Thumb test may record difficulties with aphasia and following instructions as well as sensation and perception. There has been no previous research in examining performance on this test in people with aphasia, and this relationship should be explored before Find the Thumb test can be adopted purely as a measure of impaired sensation and perception. Equally Connell, Lincoln & Radford (2008) suggest that different sensory functions are discrete and Find the Thumb test makes no reference to tactile sensation. A more comprehensive assessment of sensation was not used in this feasibility study due to the anticipated difficulties in completing assessments in people with aphasia. However it may be possible to use a more comprehensive assessment of sensation such as the Nottingham Sensory Assessment (Lincoln, Jackson & Adams, 1998) on some of the participants in a larger study. Alternatively there is the potential of using another simpler measure of an alternative sensory function such as use of mono-filaments (Zackowski, Dromerick, Sahrman, Thach & Bastian, 2004) to assess tactile sensation.

8.3.4 Mood

Mood was assessed at baseline using the Stroke Aphasic Depression Questionnaire Hospital version-10 (SADQH-10). A summary of the results is in Table 20 (p.110) and a histogram of the distribution of participant's scores on the SADQH-10 is shown in Figure 14. A range of scores were recorded from 0 to 23 and the data appears to be normally distributed with a mean score of 9.0 and a median score of 9.2. SADQH-10 was originally designed as a continuous measure but Bennett & Lincoln (2006) originally identified that a score of 6 or greater may indicate an increased risk of depression and this cut off is recommended for identifying risk of depression in clinical practice (Gilham & Clark, 2011). Studies that have used this measure typically identify rates of depression of about 32% in a general population of people with acute stroke (Hacker, Stark & Thomas, 2010). However scores for SADQH-10 for the participants in this study indicate potential rates of depression of over 75% (31 of the participants).

Figure 14: Distribution of scores on the SADQH-10 at baseline



It is possible that rates of depression are much higher within this sample as depression is related to stroke severity (Vataja et al, 2004). However a review of the scores of individual items of the measure may offer an alternative explanation of the relatively large number of higher scores seen. Eleven of the participants scored 2 or 3 on the SADQH-10 item regarding maintaining eye contact with staff (where a higher score indicated that the person made less eye

contact, a behavior related to greater risk of depression). However all of these participants had a degree of inattention, which affected their ability to maintain eye contact, which may account for this behaviour, rather than depression. Equally the majority of participants in the sample scored highly on the items 'Does he/she sit without doing anything?' (where less activity gave a higher score) and 'Does he/she keep him/herself occupied during the day?' (where being less occupied also gave a higher score). As a large number of participants in the sample were quite severely disabled they were frequently very fatigued and less able to participate in every day activities. In this feasibility study participants often scored highly in these areas and hence were given high scores on the SADQH-10 even when they remained relatively well engaged with staff and in rehabilitation programmes, and were not perceived to be depressed by the multi-disciplinary team.

For these reasons the SADQH-10 may record a higher number of false positive assessments of people who are depressed post-stroke if the original cut-off of 6 is used. However this is likely to be the case with many observational tools, and use of more sophisticated questionnaires would exclude many of the participants with more severe cognitive or language problems from taking part. A number of the participants and carers interviewed stated that they felt that mood and psychological state did have an impact on recovery and use of the arm:

"She's not one for self pity.... Very occasionally she's had a little tear and said 'why me' but apart from that she just gets on with it ... everyone that's seen her has been a little surprised at how good her recovery has been- that is down to her- she's very brave and she just gets on ... I would imagine a lot of people in her position would give up."

Carer of Interviewee 2, age 67

"I've lost interest... this is what gets me down- I feel I'm too fatigued to go and do a meal I just feel rotten... I do exercises but I never see any benefits from them."

Interviewee 6, age 70

In summary, participants with stroke and carers interviewed supported the concept that mood could impact on recovery and use of the arm, and supported the assessment of mood as a potential predictor of difficulty caring for the arm. The SADQH-10 was used to collect data concerning all 40 participants and recorded a range of scores. However the traditional cut off of 5-6 points being used to indicate a higher chance of depression may not be relevant in this group and it may be better to treat the data as continuous as originally devised.

8.3.5 Spasticity at baseline

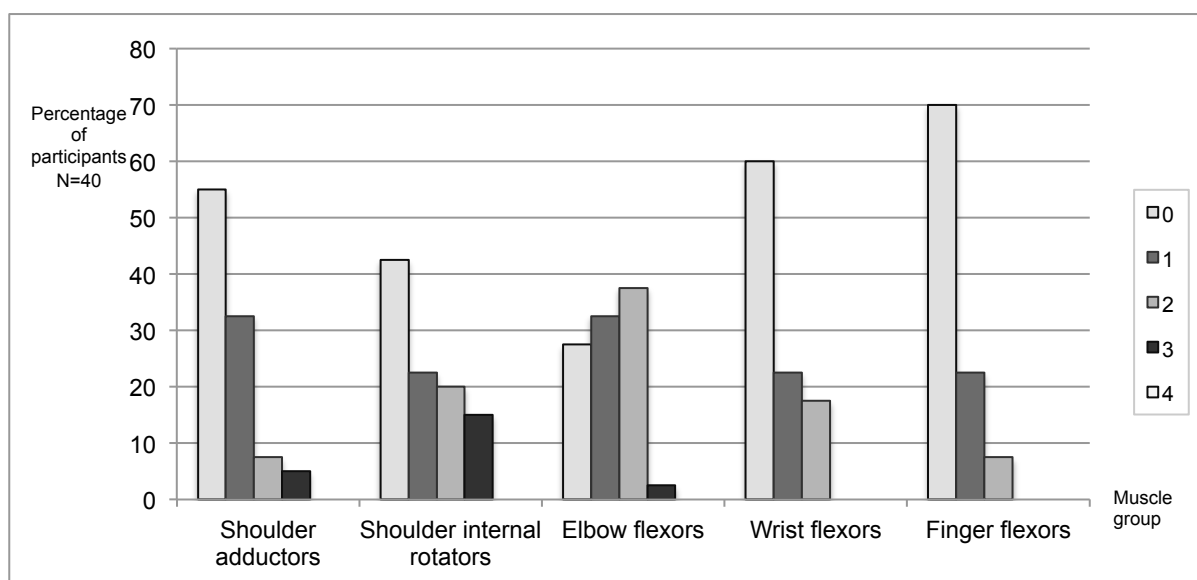
Spasticity was assessed using the Modified Modified Ashworth Scale (MMAS) rating the resistance to passive movement of the arm within five muscle groups (Ansari et al, 2006). It was possible to obtain measures of spasticity for all participants for all of the selected muscle groups included in the assessment, indicating that the assessment was acceptable at this time-point. Data were analysed in two ways. Firstly in terms of the highest spasticity score that occurred in any muscle group in each participant, and secondly with regard to the distributions of the spasticity scores for each muscle group. A score of 0 on the MMAS indicates no spasticity, and a score of greater or equal to Grade 1 indicates some degree of spasticity, with scores of Grade 4 indicating rigidity.

A summary of the highest MMAS score in any of the muscles groups in the arm is included in Table 20 (p.110). At baseline, 10% of the sample did not have spasticity in any muscle group assessed in the arm, 37.5% had spasticity as indicated by Grade 1 on the MMAS in at least one group, 35% had Grade 2 and 17.5% had Grade 3. None of the participants had spasticity at Grade 4 at this time point. These incidences are higher than those found in many of the studies included in the systematic review in Chapter 4 which reported the highest Ashworth score in any muscle group (de Jong et al, 2011; Lundstrom et al, 2010; van Kuijk et al, 2007). However, this may not be unexpected given the sample in the feasibility study contained people with a higher degree of motor disability.

The distributions of the spasticity scores for each muscle group at baseline are shown in Figure 15. With the exception of the elbow flexor group, the distribution of MMAS scores in each muscle group was linear, with the highest

number of scores at each joint being 0, then 1, and so on. This pattern is in keeping with the expected development of spasticity, where muscles will often initially present as flaccid post-stroke with spasticity gradually developing over time (Kong et al, 2012). The distribution of MMAS scores within the elbow flexor group demonstrated a different pattern with higher incidences of more marked spasticity and 37.5% of participants experiencing spasticity graded at level 2. It is unclear if this is purely due to chance, although the elbow is a joint which seems more predisposed to developing spasticity than the shoulder and fingers (Kong et al, 2012).

Figure 15: Distribution of MMAS scores at each muscle group in the arm at baseline



In summary, it was possible to collect data from all muscle groups of all participants and to record a range of MMAS scores (with the exception of Grade 4). A further review of the use of the MMAS as an outcome measure, and qualitative data collected about its use will be included in Chapter 9.

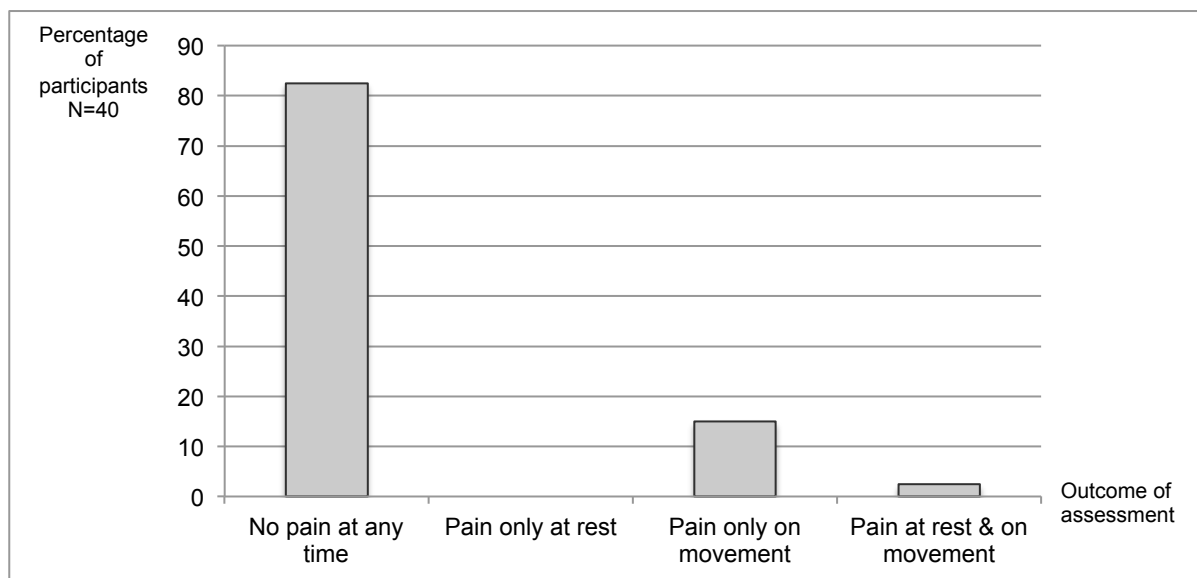
8.3.6 Pain

Pain was recorded during the physical assessment conducted at baseline. At the beginning of the assessment participants were asked if they had any pain while they were at rest. The researcher then recorded if the person expressed pain during any part of the physical examination. Thus there were four potential categories to record pain: no pain at any point; pain only at rest; pain only on

movement; or pain at rest and on movement. At the baseline assessment three of the participants were not able to respond to the verbal question, gesture, or pictographic resources to indicate if they had any pain. These three participants had the most severe impairments of communication and were not able to produce any words or sounds to indicate their feelings. The remaining participants were all able to respond in some way to the resources provided to indicate the presence or absence of pain. For the participants who were unable to respond to the resources the researcher consulted with family and carers who were present and these individuals indicated whether they perceived the person was in pain at rest or during movement of the arm. However the validity and reliability of carers providing proxy assessments of pain has not been formally assessed. In other areas of health, such as care of people with dementia, behavioural assessments of pain have been developed. These include the Pain Assessment in Advanced Dementia Scale (PAINAD) (Warden, Hurley & Volicer, 2003) and the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (Fuchs-Lacelle & Hadjistavropoulos, 2004), both of which have been recommended for use in older people. However neither has been validated with people with aphasia (Herr et al, 2010), although PAINAD was used in a recent study of people with spasticity in care homes (Lam et al, 2012). Further work needs to be conducted to either validate the use of family and carers indications of pain, or to develop a new or evaluate an existing behavioural scale for use with people with severe aphasia in this group.

The results of the data on pain that were collected are shown in Figure 16. Over eighty percent of participants reported being pain-free in the arm at the time of the initial assessment. Six of the participants (15%) reported pain on movement but not at rest with the remaining participant reporting pain on both movement, and at rest. Incidences of pain in the sample appear very low when compared with the studies of people with arm weakness included in the systematic review (Roosink et al, 2011; Zorowitz et al, 1996).

Figure 16: Distribution of participants' pain during baseline assessment



The sample is relatively small which may account for this difference. Equally the studies included within the systematic review generally considered whether the participants had experienced pain over the preceding days rather than at one specific time point. The measure used of pain, will be discussed further in Chapter 9, where it's use as an outcome measure will be reviewed.

8.4 Chapter summary

In summary, the baseline demographic characteristics of the forty participants recruited to the study largely appear to reflect what may be expected in a group of people more severely affected by stroke. It was possible to collect data on the six predictor measures from almost all of the participants, and each scale collected a range of data. Participants' comments at interview supported the choice of motor control, mood and sensation/perception as predictors of difficulty caring for the arm.

However, it is possible that for this cohort of stroke survivors some of their disabilities (including inattention) may lead to higher scores on the SADQH-10, and the relationship between the 'Find the thumb test' with aphasia requires further exploration prior to adoption of the measure for a larger study.

The dichotomous response could not be utilised in three of the participants. Further work is required to consider assessment of pain in those with most severe communication disability. As measures of both pain and spasticity were

also included as outcomes, there will be a further review of these measures in Chapter 9. In the next chapter the data collected from the outcome measures of impairment will be considered.

Chapter 9: Impairment in the profoundly-affected arm

9.1 Chapter overview

This chapter contains an analysis and discussion of the results of the outcome measures that were associated with the ICF (WHO, 2001) concept of impairment. These outcome measures related to spasticity, pain, range of movement, and skin integrity, the majority of which were based on physical examination. In addition the full subjective questionnaire related to quality of life contains one question concerning body image, which is considered in this chapter. This chapter relates to the third objective of the feasibility study, to establish the acceptability and responsiveness of the outcome measures. Therefore, each of the outcome measures is considered with reference to how much data was collected as an indicator of the acceptability of the measure, and the distribution of data collected and trends over time as indicators of the responsiveness of the measure. In accordance with the recommendations of the MRC Complex Interventions Framework, statistical analyses of the outcome measures are not explored at this time, since the feasibility study was not powered to detect significant changes. Qualitative data from interviews is used to ascertain more detailed feedback from participants of the outcomes, and to establish whether the impairments that were identified in the original model of the profoundly-affected arm (Figure 1, p.32) were relevant and if any other impairment should be considered in a larger study.

9.2 Spasticity

Spasticity was assessed in five muscles groups in the arm using the Modified Modified Ashworth Scale (MMAS) (Ansari et al, 2006) at baseline, and at three and six months post-stroke.

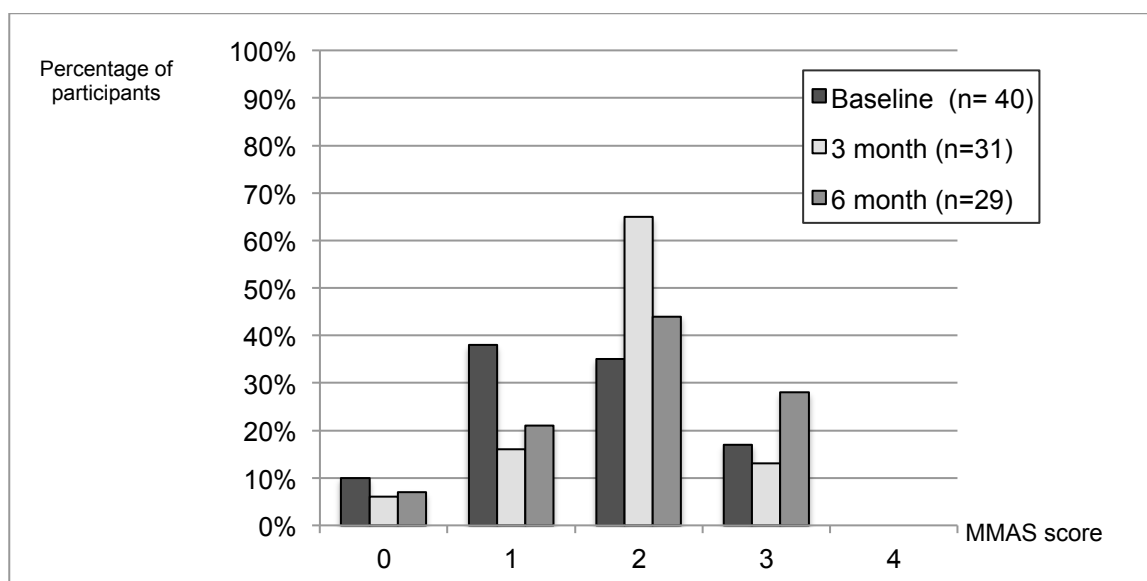
9.2.1 Extent of data collected

During the feasibility study it was possible to record measures of spasticity in each muscle group at each time-point for each participant seen, with the exception of two participants at the 3-month assessment. One of these participants indicated that he was in too much pain to have any physical measures conducted and one (who also had a learning disability) declined to let the researcher conduct the MMAS on his shoulder adductors, shoulder internal rotators, and wrist flexors. Therefore, in total 97% of the total potential measures of spasticity in the arm at 3 and 6 months were recorded.

9.2.2 Distribution of data collected

Distribution of MMAS scores are considered with reference to the highest score recorded in any muscle group of the arm at each time-point and with reference to the presence of each grade of spasticity in each muscle group at each time-point. Figure 17 shows the incidence of the highest level of spasticity in the arm in any muscle group at each time-point during the study.

Figure 17: Profile of the incidence of the highest level of spasticity in any muscle group during the study



The data indicate there were a number of participants at each time-point who did not experience any spasticity in any of the muscle groups assessed. However there were at least 90% of participants at any time-point where there was some spasticity in at least one muscle group. At six months post-stroke 28% of participants had severe spasticity (as characterized by MMAS score of 3 or more) in at least one muscle group in the arm. Incidences of severe spasticity in the arm are 8% at six months in a population of all survivors post-stroke (Lundstrom et al, 2010) and 38% at one year of people who required rehabilitation (Kong et al, 2010). No participant in this study was assessed as having spasticity at Grade 4 (classified as rigid) during this study. This is not unexpected as the incidence of this severity of spasticity is relatively rare: Urban et al (2012) found that 4% of those with arm spasticity had this to Grade 4 on the Modified Ashworth Scale at six months post-stroke, and Kong et al (2010) found an incidence of 2% at 1 year. Figures 18 to Figure 22 present data on the profile of spasticity in each of the muscle groups assessed.

Figure 18: Profile of spasticity in shoulder adductors

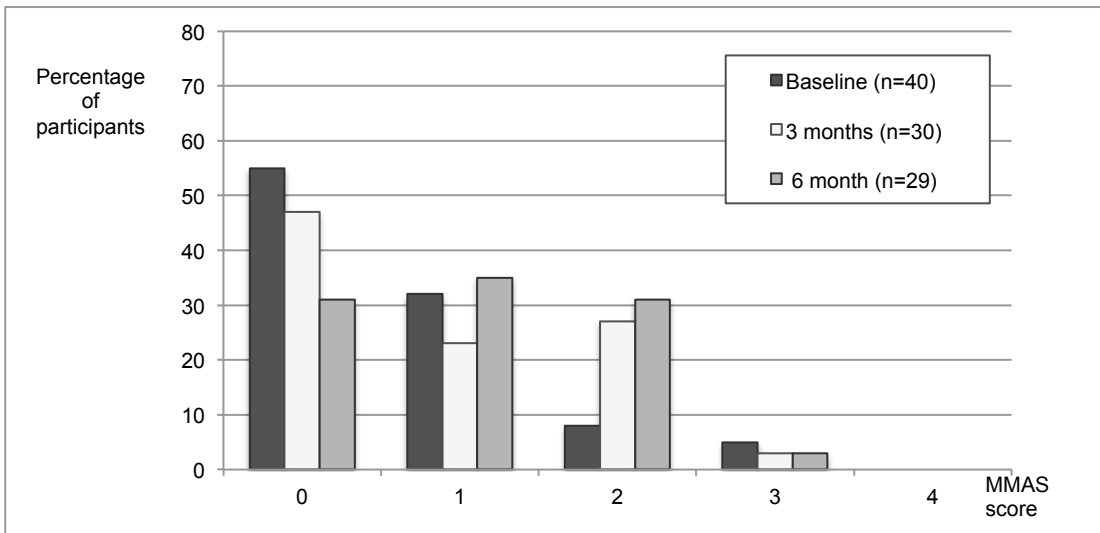


Figure 19: Profile of spasticity in shoulder internal rotators

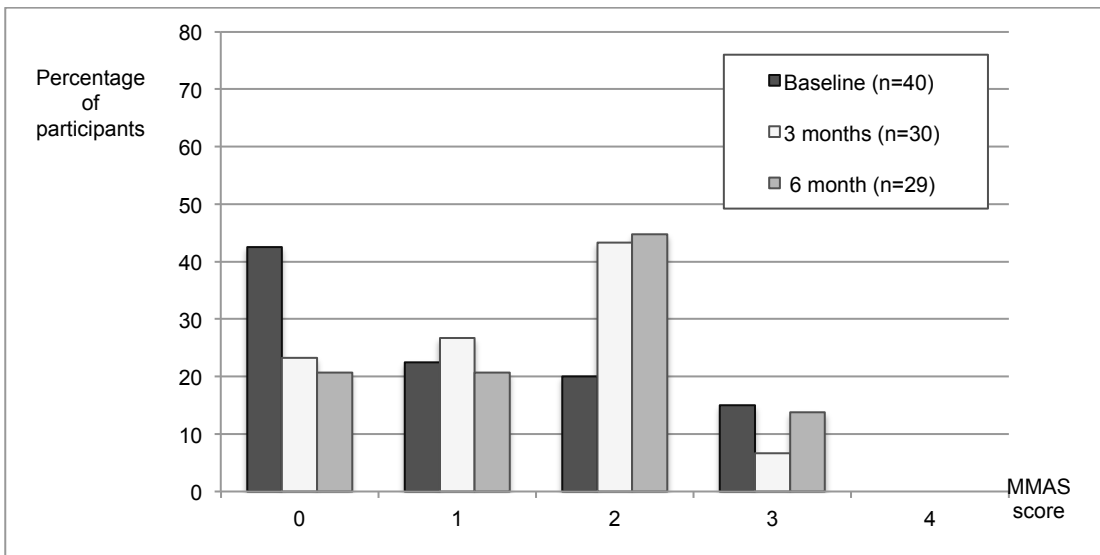


Figure 20: Profile of spasticity in elbow flexors

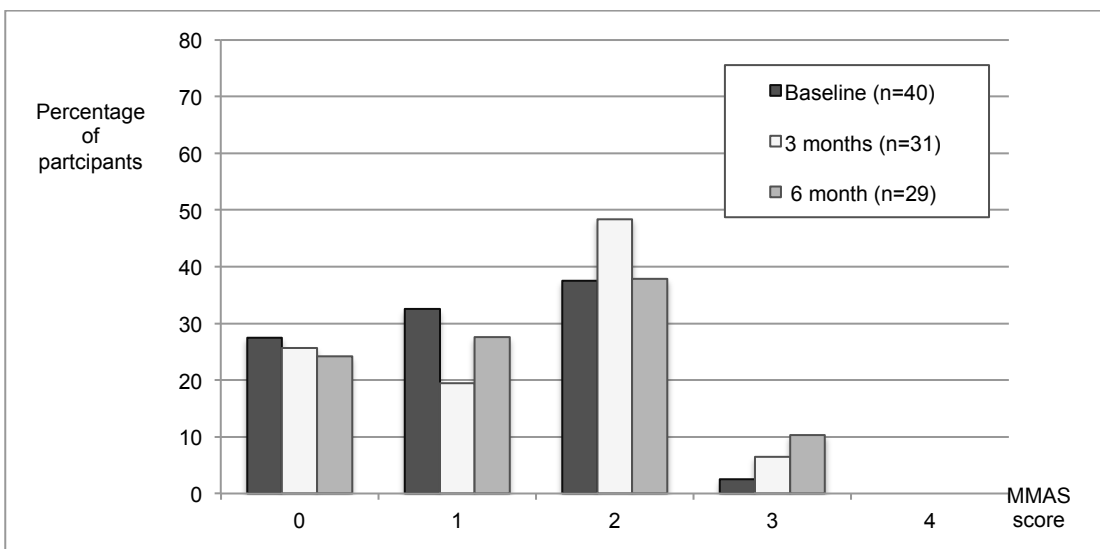


Figure 21: Profile of spasticity in wrist flexors

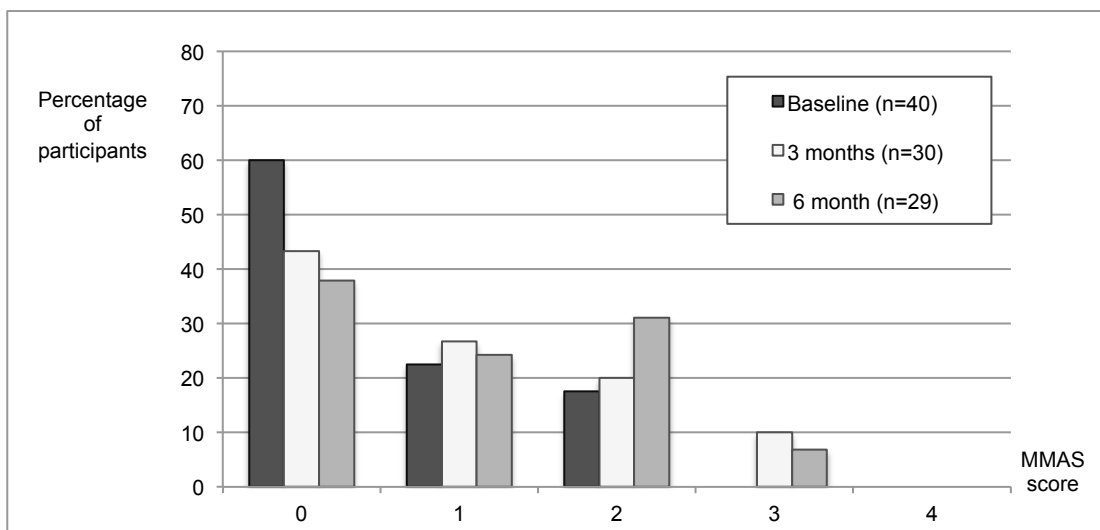
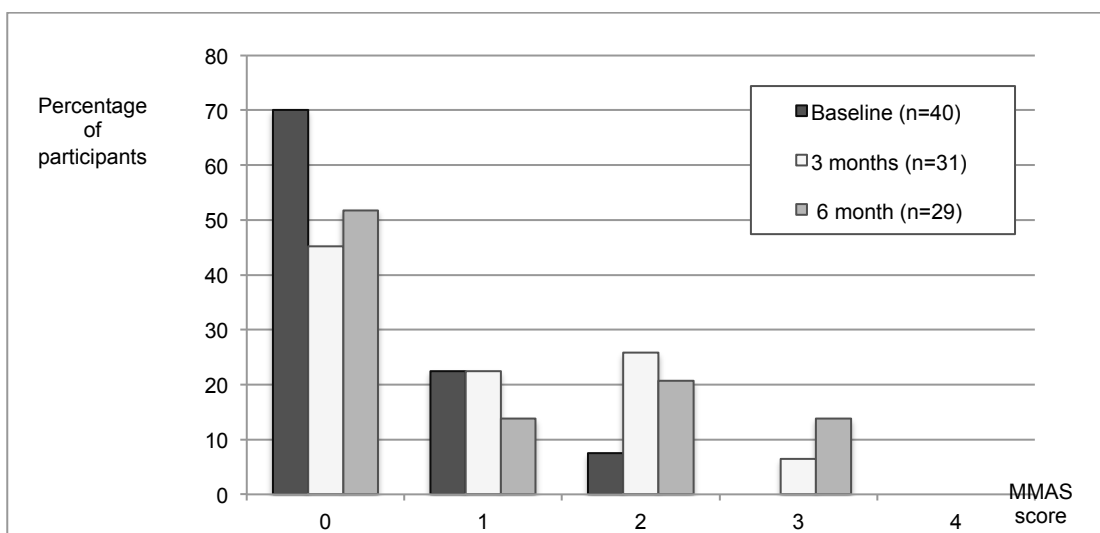


Figure 22: Profile of spasticity in finger flexors



There is a trend for the proportion of participants who develop spasticity to generally increase over time. This is in keeping with findings of other studies (Kong et al, 2012; de Jong et al, 2011). However, for those exhibiting spasticity there is no apparent pattern to how the severity changes over time. This may be a consequence of the relatively small numbers of participants receiving follow-up in this study but it may also reflect the dynamic component of spasticity which may vary under the influence of both intrinsic and extrinsic factors (Barnes, 2008).

9.2.3 Qualitative data concerning the impairment and its measure

Nine of the participants and carers who were interviewed spontaneously made

some reference to the presence of muscle stiffness in the arm. For two participants this related to relatively mild signs of increased tone such as occasional involuntary gripping of the hand and muscle spasm:

“My arm jumps when I hear a loud noise.”

Interviewee 10, age 72

“She has one slight problem, when she’s out with me and holding onto me she has like a spasm- she keeps doing that (demonstrates making a fist) on my arm- it’s rather painful... it seems to be involuntary..... occasionally I’ll see her sitting there and she’ll have the odd twitch if you like or spasm.”

Carer of Interviewee 2, age 67

Other participants experienced more severe muscle stiffness and commented on the difficulty opening the hand at all:

“I can’t get it open (of hand)- I’ve just accepted it. Sometimes it’s difficult and sometimes it’s impossible.”

Interviewee 3, age 65

“At times it’s a bit stiff to open the hand... we go swimming on a Thursday with a very good instructor who’s been doing a lot of work on her hand- and he really has to struggle to get the hand extended -it takes quite a long time for him to get those fingers out- once you work on it or someone works on it for you it loosens up.”

Carer of Interviewee 4, age 38

A number of participants and carers identified that the stiffness was quite variable day to day:

“No day is the same – some days we can’t straighten- when we stretch her fingers out- some days she can only go that far (gesture to show semi-clenched hand) and can’t get them right out... It’s random really- there’s no pattern.”

Carer of Interviewee 8, age 59

As previously discussed, it is well recognised that the presentation of spasticity can be quite dynamic and may vary dependent on posture, activity, sensory

input, external stimuli or internal changes such as bladder and bowel function (Barnes, 2008).

9.2.4 Summary

The large amount of data collected appears to indicate that the MMAS was an acceptable measure to use for the majority of participants. The range of values of these results appear to indicate it was able to detect a range of presentations of stiffness within the participants, but that this presentation may be quite dynamic over time. The comments made by people with stroke (pwS) and their carers would suggest that this stiffness and the impact it has on daily living is very relevant to them. Consequently although there is ongoing debate about whether measures of resistance to passive movement are valid measures of the neural component of spasticity, the use of the Modified Modified Ashworth Scale as a measure of muscle stiffness within the construct of spasticity and hypertonia appears to be appropriate.

9.3 Pain

Pain was recorded with a yes or no response to pain at rest and then on passive movement at baseline, and at three and six months post-stroke.

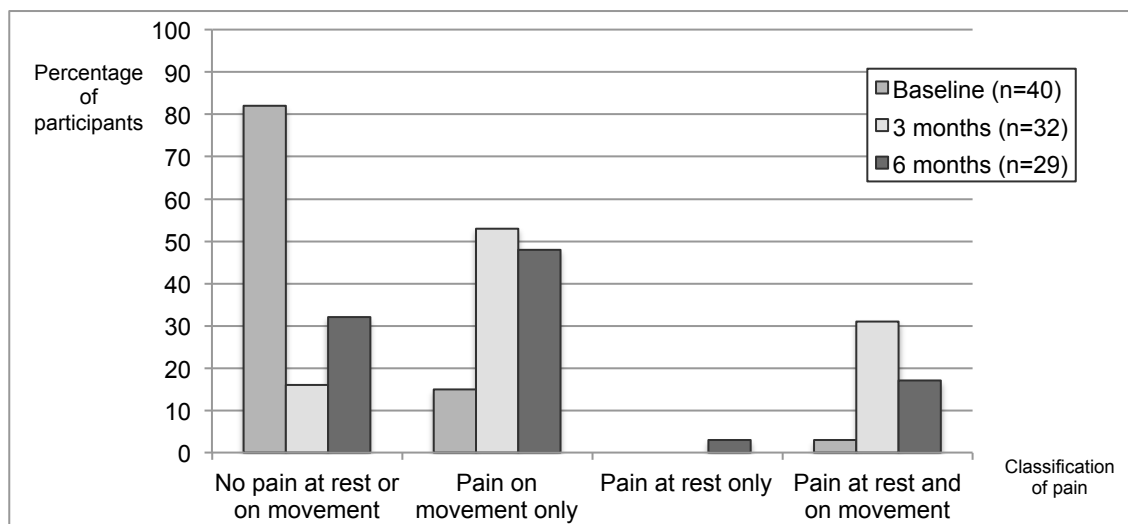
9.3.1 Extent of data collected

As previously discussed (Section 8.3.5) there were three participants who were unable to indicate if they had pain even using the communication resources available at baseline. This difficulty continued for two of the participants throughout the study, and the third participant died prior to the 3-month follow-up point. For the two participants who were unable to indicate if they experienced pain a proxy decision on the presence of pain was made in conjunction with their carer. The remaining participants were all able to indicate an opinion at three and six months. In total 93% of the total potential measures of pain in the arm at 3 and 6 months were recorded from participants report. The remaining 7% were collected from proxy report.

9.3.2 Distribution of data collected

Figure 23 summarises the incidence of pain at each of the time-points during the study.

Figure 23: Profile of pain at each time-point



The responses of participants indicate that although over 80% of participants had no pain at baseline, pain was highly prevalent at follow-up with 84% of participants reporting some pain at 3 months, and 68% at 6 months post-stroke. These incidences are higher than the incidences of pain identified in the systematic review (Chapter 4). It could be argued that this study has adopted a more liberal means of identifying pain leading to higher incidences detected at follow-up but this seems unlikely given the low incidence of pain detected at baseline using the same method. Lord et al (2010) argue that pain is frequently underestimated post-stroke and may be a more significant issue than currently recognised. There does not appear to be any specific trend to how pain changed over the two follow-up time-points. This is in keeping with other studies where pain was found to be a very dynamic construct (Lindgren et al, 2012; Hadianfard et al, 2008).

9.3.3 Qualitative data concerning the impairment and its measure

The majority of participants who were interviewed reported that they had experienced pain at some point during the study period and for some this had been a very negative experience:

“On the television they show the stroke and the paralysis- no mention of pain-it was a shock to us to find that there was so much pain involved- I mean she is fairly well covered with the different painkillers now but at one time there was such a lot of pain...”

Carer of Interviewee 5, age 69

A number of participants associated the occurrence of pain with the position of the arm, or the amount of movement they had put the arm through:

“I have pain all the time. sometimes it depends on where I put it to rest the arm- usually I put it quite close to me and that’s comfortable area to have it.”

Interviewee 4, age 38

“It’s killing me the next day if I’ve overdone it.”

Interviewee 3, age 65

“In the evening it seems to hurt more- mornings aren’t quite so bad- when I’m tired is when it hurts more.”

Interviewee 5, age 69

The binary method of recording pain appears to have been fairly sensitive as it identified a significant number of people with pain. However, one carer indicated that he felt anyone would be likely to feel pain towards the end of some passive movements:

“She’d say ‘oh yes that’s giving me pain’ but I thought well anyone who attempts to do that gets pain anyway- you try doing things like that yourself (moving the arm into external rotation) – it starts to hurt me.”

Carer of Interviewee 2, age 67

However, all of the other participants and carers who were interviewed indicated that they found the method of pain assessment acceptable. Some of the participants did not report much pain at the interview when it had been apparent during their earlier assessments. Occasionally carers would remind participants that pain could be difficult for them:

“But then it does ache- at night- it does ache doesn’t it- that’s why we take the sling and your splint off, and take the paracetamol.”

Carer of Interviewee 8, age 59

9.3.4 Summary

The comments of pwS and their carers who were interviewed indicate that pain in the arm can be a significant issue post-stroke for this group, and is highly

relevant to consider in research of this nature. The binary measure chosen was largely acceptable to participants, and collected a range of responses. It was possible to use the measure as designed for the feasibility study with 93% of the participants. However it was not possible to use this method with three participants at baseline, and two participants throughout the remainder of the study. A proxy measure agreed with their carer was used for these participants but more work is required to establish the validity of this approach, or, as discussed in Chapter 8 to develop or validate an existing behavioural pain scale on people with aphasia.

9.4 Range of movement

Range of movement was measured at the shoulder (flexion, abduction and external rotation), elbow (flexion and extension), wrist (extension), index and 4th finger and thumb (extension at each joint) at three and six months post-stroke. A summary of the data collected is shown in Table 22 (p.113).

9.4.1 Extent of data collected

It was possible to record range of movement at each time-point for each participant, with the exception of the two participants identified in Section 9.2.1 as not completing all the physical measures due to pain or declining assessment. In total 97% of the total potential measures of range of movement in the arm at 3 and 6 months were recorded.

9.4.2 Distribution of data collected

The summary data shows that for all the measures of the shoulder, elbow and wrist a range of values were evident in participants (Table 22, p.113). However, for measuring extension in each of the finger joints, the majority of participants were measured as having full range of movement. Previous studies of contracture in the arm post-stroke have focused on the wrist (Malhotra et al, 2011; Pandyan et al, 2003), so the incidence of changes in finger range of movement is not known. For the purposes of this thesis contracture was defined as 'functionally significant loss of joint range' (Kwah et al, 2012). Other research suggests that the course of the development of contracture is fairly linear over time (Pandyan et al, 2003), with a gradual reduction in range of passive movement until the degree of loss stabilises. However the data collected in this

study are at odds with this expectation. The data on range of shoulder external rotation and wrist extension are used to demonstrate this and are given in Table 32, where only data for those participants who completed measures at both time-points are included. The table contains the measures taken at each time-point, and the net differences. The data indicates that while some participants have lost range of movement over the two time-points (and potentially developed a degree of contracture), just as many participants have gained range of movement. The process of the development of contracture would normally be expected to be linear but the findings of this feasibility study are at odds with this and there may be a number of reasons to consider. These include the impact of pain on range of movement, and the more general reliability of the measure, each of which will be discussed in turn.

Table 32: Measures of shoulder external rotation and wrist extension at three and six months post-stroke

Participant (only those with completed measures are included)	Shoulder ext. rot. at 3 months (°)	Shoulder ext. rot. At 6 months (°)	Change in shoulder ext. rot. (°)	Wrist extension at 3 months (°)	Wrist extension at 6 months (°)	Change wrist extension (°)
1	20	30	10	60	60	0
2	-10	5	15	0	-10	-10
3	30	40	-10	30	60	30
4	30	20	-10	50	50	0
5	40	40	0	10	30	20
6	50	40	-10	60	60	0
7	-25	15	40	20	20	0
11	0	40	40	50	40	-10
12	-10	-25	-15	20	30	10
13	65	45	-20	55	45	-10
16	25	25	0	5	-10	-15
18	30	30	0	50	30	20
20	25	20	-5	40	40	0
21	35	20	-15	50	40	-10
22	40	40	0	50	55	5
24	30	20	-10	20	15	-5
25	20	30	-10	20	10	-10
27	20	-10	-30	40	30	-10
28	25	45	20	50	60	10
30	25	15	-10	20	5	-15
31	40	45	5	30	30	0
34	15	20	5	20	30	10
35	30	25	-5	40	50	10
36	40	40	0	40	50	10
38	30	20	-10	40	50	10
39	30	30	0	45	60	15
40	20	20	0	60	80	20

There have been two other studies of the incidence and time course of contracture at the wrist. Pandyan et al (2003) included 14 participants with non-functional arm and Malhotra et al (2011) studied 25 participants. Pandyan reported that measures of passive range of movement at the wrist were taken within a pain-free range but Malhotra's protocol was not clear on this. Both studies reported a mean decrease in passive movement, although Pandyan et al (2003) referred to a trend for this, indicating this was not a universal finding.

As discussed in Section 5.4.3 variations in range of movement were seen when testing the method. In both the preliminary work and during this feasibility study it appears that differences of up to 20 degrees of movement may occur as a result of measurement error. The preliminary work showed that there was more likely to be a difference in measurement range when the participant experienced pain. De Winter, Heemskerk, Terwee et al (2004) made similar findings in the amount of error when measuring patients with musculoskeletal disorders causing shoulder pain. In section 9.3 data showed that 84% of the participants experienced pain on passive movement at three months, and 65% at six months post-stroke. It may be that measuring the construct of range of movement as limited by pain should be seen as a more dynamic construct than measuring contracture. Alternatively it may be that the method of measuring range of movement in this way is less reliable than previous work has suggested. This may warrant further investigation. Clinicians need to consider that differences of up to 20 degrees particularly in people with pain may be due to error rather than showing a clinical meaningful change.

9.4.3 Qualitative data concerning the impairment and its measure

At interview one participant who had apparently lost a significant degree of passive range of movement in the arm was included. Her comments indicate that contracture has significant consequences:

“Everything is difficult because I can't open my fingers out.”

Interviewee 5, aged 69

9.4.4 Summary

In summary, the high proportion of data collected would appear to suggest that measuring range of movement in this way was acceptable to the participants. However the distribution of data collected suggests that either the range of passive movement available on a given day may be quite dynamic (potentially influenced by pain) or the method of measurement is not reliable. Further work is required to both clarify the reliability of the measure and to explore the natural course of changes in passive movement in the arm post-stroke.

9.5 Skin integrity

Skin integrity was assessed at three and six months post-stroke, using a nominal scale with skin condition classified as 'dry and intact', 'macerated', or having a 'pressure area'.

9.5.1 Extent of data collected

It was possible to collect classifications of skin condition for every participant at each time-point seen.

9.5.2 Distribution of data collected

For all the participants skin condition was rated as 'dry and intact' at each point. Whilst it is recognised that severe spasticity in the profoundly-affected arm can cause difficulty with hand hygiene and tissue breakdown (RCP, 2009), the incidence of this is not known. It is possible that the proportion of people who may develop macerated skin or tissue breakdown may be too small to detect within this small sample, or that these difficulties are more likely to develop beyond 6 months post-stroke.

9.5.3 Qualitative data concerning the impairment and its measure

At interview none of the ten participants interviewed identified any difficulty with their skin integrity, although one carer noted some changes in overall skin condition:

“That arm feels different- it feels completely different- the skin and the texture- I don't know if it's because it's a bit more swollen.”

Carer of Interviewee 10, age 72

9.5.4 Summary

Data on skin condition were collected from every participant at each time-point so the outcome measure appears highly acceptable. A larger sample and longer period of data collection would be required to develop assurance that the classification used within the feasibility study is responsive.

9.6 Body Image

A formal specific measure related to participants perceptions of the appearance of the arm was not used in this study as, to date, there are no measures that have been developed for use in this area with people after stroke. However, the measure of quality of life (Subjective Index of Physical and Social Outcome SIPSO) contains one question related to the respondents' feelings about their appearance: 'Since your stroke, how do you feel about your appearance when out in public?' (Trigg & Wood, 2000). The question has five categories of response ranging from 'perfectly happy' to 'I try to avoid going out in public'.

9.6.1 Extent of data collected

There were four of the thirty-two participants at the 3-month time-point and three of the twenty-nine remaining participants at 6 months who could not attempt to answer this questionnaire due to their aphasia. Where people are unable to complete the SIPSO themselves, proxy completion by a carer has been shown to have good validity and reliability (Trigg & Wood, 2003).

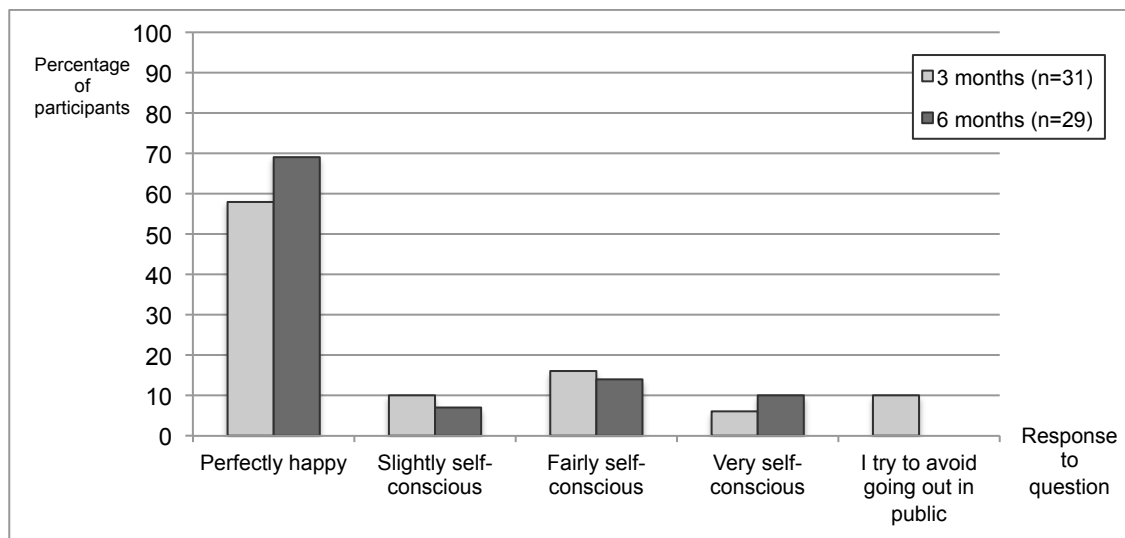
Therefore for the participants who were unable to respond a carer completed the question on their behalf. Therefore it was possible to collect data for this question from 89% of the participants themselves, with data for the remaining 11% from proxies.

9.6.2 Distribution of data collected

The responses of the participants to this specific question are given in Figure 24. The data they provided show a range of responses. Although the majority of participants indicated that they were 'perfectly happy' with their appearance, a significant number (42% at 3 months post-stroke and 31% at 6 months) indicated that they felt self-conscious to some degree or avoided going out. There was a slight trend between the two time-points for participants to become

less self-conscious with time, which corresponds with the findings of qualitative studies of body image after stroke (Kvigne & Kirkevold, 2003).

Figure 24: Participants responses to the SIPSO question concerning their perceptions of their appearance



9.6.3 Qualitative data concerning the impairment and its measure

At interview participants and carers were asked if they perceived there were any issues about the appearance of the arm. The majority of the participants interviewed (eight) indicated that they had no concerns about the appearance of the arm (or themselves in general). However two of the female participants who were interviewed commented that they felt embarrassed about how they looked:

“When I go out - I put a rug over me to hide over my left arm.”
Interviewee 5, age 69

Kvigne & Kirkevold (2003) also found that women with arm contracture post-stroke commented on this as a source of stress when meeting new people. The other participant who expressed concern about her appearance did not relate this to the physical appearance of their body, but appeared to comment more in relation to how she perceived the loss of her former self:

“I don’t feel that I’m normal... the way I look- that’s how I want to be again (gestures to a photograph of herself pre- stroke).... But I don’t worry about this one at all (gestures to arm with sling and splint).”

Interviewee 8, age 59

Kvigne & Kirkevold (2003) related how stroke survivors who did not have a changed appearance still perceived that their body appeared different and 'unbalanced' (p.1304). It is apparent from the responses to this particular question that a number of the participants of this study were concerned to some level about their appearance in public. From the interview data one participant related this specifically to the appearance of her affected arm but another related this more to a general perception of being different since the stroke.

9.6.4 Summary

The qualitative data collected in this feasibility study suggest that, in a larger study, it would be valuable to collect some measure related to body image. There has been no work on evaluating the use of the individual question about appearance in the SIPSO for stand-alone use. The data collected in this study would suggest that it is a question that stroke survivors with profoundly-affected arm find acceptable to answer and which is sensitive to a range of responses. More work is required to establish its validity and reliability.

9.7 Impairments identified in the original model that were not formally measured

9.7.1 Joint subluxation

Joint subluxation was included in the initial model of impairment of the profoundly-affected arm but no attempt was made to formally measure it as part of the feasibility study because no reliable measures for all types of subluxation for use in clinical practice were identified. However one participant spontaneously referred to a perception of shoulder joint instability during her interview:

“At the top of my arm it feels like it’s not in the socket- is that just a feeling- it feels like it’s out of place... when I go it use it it hurts there like it’s not normal- it hurts- it hurts like it’s not in the socket kind of thing.”

Interviewee 6, age 70

This would appear to indicate that, for some pwS, joint subluxation or instability may cause difficulties. If a larger study was to be conducted and a valid and reliable measure of subluxation that could be used in a clinical setting had been developed, it would be worth considering whether to include this.

9.8 Impairments that were not identified in the original model

9.8.1 Temperature changes

There was no formal assessment related to the temperature of the arm after stroke as it was not identified as an impairment associated with the profoundly-affected arm in the original model (Chapter 2). However four of the participants who were interviewed commented that they found the arm very cold to touch. Carers also noted this, which appeared to indicate it was not a sensory perception of the participant:

“It’s stone cold it is- coldness makes me worry- it’s just so cold.”
Interviewee 3, aged 65

“I get cold around my shoulder quite a lot.”
Interviewee 10, age 72

There have not been a large number of studies of skin temperature changes post-stroke although anecdotally it is fairly commonly reported phenomenon (Adams & Imams, 1983). A number of small studies have been conducted that demonstrated incidence of skin temperature changes in between 19% (Chang, Shin, Cha & Park, 2012) and 60% of survivors (Korpelainen, Sotaniemi & Myllyla, 1995). They have been associated with sensory dysfunction (Doyle, Bennett, Fasoli & McKenna, 2010), reduced blood perfusion (Adams & Imms, 1983) and autonomic dysfunction (Korpelainen, Sotaniemi & Myllyla, 1995). The comments of the participants interviewed indicate that some find this quite a troublesome symptom. Therefore, it may be worth considering how this could be assessed in a larger study. Previous measures of limb temperature have included digital infrared thermal imaging (Chang, Shin, Cha & Park, 2012) or digital thermometers (Korpelainen, Sotaniemi & Myllyla, 1995).

9.9 Chapter summary

This chapter contained a review and discussion of the outcome measures associated with impairment that were collected during the feasibility study. At interview comments from participants and carers suggest that spasticity, pain, range of movement and changes in body image are relevant impairments to people living with a profoundly-affected arm. Problems associated with temperature changes and joint instability were also raised as areas of concern

but problems with skin integrity were considered less relevant. Using the outcome measures identified in Chapter 5 it was possible to collect 97% of the potential data concerning spasticity and range of movement, and 100% of data on skin integrity suggesting these measures were highly acceptable to the participants. A small number of participants were unable to indicate if they had pain and or respond to questions about body image. In these cases a proxy measure from a carer was taken. No measures were available to test joint subluxation, and no measure of temperature was included.

The data collected on spasticity, pain and body image showed a range of results. There were trends for spasticity and pain scores to increase between baseline and follow-up, and for the indicator of concern with appearance to reduce. These trends are in agreement with other studies and hypotheses about changes in these impairments over time, supporting the responsiveness of the measures. However, the data collected on range of movement appears at odds with previous studies of contracture in the arm and hypotheses for its development (Malhotra et al, 2011; Pandyan et al 2003).

The battery of measures of impairment tested shows some potential for recording change in this cohort of participants after stroke. Further work is required to test the validity and reliability of carer proxy measures of pain (or to develop a behavioural pain assessment) and to test the process of measuring range of movement. Consideration should be given to the potential of measuring temperature in the arm and of assessing joint subluxation if a valid, clinically based measure becomes available. In the next chapter the measures of activity and participation will be reviewed.

Chapter 10: Disability and related factors in the profoundly-affected arm

10.1 Chapter overview

This chapter contains a review and discussion of the results related to the outcomes associated with the ICF (WHO, 2001) concepts of activity, participation and environmental factors. These include passive function, active function, quality of life, carer burden, and use of products and technology, and health and social services. Unlike the assessment of impairments that were based on physical assessment, all of the data presented in this chapter is obtained from subjective report and the use of structured questionnaires. In line with the NIHR definition of feasibility studies (NIHR, 2012) and with reference to the third objective of this study particular attention is paid to ensuring the acceptability and responsiveness of the measures. Acceptability was assessed by analysing completion rates of the questionnaires, and responsiveness was assessed by examining the distribution of the data collected and trends over time. In accordance with the recommendations of the MRC Complex Interventions Framework, statistical analyses of the outcome measures are not explored at this time, since the feasibility study was not powered to detect significant changes. With reference to the Leeds Arm Spasticity Impact Scale (LASIS), where there is little previous work on establishing the psychometric properties of the questionnaire, the relationships between the data collected on the LASIS and data concerning related constructs was analysed to give a preliminary indication of validity. Qualitative data from interviews is used to further support the analysis of the measures.

10.2. Passive Function.

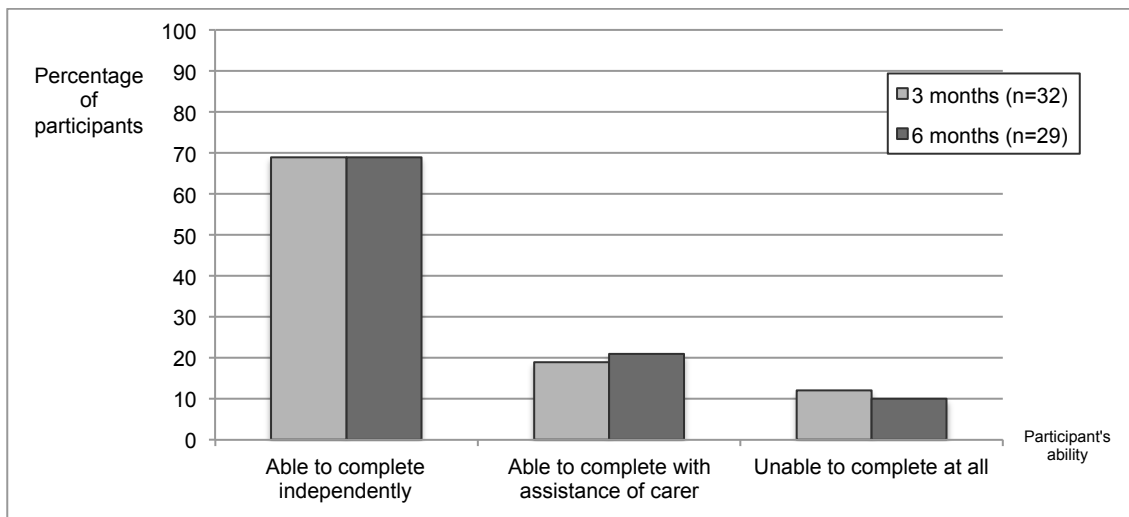
Passive function was assessed using the Leeds Arm Spasticity Impact Scale (LASIS) (RCP, 2009). This is an item bank of 12 tasks involving care of the arm where the respondent indicates the items that are relevant to them and then scores these against a five-point scale. The original measure was published with a scale for people with spasticity to complete. Carer views were sought only if the person was unable to complete the described task by themselves. Neither participant or carer reported questionnaires have been validated. For the purposes of the pilot every opportunity was made for the person with stroke to complete the scale, but a record was made of when this was not possible.

10.2.1 Extent of data collected

Figure 25 illustrates participants' ability to complete the LASIS questionnaire, which was also the same for both the MAL-14 and SIPSO. Only 69% of the participants were able to complete the questionnaire independently at each time-point. At least 10% (four people at three months and three people at six months) of participants were unable to complete the questionnaire at all due to levels of aphasia or cognitive impairment, and approximately 20% asked their carer to assist them with some of the questions. With this level of assistance the questionnaire was completed at each time-point with the exception of one participant at three months who would not complete the assessment and who did not have a carer available to assist.

During some of the follow-up assessments of the LASIS it was noted that when participants who were able to give their views were responding to the questionnaire carers who were present would often interrupt and give their own view of the difficulties in caring for the arm. This issue was explored with both participants and carers at interview.

Figure 25: Participants ability to complete the LASIS, MAL-14 and SIPSO questionnaires

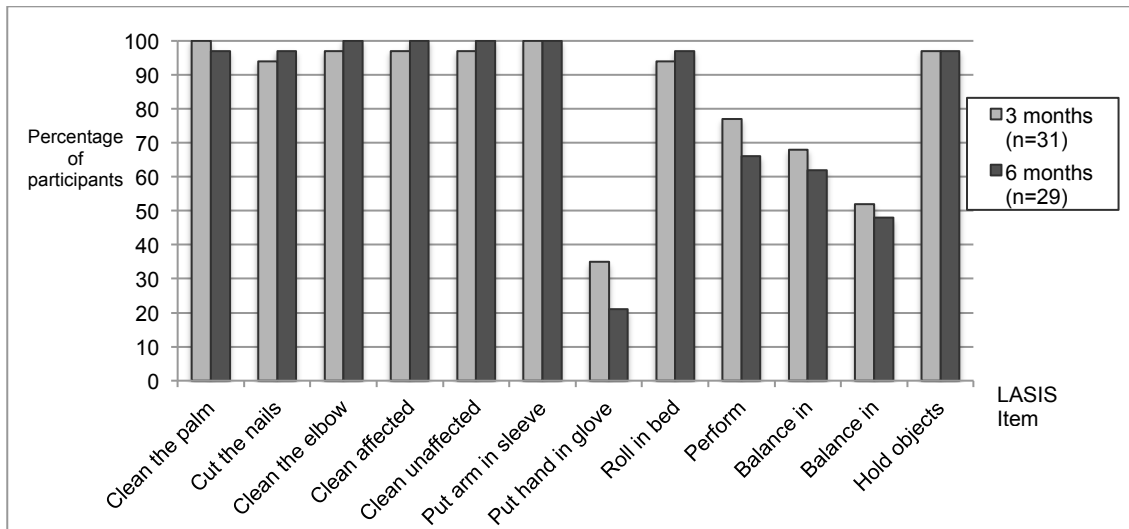


10.2.2 Distribution of data collected

The items of the LASIS were originally developed following interviews with people with profoundly-affected arm (Bhakta et al, 1996). Figure 26 illustrates the items of the LASIS that were considered relevant by participants at each

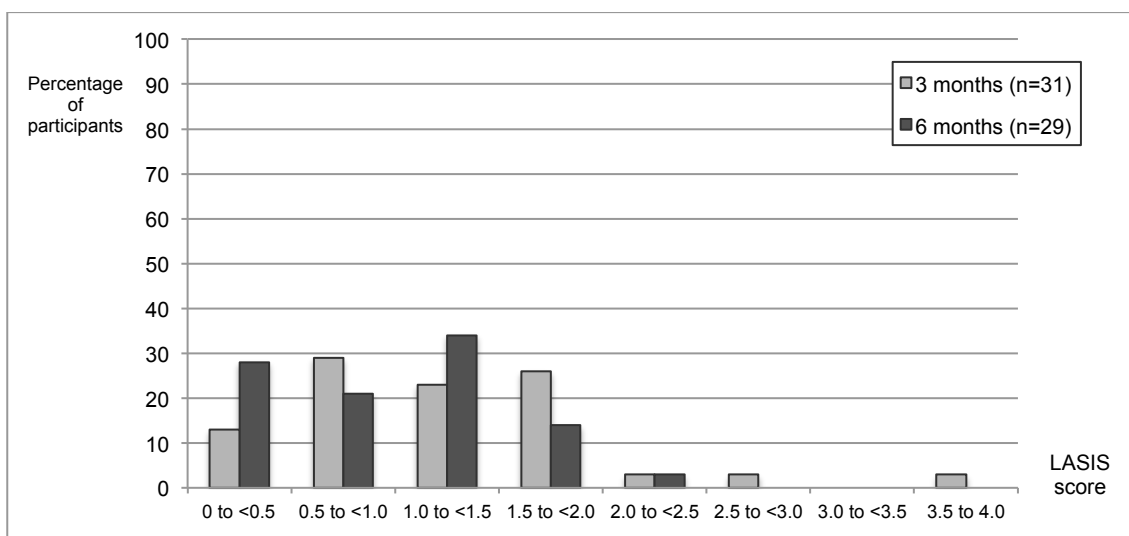
time-point. Eight of the items were rated as relevant by 94% or more of the participants and carers. Items that were considered less relevant included putting on a glove, performing exercises, and the impact of the arm on balance.

Figure 26: Percentage of participants who considered each LASIS item relevant



The score of the LASIS is produced by calculating the mean score of the relevant items for each participant. Therefore, the range of results varies from zero indicating no difficulty with any care task to four indicating that it is not possible to perform any relevant care task. The distribution of participants' scores is illustrated in Figure 27. A range of scores were collected at each time-point but there was no specific trend for how the data changed over time.

Figure 27: Distribution of participants LASIS scores at each time-point



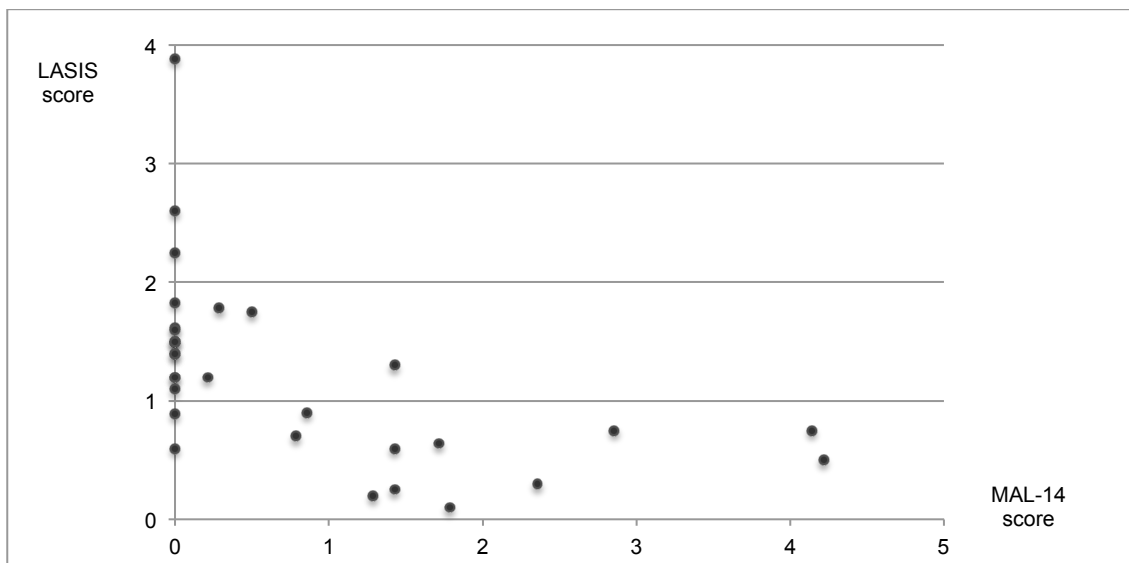
10.2.3 Relationship between LASIS scores and related constructs

There has been no previous work to validate the LASIS, and a full formal evaluation of this was beyond this study. However it was possible to look at the relationship between the LASIS scores and other data that were collected. Traditionally it has been considered that difficulty caring for the arm is more likely to affect those who have little or no functional use of the arm and those with spasticity (Kong et al, 2010; Lundstrom et al, 2008). The relationship between LASIS scores and the measure of active function, and LASIS scores and the measure of spasticity was therefore examined.

LASIS scores and active function

Figure 28 demonstrates the relationship between LASIS scores and Motor Activity Log-14 (MAL-14) scores at three months post-stroke, and Figure 29 the relationship at six months.

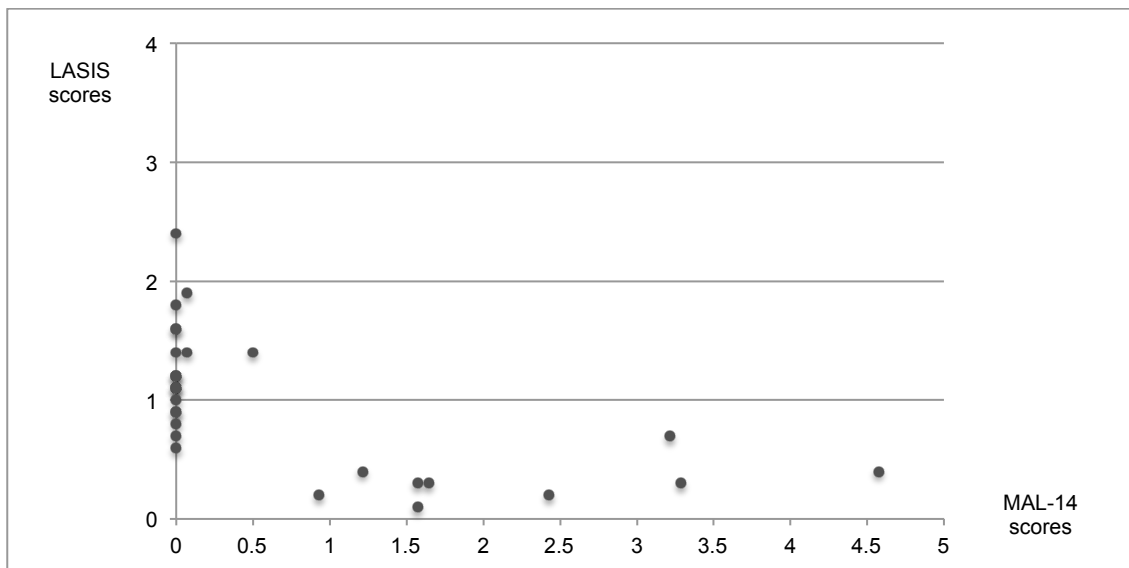
Figure 28: Relationship between LASIS scores and MAL-14 scores (active function) at 3 months (n=31)



There may be a potential inverse exponential relationship between the scores (such that very low MAL-14 scores are associated with high LASIS scores, declining exponentially as MAL-14 increases), or alternatively a binomial distribution (such that the data indicate two distinct sub-populations). For participants who had some recovery of active use of the arm (those who scored

greater than 0 on the MAL-14) there appears to be a weak negative correlation between the increasing scores on the MAL-14 and reducing scores on the LASIS. This may suggest that those participants with most active functional use of the arm experienced the least difficulty with passive function. However, for participants with no functional use at all (a score of 0 on the MAL-14) there is a wide range of LASIS scores. This may suggest that, in those with no functional use of the arm there are other factors that account for the degree of difficulty caring for the arm. There is not sufficient data to draw stronger conclusions, and further experimental studies in larger samples are needed to explore these hypotheses.

Figure 29: Relationship between LASIS scores and MAL-14 scores (active function) at six months (n=29)



LASIS scores and spasticity

Figure 30 demonstrates the relationship between LASIS scores and summed Modified Modified Ashworth Scale scores (MMAS) at three months post-stroke, and Figure 31 the relationship at six months. There may be the suggestion of a linear relationship and a line of best fit has been added to each graph. The coefficient of determination (R^2) between the two variables is 0.36 at three months, and 0.30 at six months, indicating a weak positive correlation between the two measures. This suggests that participants with higher levels of spasticity throughout the arm may report greater difficulty caring for the arm. Again, data

are insufficient to draw conclusions and further experimental exploration of the relationship between the measures would be valuable in future studies.

Figure 30: Relationship between LASIS scores and summed MMAS scores (spasticity) at three months (n=30)

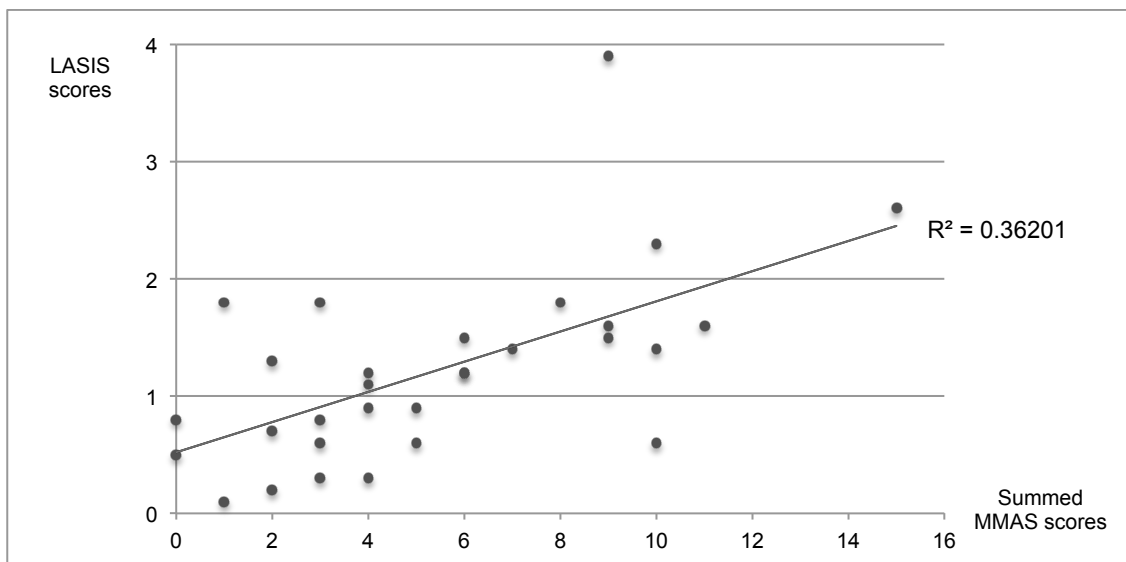
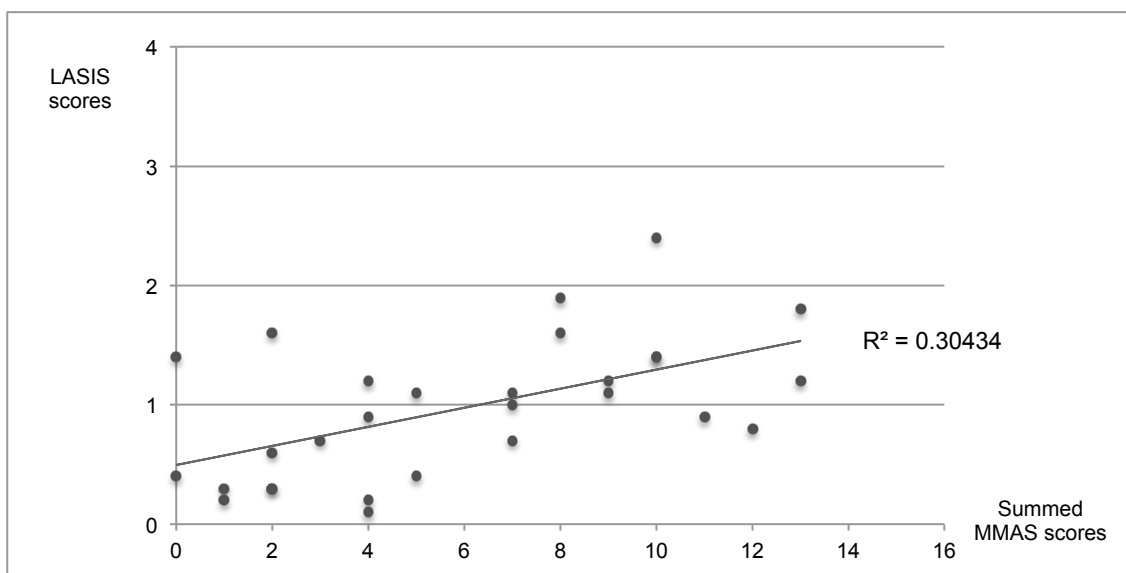


Figure 31: Relationship between LASIS scores and summed MMAS scores (spasticity) at six months (n=29)



10.2.4 Qualitative data concerning the disability and its measure

Comments from participants and their carers indicated that passive function of the arm could present considerable challenges for this group of people:

“Her hand was getting worse with her fingers (getting stiff) Up until a few months ago I was able to cut her nails while we can’t now.”

Carer of Interviewee 9, age 73

“I have a lot of problems with dressing- the carers do it for me in the morning but I can’t do it myself.... I can’t do anything myself....everything is difficult because I can’t open my fingers out.”

Interviewee 5, age 69

All the participants and carers indicated that they thought it was important to measure difficulty with passive function of the arm but the method of measurement produced some debate. There was agreement that the items included in the LASIS reflected the difficulties in daily life: and they had no further items to add:

“She can’t do that (wash the armpit) because she can’t lift this arm up enough- long enough to wash.”

Carer of interviewee 8, age 59

However, some carers indicated that the scoring system was too complex for people with cognitive problems or communication disability to complete:

“No those questions are hard to be honest because of the confusion and the strokes she can’t answer that.”

Carer of Interviewee 9, age 73

One carer felt very strongly that the participant, although able to express a view would not be able to do so accurately:

“Do you consider the cognitive ability? I work with the speech therapist- we use a choice of three- that questionnaire to me seems to contradict all the things I have learnt from the speech therapist- it’s too much.”

Carer of Interviewee 7, age 80

Equally there were times when the participants did not perceive care provision as difficult but recognised that the carer who may be assisting with the task did:

“It’s a tiny bit difficult for me but not really. Mum does that (cuts the nails) and she has problems – that ones fine (gestures to sound arm) but this one she has problems trying to get it out to cut the nails.”

Interviewee 4, age 38

This raises two areas for consideration. Firstly this feasibility study shows that some participants are unable to complete the LASIS questionnaire themselves. During the study if this occurred a carer completed the questionnaire on their behalf. However to date there has been no research to ascertain if this is reliable or valid method of obtaining this information. In addition to the perceived accuracy of the participants view of the questionnaire there is also the issue of whether the process of providing care to the profoundly-affected arm as a carer may be different from the process of receiving the care. Given that a key goal of improving the ease of passive function can be the reduction of carer burden (RCP, 2009) it would seem appropriate that carers complete a LASIS in their own right indicating the difficulty they perceive in providing care.

10.2.5 Summary

In summary the quantitative and qualitative data indicate that the concept of ‘passive function’ can be a significant issue for people with profoundly-affected arm and their carers. It was possible to obtain completed LASIS questionnaires to measure the degree of difficulty with care for virtually all the participants but less than 70% were able to complete these independently. Some carers raised concern that the questionnaire may be too difficult for those with cognitive or communication disability to complete and queried the accuracy of this. Participants also commented that what they may not consider a difficulty may be so for their carer. With the exception of putting on gloves, all the items in the LASIS were considered relevant to the majority of people. This, along with participants’ comments on difficulty caring for the arm at interview supports the face validity of the measure. There is also a correlation between LASIS scores and those of spasticity, offering some preliminary support to the construct validity, although the relationship with scores of active function is less conclusive. In future it is recommended that participants and carers complete the tool separately to record their perceptions of difficulty with care.

10.3 Active Function

Active use of the arm was assessed using a self-reported measure, the Motor Activity Log-14 (MAL-14) (Constraint Induced Movement Therapy Research Group, 2004) at three and six months post-stroke. The participants completed a questionnaire rating the amount that they are able to use their hemiparetic arm for 14 tasks, using a scale of zero (to denote no use) to five (equal to pre-stroke use). The scores were then averaged. A total score of five would indicate that the participant used the arm as much as they were able to prior to their stroke. Park et al (2008) have suggested that a score above three denotes a significant return of functional use of the arm post-stroke.

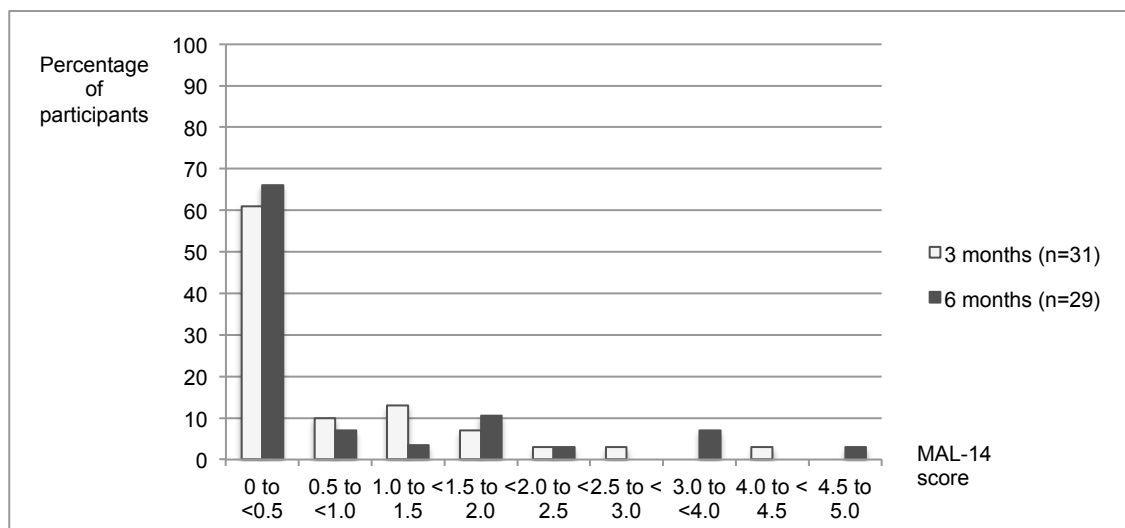
10.3.1 Extent of data collected

As was found for the LASIS approximately 70% of participants completed the MAL-14 independently, 20% completed it with the assistance of a carer and 10% could not complete it at all and it was wholly completed by a carer (Figure 25, p.171). However, in contrast to the LASIS, there is a strong correlation between self-rated use and carer observed use of the arm using the MAL-14 (Uswatte et al, 2005). One participant who could not complete the questionnaire did not have a carer available at one time-point so it was not possible to record this data then. Therefore, in total, 98% of the potential data was collected.

10.3.2 Distribution of data collected

The summary of the results are given in Table 21 (p.112) and the distribution of MAL-14 scores recorded at each time-point are illustrated in Figure 32. As expected from the eligibility criteria the majority of participants did not recover much functional use of the arm. Only one participant at three months (3%) and three participants at six months (10%) scored above three points indicating significant recovery. For the other participants who reported some return of use in the arm there was a spread of scores indicating varying lower level use.

Figure 32: Distribution of MAL-14 scores



10.3.3 Qualitative data concerning the disability and its measure

For a number of the participants and their carers who were interviewed, the active use of the arm was not the most important aspect of life post-stroke, as they perceived that other impairments and disabilities had a greater impact on life. This included concerns about swallowing and general mobility:

“Well it’s not the main issue now- the main issue now is her difficulty in swallowing and drinking and food tends to get into her lungs and that sets up infection... she now has to have thickened fluids and pureed foods.”

Carer of Interviewee 1, age 83

“Walking is more important to me (than my arm).”

Interviewee 8, age 59

However the participants who regained some use of the arm valued this:

“I tried last night picking up a spoon and after about six attempts I could pick up the spoon.”

Interviewee 6, age 70

“I can grip now (demonstrates how he is able to grasp the bar of a Rota stand transfer device).”

Interviewee 3, age 65

Others did not recover any active use of the arm but still tended to focus on this even when it was many months since the stroke and their function had not changed:

"I can't clean up- use the cleaner... I can't hold anything.... I can't dust."

Interviewee 5, aged 69

"I don't think I'm getting any better- I can't do anything for myself- I can't even eat a boiled egg- she has to feed me."

Interviewee 10, age 72

Their comments illustrate that although the concept of passive function and care of limbs is becoming increasingly recognised in professional literature (RCP, 2012), participants and carers still concentrate very strongly on active function. At interview participants commented that they found the MAL-14 questionnaire acceptable. One carer suggested that it should be expanded to include reference to the person's ability to use the arm to help them hold a rail when negotiating stairs:

"Possibly going up stairs and making sure you've got sufficient grip."

Carer of Interviewee 2, age 67

Otherwise none of the participants or carers felt there were any additions to be made.

10.3.4 Summary

In summary, the qualitative data suggest that people with profoundly-affected arm are still focused on the potential for return of active function and value relatively small improvements in function that can occur. It was not possible for all participants to complete the MAL-14, but previous research suggests carer completion is as reliable and valid as participant completion (Uswatte et al, 2005). Across the participants who had regained some return of use, the MAL-14 appeared to collect a range of scores. Participants and carers who were

interviewed supported the items within the measure, although there were also some suggestions for other items that may be useful to consider.

10.4 Quality of Life

Participants' quality of life was assessed using the Subjective Index of Physical and Social Outcome (SIPSO) (Trigg & Wood, 2000). This questionnaire contains ten questions with five related to physical status and five related to social integration. Each sub-scale should be summed independently (Trigg & Wood, 2000). Each questions has a choice of five responses scored from 0 to 4, giving each sub-scale a potential range of scores from 0 to 20.

10.4.1 Extent of data collected

As occurred for both of the previous questionnaires approximately 70% of participants completed the SIPSO independently, 20% completed it with the assistance of a carer and for 10% it was wholly completed by a carer (Figure 25). Trigg and Wood (2003) found there was acceptable agreement between people with stroke (pwS) and their proxies on completion of the SIPSO, although studies of proxy measures with other quality of life scales suggest that proxies tend to score pwS as more severely affected than they score themselves (Williams et al, 2006; Duncan et al, 2002; Sneeuw, Aaronson, de Haan, et al, 1997). It was possible to obtain data on all the participants at each time-point, with the exception of one participant at three months whose carer was not available so 98% of potential data was collected.

10.4.2 Distribution of data collected

The summary of the results are given in Table 21 (p.112). Figures 33 and 34 illustrate the distribution of scores across the two sub-scales at each time-point. Scores for the physical sub-scale ranged from 0 to 18 but were skewed to lower scores, which may be expected given that the population in this study sample had a high level of physical disability. Scores for the social subscale also ranged from 0 to 18 but are more normally distributed around a mean and median score of 10 points at three months and 11 points at six months. There did not appear to be significant differences in scores at three and six months, in keeping with findings in larger population studies of quality of life post-stroke (Patel et al, 2006).

Figure 33: Distribution of SIPSO physical sub-scale scores

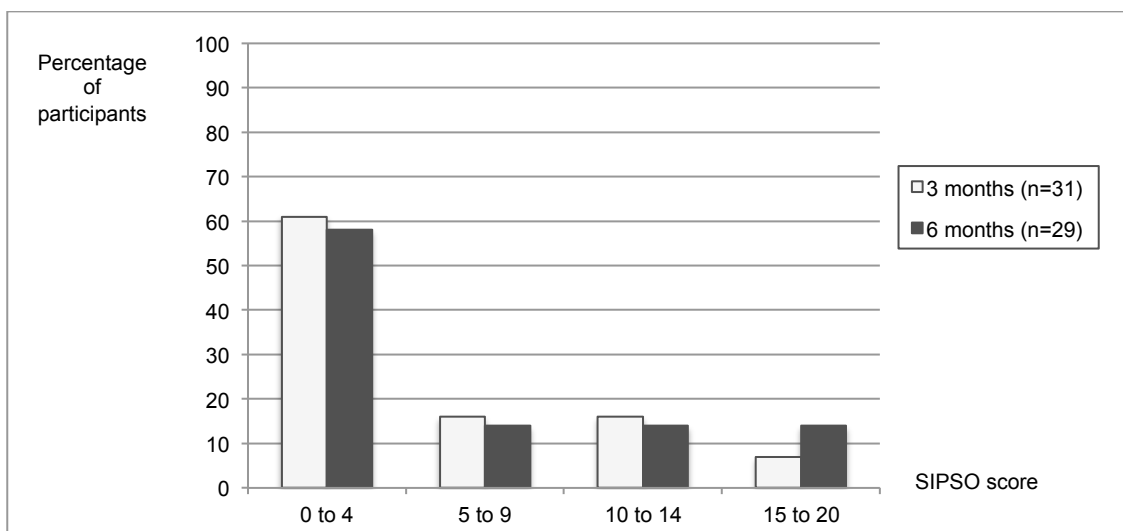
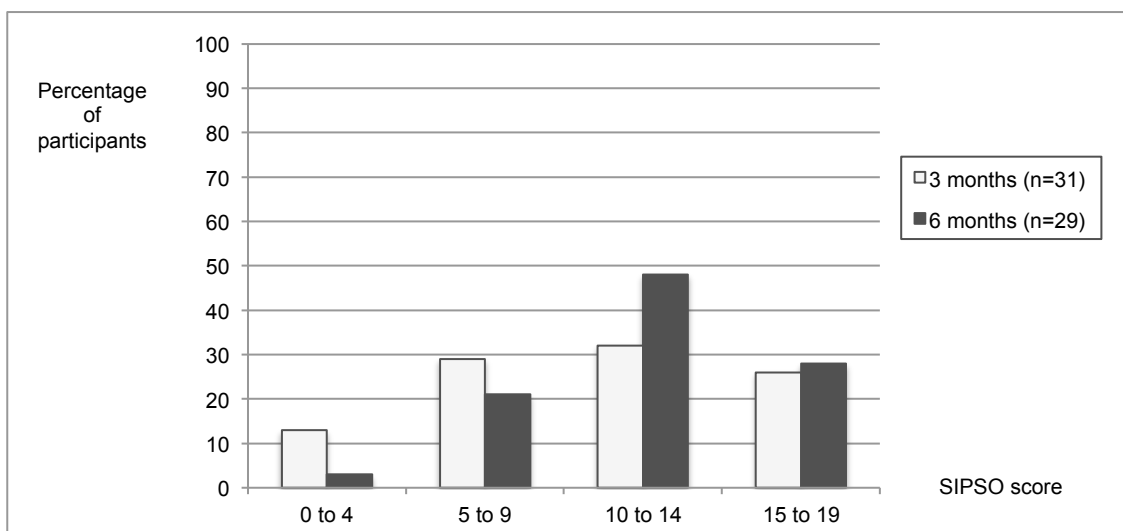


Figure 34: Distribution of SIPSO social sub-scale scores



10.4.3 Qualitative data concerning the impairment and its measure

At interview, participants and their carers endorsed the items within the SIPSO scales and related them to feelings of wellbeing:

“This is what gets me down as well- I’ve only been out once this week- that was to the doctors and just not getting out these four walls it’s awful- I feel I haven’t got a life anymore- my friend was going to New Look this morning and that’s what I used to do when I was well- I’d pop to the shops- all that’s kind of gone now.”

Interviewee 6, age 70

“M’s got a very low opinion of herself- she thinks people are staring at her and she feels like she is a freak and gets really down a lot.”

Carer of Interviewee 8, age 59

10.4.4 Summary

In summary the qualitative and quantitative data suggests that including quality of life within the model of how the profoundly-affected arm affects people post-stroke is highly relevant. It was possible to collect complete data from all but one participant at one time-point, although proxies were used to complete the questionnaire for four of the participants. The scale collected data within a range of scores.

10.5 Carer burden

Carer burden was recorded using the Self-rating scale where carers mark their response to the instruction ‘Please indicate with an ‘X’ on the scale how burdensome you feel caring for or accompanying your partner is at the moment’ on a visual analogue scale (van Exel et al, 2004). The result is used to provide a score from 0 where 0 indicates ‘not all all straining’ and 100 indicates ‘much too straining’.

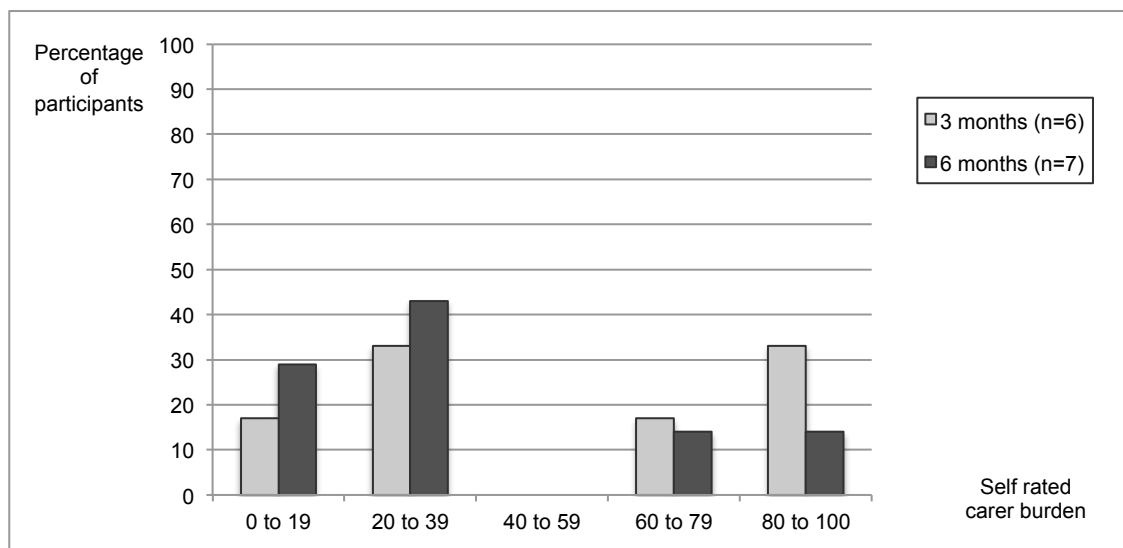
10.5.1 Extent of data collected

Six carers completed scales at three months post-stroke and seven carers at six months. As discussed in Chapter 7 a different approach is required to maximise the recruitment and participation of carers, but when carers were available for follow-up appointments they all completed the scales.

10.5.2 Distribution of data collected

The distribution of data collected are shown in Figure 35. Although there were only thirteen pieces of data of carer burden, there was a large range of response between values of 4 and 90.

Figure 35: Distribution of scores of carer burden



10.5.3 Qualitative data concerning the construct and its measure

At interview carers indicated that they felt recording how carers were feeling was an important aspect of life after stroke:

“We have the odd bad day obviously but other than that ... it’s my natural personality to have a strong sense of duty.... and I love her... I don’t look at it as an unwelcome task but other people might not feel the same way that I do.”

Carer of Interviewee 2, age 67

This same carer indicated that he felt that other carers might not feel comfortable in truthfully expressing how they felt:

“But the only thing about that, and I’m not saying I’m guilty of it in anyway, but people will look at that and think ‘hang on- I’m not going to say I have problems 95% of the time or to a degree of 95% because you’re shooting yourself in the foot- now that could put a lot of people off answering honestly.....people may look on that as their personality being suspect – they may look on it- he doesn’t want the bother, it may be getting him down, he doesn’t want to admit it- reasons like that.”

Carer of Interviewee 2, age 67

However the wide range of scores collected suggests that some carers did not feel constrained by expressing how they felt on the scale. One carer who had reported a high level of perceived burden who was subsequently interviewed,

generally indicated that they felt the report their gave on the scale reflected how they were feeling.

“How burdensome?- it’s high isn’t it- a couple of months ago I’d have gone even higher and I think that it’s the emotional rather than the physical side.”

Carer of Interviewee 9, age 73

This comment is in agreement with other research that has found that carer burden is not correlated to the degree of physical disability (Thommessen et al, 2001).

10.5.4 Summary

In summary, the comments of carers indicated that the level of burden should be considered as part of a larger study. Aside from the difficulties with carer recruitment, those who did opt in to the study all completed the scales that were available. Although one carer suggested that others may not feel comfortable completing the scale honestly, this was not borne out within the small amount of data collected and a large range of scores were evident.

10.6 Products and technology

At each time-point participants were specifically asked if they used a splint for their profoundly-affected arm, and, if so, the amount of time that they wore it each day. They were also asked if they used any other product or technology in relation to their arm.

10.6.1 Extent of data collected

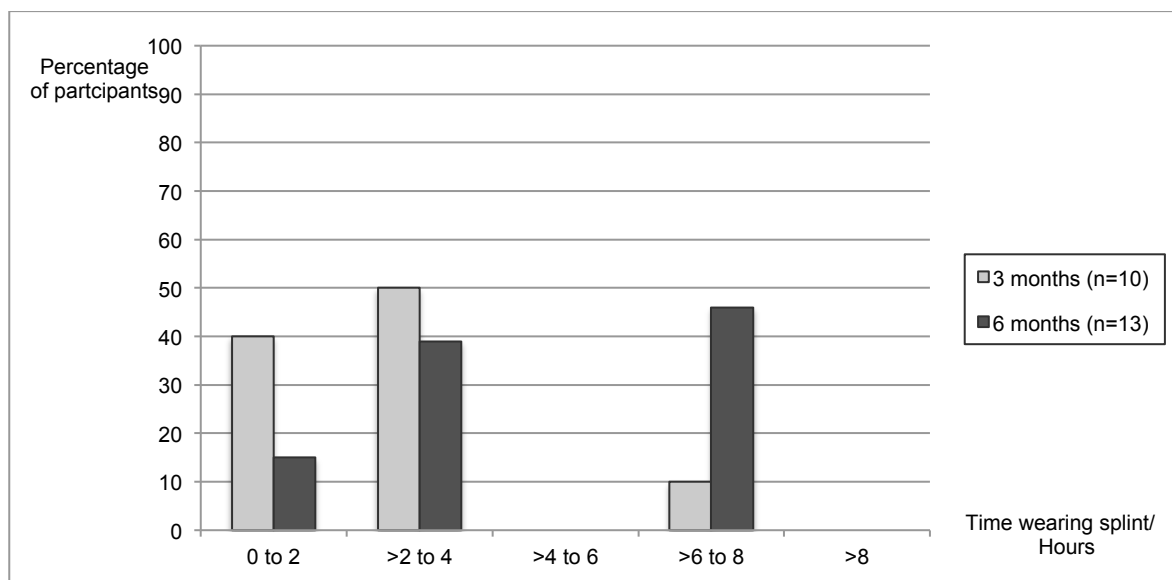
All of the participants or carers responded to the question concerning use of splints and other products.

10.6.2 Distribution of data collected

At three months, 31% of participants (10) reported using a splint. By six months this had increased to 45% (13 participants). In addition, some participants at interview commented that they had been given splints to wear in the acute unit but had discarded them, so the number of participants issued with splints at some point post-stroke is likely to be higher. The amount of time that splints

were worn is shown in Figure 36. There is a wide variation in the time spent wearing splints which is not unexpected as it reflects the variations in prescribed splinting regimes in the research literature (Lannin & Herbert, 2003).

Figure 36: Reported times that participants spent wearing splints each day



10.6.3 Qualitative data concerning the construct and its measure

Five of the participants who were interviewed had used a splint at some point after their stroke. Many expressed quite negative feelings about the experience:

*“Pain in the a**e- I wear it because I want it (my hand) to straighten out.”*

Interviewee 8, age 59

“Waste of time- in the end it was very painful to put on-that is why I don’t wear it- I used to wear it at two hours in the morning and two hours in the afternoon but the shape of my hand has changed so- in the end it did hurt.”

Interviewee 4, age 38

In addition to splints, two participants referred to the use of slings at interview:

“The sling it used to hurt her neck. There she got the cuff thing but that was the same she doesn’t really like anything around her neck.”

Carer of Interviewee 10, age 72

Some participants had also received information about devices designed to improve life with a disability but not all welcomed this:

“I don’t want that (gadget for one handed knitting)- I only want to knit with two hands.”

Interviewee 10, age 72

10.6.4 Summary

It was relatively easy in the feasibility study to collect information on the use of splints. The data collected suggests that splints are still used with a significant number of people, although there was no attempt to corroborate what participants reported (for example from clinical records). Any data collection in a future study could be expanded to include prompts about the use of slings and other devices.

10.7 Health and social services

At each time-point participants and carers were asked which healthcare interventions they received for the treatment of their arm. This included specific prompts about formal therapy, home exercise, analgesia, medications for spasticity, and the chance to describe any other intervention that they felt was relevant.

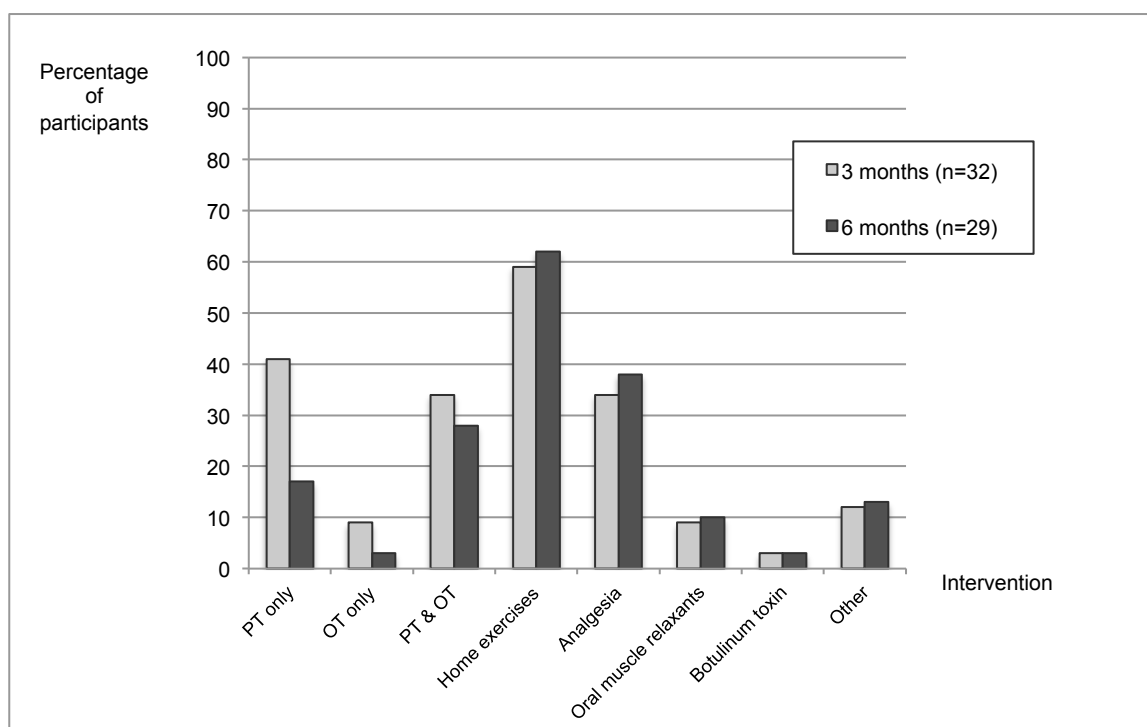
10.7.1 Extent of data collected

As occurred with the self reported questionnaires approximately 70% of participants were able to independently describe which services and interventions they received, 20% responded with the assistance of a carer, and 10% were unable to respond so their carer gave the information on their behalf. There is no specific reason to doubt what participants and carers reported but assurance of the accuracy of self- reported information could be obtained by comparing reported use with actual therapy received recorded in clinical records.

10.7.2 Distribution of data collected

Figure 37 presents the results for the healthcare interventions that were provided at each time-point.

Figure 37: Healthcare interventions received



Therapy and home exercise

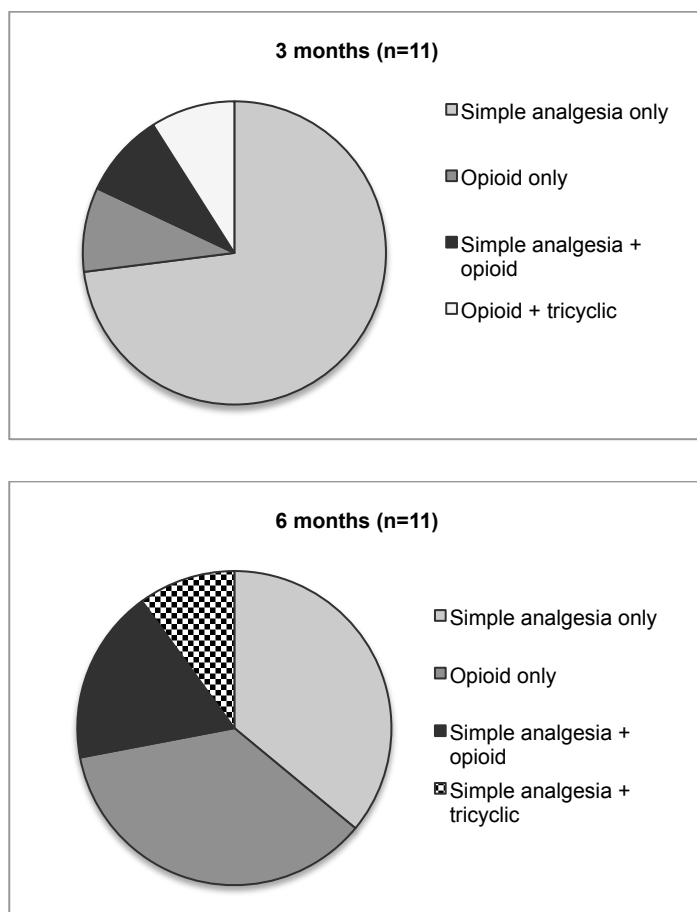
At three months post-stroke 84% of participants reported still receiving physiotherapy and/or occupational therapy for their arm. By six months this had fallen to 48%. There have been few studies which have recorded the provision of therapies longer-term post-stroke but de Jong et al (2011) found that 66% of people with weak arm were receiving physiotherapy at six months and 13% occupational therapy. No attempt was made to record the number or length of therapy sessions so economic analysis of the cost of the profoundly-affected arm would not be possible without more detailed data. At three months post-stroke 59% of participants reported using a home exercise programme. By six months this was 62%.

Medications

Analgesia. It is noteworthy that although 84% of participants experienced pain at three months, and 68% at six months post-stroke (Section 9.3), less than 40% (11 participants at both time-points) reported taking analgesia. Participants who were taking analgesia were asked which specific medications they were taking and these were then classified as simple analgesia (paracetamol and non-steroidal anti-inflammatory drugs), opioids, or tricyclic antidepressants used

for neuropathic pain. Figure 38 shows the groups (or combinations of groups) of analgesia that participants were using.

Figure 38: Analgesia taken at each time-point



At three months post-stroke, the majority of participants who were taking analgesia were using only simple analgesia, but by six months post-stroke, over 50% of those taking analgesia were prescribed opioids. There is little previous research with which to compare this data.

Muscle relaxants. Three participants reported using oral muscle relaxants at three months. They were all prescribed baclofen. By six months post-stroke one of these participants had discontinued them but the other two continued. An additional participant had been prescribed diazepam at six months post-stroke. One participant within the sample was treated with botulinum toxin during the study period. There is currently no data to suggest the proportion of people prescribed oral muscle relaxants or botulinum toxin post-stroke to compare data from this study with.

Additional interventions

At three months post-stroke three of the participants reported additional interventions that they were using for their arm and by six months this had increased to four (see Table 24, p.114). Additional treatments included swimming, massage, acupuncture and using a Nintendo Wii.

Social services

Details of the social services provided to participants are shown in Table 23 (p.114). At each time-point 28% of participants were residing in care homes, and 41% were receiving 'packages' of care to enable them to live at home. Only 25% of participants at three months and 28% at six months lived at home without any social care support.

10.7.3 Qualitative data concerning the construct and its measure

At interview both participants and carers made clear that they valued some of the physical interventions they had received:

"We have our own physiotherapist once a week - she tended to push D a little more than I might have done myself and I think that helped her- she had more confidence in the physio."

Carer of interviewee 1, age 83

"I find massage very helpful. I go to this place once a week where they put this thing on, this electrical thing to stimulate the arm- it feels really wonderful all the nerves are tingling and it makes it feel alive again."

Interviewee 10, age 72

One carer felt that formal therapy was withdrawn too quickly:

"We tended to think it would go on and on - I know the budget wouldn't stand it if they kept treating everyone - but we were hoping for more physio- I mean she was fine- at the hospital she was really looked after excellently but after so many weeks of not showing a marked improvement it tends to tail off which is a disappointment in a way- I don't know if it would have helped but we would have felt better for it."

Carer of Interviewee 5, age 69

Medications to reduce spasticity were also considered useful:

“I had jumping pains – it (baclofen) kept it calm.”

Interviewee 4, age 38

“Since the Botox it’s relaxed- where they were like this (shows clenched hand)- in fact you could see an indentation in mum’s palm- now they’re a bit more relaxed while we can get in there (to wash)- there’s been a definite amount of relaxation.”

Carer of Interviewee 9, age 73

However, as was found in the original Patient and Public Involvement focus group prior to the study, many participants and carers were left not understanding the best course of treatment or how to help themselves:

“Like you get all the leaflets and read it- the general information is ‘there is paralysis’ and that’s it really...”

Carer of Interviewee 5, age 69

10.7.4 Summary

A significant amount of data related to health and social care services was collected. Comments at interview confirm that formal therapy, home exercise, medications for pain and spasticity, and social care services were relevant to this group.

10.8 Chapter summary

It was not possible for a tenth of participants to complete the self-reported questionnaires related to passive function, active function and quality of life so in these cases carers completed them by proxy. Thus it was possible to collect a range of data related to active arm use and quality of life, and comments from participants and carers supported the content of these particular measures. Regarding measurement of difficulty with passive function qualitative data suggests this is also a relevant construct to include, and preliminary analysis supports the face validity, construct validity and responsiveness of the LASIS. In future it is important for pwS and carers to each complete a LASIS in their own right as participants views of difficulty in receiving care of the arm may differ from carers views of providing it. More detailed work on the psychometric properties of the LASIS and its relationship with other measures is required.

There were fewer measures of carer burden taken but these also recorded a range of scores. Finally, it was possible to collect a significant amount of data concerning other environmental aspects of care including use of health and social services as well as assistive devices. In the following and final chapter the conclusions for this study will be discussed.

Chapter 11: Conclusions

11.1 Chapter overview

The purpose of this thesis is to report a feasibility study as defined by the National Institute of Health Research and Medical Research Council (NIHR, 2012; Craig et al, 2008). This work is an essential step in the trajectory towards a definitive study, using a longitudinal research design. The aims of a definitive study relate to developing an improved understanding of the profile of impairment and disability in the profoundly-affected arm after stroke, and identifying if any potential predictors assessed early after stroke could distinguish those most at risk of impairments or difficulty caring for the arm. In order to design a definitive study, the specific objectives of the feasibility study were to assess (i) the recruitment and follow-up processes with particular attention to the ability to involve people with cognitive impairment and communication disability; (ii) the characteristics of the sample to establish if this was likely to be representative of the target population and (iii) to establish the acceptability and responsiveness of the outcome measures. This chapter is structured to summarise the key findings related to each of these objectives, and to produce a series of recommendations for further work. Finally, the limitations and strengths of this study are discussed, conclusions are drawn and the original contribution of this work to the body of knowledge is reviewed.

11.2 Recruitment and follow-up processes

Over the recruitment period of 30 weeks forty people with stroke (pWS) were recruited to take part, which was over 90% of those identified as eligible. Most were recruited while they were still inpatients but four were recruited under the Early Support Discharge scheme. Related data concerning cognitive and communication assessments show that it was possible to recruit people with significant communication disability and cognitive difficulties, either supporting them with enhanced communication resources or by using personal consultees. Ten of the participants recruited had a personal consultee who gave assent on their behalf, but developing a robust process for the use of a nominated consultee would enable participants without a close friend or relative to also have the opportunity to engage. Over the six months of the study 27.5% of participants were 'lost to follow-up' which is comparable with other studies that have recruited those with the most severe physical disability. There were a significant number of adverse events reported within the study population but

this was as expected in this cohort of stroke survivors and none were considered to be related to the study conduct.

Recruitment of carers was less successful than pwS as only nine took part. During the feasibility study carers were recruited at the time of the first participant follow-up visit following a written letter when the visit was booked. One method of increasing carer recruitment may be to approach potential carers for consent during the participants' inpatient stay and then arrange their carer follow-up appointments in their own right as direct approaches give higher recruitment rates than postal invitations (Markgraf et al, 2009). Qualitative data from both pwS and carers suggests they found the process of being approached was acceptable, that they valued the experience of engagement in the research study, and that conducting follow-up appointments as home visits was a factor in ensuring ongoing engagement with the study.

11.3 Characteristics of the sample

The baseline demographic characteristics of the forty participants recruited to the study largely appear to reflect what may be expected in a group of people more severely affected by stroke, and thus the participant group can be considered to be representative. It was possible to collect data on the six predictor variables from almost all of the participants. Complete data on stroke severity, measures of spasticity and motor control were obtained and showed a range of results. The dichotomous response used to record pain could be used in all but three of the participants and also collected a range of responses. A range of data was collected related to mood using the Stroke Aphasic Depression Questionnaire-Hospital 10, but it was identified that for this cohort of stroke survivors some of their disabilities (including inattention) may lead to higher scores using the tool. Equally, the performance on the 'Find the thumb test' of perception and sensation in people with aphasia and dyspraxia requires further exploration prior to its adoption for a larger study. Participants' comments at interview supported the choice of the selected impairments as predictors.

11.4 Acceptability and responsiveness of the outcome measures

11.4.1 Impairment based measures

Interviews with participants and carers suggest that spasticity, pain, range of movement and changes in body image are relevant impairments for people living with a profoundly-affected arm. Problems associated with temperature changes and joint instability were also raised as areas of concern but problems with skin integrity were considered less important. No measures were available to test joint subluxation, and no measure of temperature was included.

However, using the outcome measures identified in Chapter 5 it was possible to collect 97% of the potential data concerning spasticity and range of movement, and 100% of the potential data on skin integrity suggesting these measures were highly acceptable to the participants. A small number of participants were unable to indicate if they had pain or respond to questions about perceived body image. In these cases a proxy measure from a carer was taken but further work is needed to either validate the use of carer report of pain or to develop or evaluate a behavioural assessment of pain.

The data collected on spasticity, pain and body image showed a range of results. There were trends for spasticity and pain scores to increase between baseline and follow-up, and for the indicator of concern with appearance to reduce between time-points. These trends are in agreement with other studies, and with theories about expected changes in these impairments over time, giving some support to the validity and responsiveness of these measures in this group. However, the data collected on range of movement appears at odds with previous studies of contracture in the arm and with hypotheses for its development (Malhotra et al, 2011; Pandyan et al 2003), in that as many participants gained range of movement as lost it. The large variation in measures of range may be due to pain, which was highly prevalent in the studied cohort, but further work is required to clarify this.

In summary, the battery of measures of impairment tested shows some potential for recording change in this cohort of participants after stroke. Further work is required to assess pain in people with most severe communication disability and to review the process of measuring range of movement. Consideration should be given to the potential of measuring temperature in the

arm and of assessing joint subluxation if a valid, clinically based measure becomes available.

11.4.2 Activity, participation and related measures

At interview participants and carers indicated that activities involved in caring for the arm were highly relevant to them, as was the potential for some recovery of active use and issues concerning quality of life. Their comments support the measurement of these constructs within a larger study. However, the measures of activity and participation all related to self-reported questionnaires and it was not possible for a tenth of participants to complete these due to cognitive or communication disability with a further 20% asking for assistance. Previous research indicates that proxy completion of measures of quality of life and active arm use is equally valid, but proxy measures have not been tested relating to care of the arm. Carers indicated that they felt participants underestimated the difficulty in caring for their arm but there was also recognition that the perceptions of the difficulty for the participant of receiving care and the difficulties of the carer of providing it may be different. In a larger study it would be wise for participants and carers to complete the assessment of passive function (Leeds Arm Spasticity Impact Scale) separately to record their individual perceptions of this difficulty.

The data concerning activity and participation demonstrated a range of results and performed as expected in this group, with few participants regaining much active function of the arm, and with a higher impact on the physical than social aspects of quality of life. Using the LASIS participants reported a range of difficulty in caring for the arm, and there was a positive correlation between the measure of difficulty and levels of spasticity, in line with theories about the impact of spasticity on ease of care.

Although only a small number of carers completed the Carer Burden scale, it collected a large range of results in those who did and appeared to agree with carer's comments about the difficulties they perceived. During follow-up visits it was also possible to collect a range of data from participants related to the on-going provision of treatments and services, although no attempt was made to verify the accuracy of these against formal records.

In summary, the battery of measures of activity, participation and related factors also shows some potential for recording change in this cohort of participants after stroke. It is recommended that the measure of difficulty with care (Leeds Arm Spasticity Impact Scale) be completed by both the pwS (where they can) and their carers separately. It would also be helpful to verify self-reported use of treatments and services against hospital and social care records for a number of participants to check the accuracy of collecting this data in this way.

The key findings and subsequent recommendations from each of the three objectives of the feasibility study are summarized in Table 33.

11.5 Study limitations

This study was designed with reference to the MRC work: Developing and Evaluating Complex Interventions: New Guidance (Craig et al, 2008). The purpose was to take a 'step back' from evaluating interventions for the profoundly-affected arm and instead focus on the work needed to develop a greater understanding of the natural course of disability within this group to then allow the design of more appropriate and targeted treatments in the future. However even this level of preparatory work requires the use of robust processes. The availability of outcome measures in rehabilitation, the use of a relatively small local service as the setting for this study, and the process of qualitative analysis are all potential limitations of this study.

Table 33: Summary of recommendations for the conduct of a definitive study

Recruitment and follow-up	Include a range of enhanced communication resources and techniques to maximise the opportunities for people with communication disability and cognitive impairment to engage.
	Develop a robust process for the use of nominated consultee for potential participants who do not have capacity to make a decision and who do not have a personal consultee
	Develop an alternative strategy for the recruitment of carers
	Ensure follow-up visits can be conducted at the persons own home
Predictor measures	Develop or evaluate an assessment of pain for use in people with most severe communication impairment (either behavioural pain assessment or carer report)
	Utilise the SADQ-H10 as a continuous variable
	Explore the relationship between 'Find the thumb' test and aphasia and dyspraxia
	Consider adding an alternative sensory assessment such as Nottingham Sensory assessment or the use of monofilaments for tactile sensation.
	Develop or validate a measure of body image post-stroke
Outcome measures	Consider adding skin temperature to the model of impairment after stroke
	Ensure that both participants and carers complete the assessment of passive function (LASIS) separately
	Verify self-report of use of treatments and services against hospital and social care records
	Review the measurement of range of movement

11.5.1 Limitations of the selected outcomes

The MRC framework states that the choice of outcomes in studies is 'crucial' (Craig et al, 2008, p.12). Traditionally healthcare research has focused on physiological outcome measures and self-reported outcomes have been viewed as potentially unreliable (Craig et al, 2008). However there is increasing

recognition that physiological measures often do not relate to the outcomes that patients consider important (Patrick & Guyatt, 2013). In this study a number of clinician assessed and participant reported measures were chosen to try to ensure that all perspectives were recognised. However, as shown in Chapter 3 many of these measures are not robust psychometrically. The measures of impairment used in this study are open to some subjective bias of the clinician involved. However, pragmatically they are widely used in clinical practice. Equally, interviews with participants and carers suggest that they believed that the self-reported measures used within this study were relevant to them, although some carers clearly had doubts about the accuracy of some of the stroke survivors in completing them. Hobart, Cano, Zajicek & Thompson (2007) suggest that most rating scales used in healthcare research are not scientifically sound, and that even current psychometric assessment of them is not robust enough. There is a tension between the quest for the ideal scientific but also meaningful outcome measure and the need to continue to generate solutions to problems currently experienced by pwS. By selecting a range of measures of impairment, activity restriction and quality of life, which have some positive psychometric properties it is hoped that sufficient data will be obtained to build on the theory concerning the profoundly-affected arm.

11.5.2 Small local study

This research was conducted within a single stroke service involving the acute stroke unit, rehabilitation unit and community teams. A large number of the eligible participants agreed to be involved in the study, which appears to indicate that it is a very acceptable design. However recruitment rates have been shown to be higher in studies involving single centres rather than multiple sites (Elkins et al, 2006). Therefore, the relatively high rate of recruitment achieved in this feasibility study should not be assumed if a larger study involving multiple centres were to be undertaken. Involving several centres in the feasibility study would potentially have given a more accurate prediction of recruitment rates for a larger study. However, it was not possible to pursue this due to the limitations with funding and the timescale of the doctorate programme.

11.5.3 Qualitative data analysis

Analysis of the transcripts of the interviews was conducted by the researcher (RA) working independently. Although this researcher has experience of qualitative data analysis (Kilbride, Allison & Evans, 2011; Allison et al, 2008) it would strengthen the validity and trustworthiness of the findings if a number of the transcripts had been scrutinised by a second researcher providing triangulation through multiple analysis (Lewis & Ritchie, 2003). However this was not possible, again due to the limitations of funding. To provide some rigour, results from the qualitative analysis were shared with the service user representative, with other members of the steering group and through supervision sessions, so findings and assumptions could be challenged. In addition to this in writing up a significant number of quotes from participants and carers have been used, using the raw data to give a greater degree of assurance of the qualitative analysis.

11.6 Study strengths

Despite a number of limitations there were also a number of strengths that are now discussed.

11.6.1 Methodical approach

This study used a methodical process, drawing on a number of recognised tools to develop a step-wise approach to building knowledge. The ICF framework was used to develop a model of the impact of the profoundly-affected arm, and then the outcome measures designed for clinical practice were appraised using an approach that has been shown to be robust for this purpose. A systematic review was conducted to identify the current knowledge base, prior to the design of the study. Whenever possible steps were taken to strengthen the rigour of the research processes, such as utilising two reviewers for each step of the systematic review and entering all observational data twice to ensure accuracy.

11.6.2 Partnership across clinical practice and academia

This project has involved a strong collaboration between clinicians working in rehabilitation on a daily basis and members of academic institutions. Consequently the project is grounded in both perspectives. Too frequently there

is a divide between clinical practice and research evidence. Clinicians are sometimes reluctant to adopt evidence even in the face of overwhelming findings for example the slow introduction of stroke units (Rudd & Matchar, 2004). Equally, academic researchers sometimes design trials of interventions that have little hope of 'working' or being commissioned in a clinical context, such as the original design of constraint-induced movement therapy post stroke that required six hours of supervision of exercise each day (Taub et al, 1993). In this study there has been a pragmatic approach to the process of design and the use of measures that can be utilised in clinical practice, which will subsequently enhance the generalisability of findings of a definitive study.

11.6.3 Patient and public involvement

There was a significant degree of patient and public involvement (PPI) prior to, and during the development and progress of the study. The original questions concerning interventions for the profoundly-affected arm were generated in a focus group set up to receive feedback about peoples' experience of using the stroke and spasticity services. An individual Joyce Picken who was present at this initial meeting then joined the study team to define the question, and plan the study. She became a co-applicant on the grant application to the Torbay Medical Projects Fund and was a member of the steering group overseeing the conduct of the study. As the design was refined the proposal was discussed with members of local stroke groups, at a Stroke conference for service users and carers, and at the hospital based Stroke Patient and Public Involvement group. Members of these groups were involved in sessions with clinical staff to help test the potential outcome measures prior to adoption, and Mrs Picken helped to develop and approved the interview schedule for the qualitative aspects of the study. This focus on user involvement evolved further by adopting the position of being as inclusive of all pwS as possible, by developing a range of resources to enable people with communication disability and cognitive impairment to participate to the maximum of their ability. Finally, our service user member has been involved in dissemination of findings from the study as co-author of some of the publications.

11.7 Thesis conclusions and contributions

This thesis describes the development and conduct of a feasibility study to test

a research design for developing a longitudinal profile of impairment and disability in the profoundly-affected arm after stroke. To our knowledge it is the first study to specifically target this group of individuals and as such makes an original contribution to the body of knowledge. An examination of the literature to date identified a model of the impairments, and factors associated with activity, participation and environmental factors relevant to the person with a profoundly-affected arm. A critical review of the outcome measures used to assess these constructs was presented and identified limitations in both the psychometric properties and their use in people with cognitive and communication disability. A review of the studies conducted to evaluate interventions for the profoundly-affected arm demonstrated an absence of appropriately designed trials and a lack of understanding of the natural course of events or of any potential risk factors for greater impairment, on which to base interventions.

A systematic review showed there was little previous work that had considered the construct of difficulty in caring for the profoundly-affected arm but there was some evidence of the profile of related impairments such as spasticity, pain and contracture in broader populations of people post-stroke. From the literature this study was designed to assess the potential of using a longitudinal study to address this gap in the knowledge base. The battery of outcome measures was developed in consultation with clinicians and people with stroke and provides a more systematic way of collecting relevant clinical information in this group than has previously been available. The feasibility study has demonstrated that it is possible to recruit a significant number of the target population of people post-stroke even those with significant physical disability. The use of enhanced communication resources has enabled the inclusion of people with significant communication disability and cognitive impairment. Interviews with participants and carers have given insight into the experience of living with a profoundly affected arm and their engagement with the research process. This qualitative data has been used to ensure the acceptability of a definitive research study. Subject to some further development of the measures and changes to the recruitment of carers, the current design has the potential to collect meaningful data to inform the future development of interventions for the profoundly-affected arm.

The findings from this research have been disseminated to audiences that included patients, carers, clinicians and academics. Further work is required to implement the suggested recommendations of the feasibility study prior to embarking on a definitive study.

Appendices

Appendix 1: Systematic review protocol

PURPOSE: The aim of this project is to systematically review the literature which examines people who do not regain the use of their arm after stroke (those who have a profoundly-affected arm). The purpose is to identify a) the natural course of impairments in the profoundly-affected arm, and b) potential predictors which can be used in routine clinical practice to identify those at risk of difficulty caring for the arm.

RELEVANCE: Seventy percent of pWS will experience arm weakness, and forty percent will not recover any useful movement of their arm. People who have a profoundly-affected arm frequently experience problems with spasticity, contracture, and pain. Many experience difficulty with passive function of the arm (activities that involve caring for the arm such as washing the hand, cutting the nails and dressing). Currently a range of treatments are available that may be used including splinting, stretching and botulinum toxin. However, evidence to support these interventions is mixed. There has been little work conducted on modelling or describing the natural course of events in the profoundly-affected arm, or on developing interventions. As there is currently little understanding of the progression of impairments and functional loss in the arm after stroke, even the optimal timing of potential interventions is unclear.

QUESTIONS:

1. What is the natural course of change of impairment and function in the arm after stroke?
2. What are potential predictors of those people who will experience persisting impairment, reduced function, and difficulty with passive function in the arm after stroke?

PARTICIPANTS: adults with a weak arm after stroke

INTERVENTIONS: NA

COMPARATORS: NA

OUTCOMES MEASURED: ease (or difficulty) of passive function of the arm, spasticity, pain, contracture/ range of movement

STUDY DESIGNS:

1. Observational studies of the natural course of events post stroke
2. Studies evaluating the ability of identified factors to predict function, pain, impairment in the arm and ability to care for the arm after stroke

METHODS: Searches will be completed of PubMed, MEDLINE, EMBASE, AMED, CINAHL, and Cochrane databases in October 2010 using the following concepts: Index Medical Subject Headings (MeSH)

<p>Group 1 stroke hemi*</p> <p>Group 2 predict* risk prognos*</p>	<p>Group 3 hand arm shoulder wrist upper limb</p> <p>Group 4 passive function spastic* hyperton* contracture range of movement pain</p>
---	---

Literature will also be identified by citation tracking using reference lists from papers. We will include studies which either model changes in the arm over time or which investigate at least one predictive variable and its relationship with impairments or difficulty providing passive function.

DATA EXTRACTION AND QUALITY ASSESSMENT: Data will be extracted, and the quality of studies rated using a tool assessing studies components that can affect risk of bias (McMasters Quality Assessment Tool). This tool assessed the risk of bias in a number of components of the studies including sample selection, study design, identification of confounding factors, blinding of assessors, reliability and validity of data collection methods, recording of withdrawals, and intervention integrity and analysis.

DATA SYNTHESIS: There will be a narrative synthesis of data.

Appendix 2: Data extraction form for systematic review

Title:

Author:

Year of publication:

Is this study:

Modelling impairments?	
Evaluating early predictors relationship with impairments or recovery?	
Evaluating correlations between impairment and recovery?	

Study design (longitudinal or cross sectional):

Setting:

Participant inclusion criteria:

Participant exclusion criteria:

Number of participants and age:

Quality assessment and risk of bias of study: (please circle rating)- See tool

Selection bias	Strong / weak
Blinding	Strong / weak
Data collection methods	Strong / weak
Withdrawals and drop-outs	Strong / weak
Integrity	Strong / weak
Analyses	Strong / weak

Predictors and how these were measured (if applicable)

Early spasticity:	
Early arm function:	
Early strength:	
Motor control:	
Inattention:	
Pain:	
Sensation:	
Global function:	
Self-efficacy:	
Mood:	
Aphasia:	
Stroke severity:	
Other:	

Outcomes assessed and scales used:

Passive function of arm:	
Pain:	
Spasticity:	
Contracture:	
Other:	

Published validity and reliability of scales:

Was this data collected part of another study?
(if so what did it concern):

Description of any (confounding) interventions?

Earliest time point post stroke:

Other time points examined:

Findings and statistics reported:
(by group if this is data from an intervention study or by cohort if this is observational)

Appendix 3: Quality assessment and risk of bias tool

1. SELECTION BIAS

Are the individuals selected to participate in the study likely to be representative of the target population?

- 1 Very likely (strong)
- 2 Somewhat likely (strong)
- 3 Not likely (weak)
- 4 Can't tell (weak)

What percentage of selected individuals agreed to participate?

- 1 80 - 100% agreement (strong)
- 2 60 – 79% agreement (strong)
- 3 less than 60% agreement (weak)
- 4 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

2. BLINDING

Were assessors blinded (between predictor measures and outcomes)?

- 1 Yes (strong)
- 2 No (weak)
- 3 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

3. DATA COLLECTION METHODS

Were data collection methods and tools shown to be valid?

- 1 Yes (strong)
- 2 No (weak)
- 3 Can't tell (weak)

Were data collection methods and tools shown to be reliable?

- 1 Yes (strong)
- 2 No (weak)
- 3 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

4. WITHDRAWALS AND DROP-OUTS

Were withdrawals and drop-outs reported in terms of numbers and/or reasons?

- 1 Yes (strong)
- 2 No (weak)
- 3 Can't tell (weak)

Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

- 1 80 -100% (strong)
- 2 60 - 79% (strong)
- 3 less than 60% (weak)
- 4 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

5. INTEGRITY

Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

- 1 Yes (weak)
- 2 No (strong)
- 3 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

6. ANALYSES

Are the statistical methods appropriate for the study design?

- 1 Yes (strong)
- 2 No (weak)
- 3 Can't tell (weak)

Rate this section

Strong	Weak
--------	------

Appendix 4: Information leaflet for participants with capacity

Information leaflet for participants

Care of the arm after stroke

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear to you or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Following a stroke, a large number of people have a very weak arm. Some people will recover some movement but not everyone will recover the full use of their arm. We currently do not really understand how recovery in the arm progresses for those people who have very little movement at the beginning. Some people may develop stiff joints or muscles and may then find it difficult to wash or care for the hand or arm. We currently do not understand which people are most at risk of this occurring.

This research study will assess people at agreed times after the stroke over a period of up to 12 months to identify the natural course of change in the arm, and to identify if there are any simple tests that can predict which people are at risk of difficulty caring for the arm. The results of this research will increase our understanding of what happens with the weak arm after stroke. If we can identify which people are at risk of difficulty caring for the arm will we be able to test specific treatments in this group.

Why have I been chosen?

We are approaching you because you have had a stroke in the past month and have a weak arm.

Do I have to take part?

No. It is your decision whether you want to take part or not. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

Initially you will be invited to attend an initial assessment. This will look at the current movement in your arm, the flexibility, and your awareness of the arm. You will also be asked if you experience any pain in the arm. In total the assessment will usually take less than an hour, but if you need to rest it can be conducted over a longer period.

Following the initial assessment we will arrange to see you again at 3 months, 6 months and 12 months after the stroke. At each of these times we will assess the movement, and flexibility of the arm. We will use a simple questionnaire to establish if you have developed any use of your arm, or if there is any difficulty caring for the arm. We will also use a questionnaire to assess your quality of life. If you have a carer we will also ask them if they would like to participate, to give their views. These assessments can be conducted at home or in the hospital- this will be your choice. At each assessment we will also ask you about any treatment or activities you are using for your arm, such as a splint.

Towards the end of the first year after your stroke, we will invite a small group of participants involved in the study to attend either a group or individual interview to discuss with us the experience of caring for their arm after stroke. We will ask you to indicate if you would consider being involved in this part of the project, and if you do you will be able to decide if you would prefer to attend a focus group or interview. The focus group will involve about 4 other people and will last up to 3 hours. The interview is likely to be shorter and can take place in your own home. The focus groups and interviews will be audio-taped and then transcribed to enable us to consider participants responses in detail.

You may wish to consider if you are already involved in any other research trials, and if so whether the number of follow up appointments will be difficult to manage. If, during the course of the study you lose the capacity to make decision about your continued involvement in the study, the data that has been collected so far will be retained and used in the analysis of the results.

What are the possible benefits of taking part?

The information we get from this study may help us predict which people are most at risk of developing difficulty caring for the arm.

If you choose to come to the hospital for your assessments, we will arrange transport for you.

If, during an assessment we recognise that you require a further intervention for your arm, such as a splint we will arrange this for you.

What happens when the research stops?

At the end of the study we will send you a summary of the results.

Will my taking part in the study be kept confidential?

All information collected as part of this study will be kept strictly confidential. The information you provide will be analysed by the Chief Investigator, Rhoda Allison. Any information about you will be given a unique number so that you cannot be recognised from it, when it is shown to other researchers. We will need you to agree for us to inform your GP and of your participation in the study so as not to affect you current treatment.

What will happen to the results of the study?

It is planned to present the results at local and national conferences and publish them in journals that will be read by healthcare workers.

Who is organising the research?

Rhoda Allison, Consultant Therapist in Stroke will be running the study. The study is part of a piece of work towards a Doctorate in Clinical Research, being completed by Ms Allison as a student at the University of Exeter.

Who has reviewed the study?

The study has been reviewed by Research Ethics Committee.

Contact for further information?

Should you have any further questions please contact Rhoda Allison on 01626 324549 or 07973 445748 or or Dr Debs Kelly on 01803 614567, who will be happy to discuss the study further.

Thank you for your time.

Appendix 5: Consent form for participants with capacity

Care of the arm after stroke

Consent Form for Participants with Stroke

Researcher: Rhoda Allison

Please initial box

1. I confirm that I have read and understand the information sheet dated 15.07.11 (Version 2) for the above study and I have had the opportunity to ask questions.
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected.
3. I agree to take part in the above study.
4. Towards the end of the study, I would also like to attend a focus group or interview, and understand that these will be audiotaped and transcribed YES/ NO
5. I agree that the research team can approach my friend or relative to ask if they would like to participate in the study and give their views YES/ NO
6. I would like a short summary of the results of the study once it has finished.
7. I agree that my GP can be informed of my participation in the study

Name of participant

Date

Signature

Witness
(if participant unable to document)

Date

Signature

Researcher
(taking consent)

Date

Signature

1 for participant; 1 for researcher, 1 for care record

Appendix 6: Information leaflet friends and relatives

Information leaflet for friends and relatives

Care of the arm after stroke

Introduction

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear to you or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Following a stroke, a large number of people have a very weak arm. Some people will recover some movement but not everyone will recover the full use of their arm. We currently do not really understand how recovery in the arm progresses for those people who have very little movement at the beginning. Some people may develop stiff joints or muscles and may then find it difficult to wash or care for the hand or arm. We currently do not understand which people are most at risk of this occurring.

This research study will assess people at agreed times after the stroke over a period of up to 12 months to identify the natural course of change in the arm, and to identify if there are any simple tests that can predict which people are at risk of difficulty caring for the arm. At the same time, if the person with stroke has a friend or relative, we will ask them to also rate if it is difficult to help the person care for their arm, and how they perceive the general level of burden of providing care. The results of this research will increase our understanding of what happens with the weak arm after stroke. If we can identify which people are at risk of difficulty caring for the arm will we be able to test specific treatments in this group.

Why has my relative/ friend been approached?

We have approached your relative/friend because they have had a stroke in the past month and have a weak arm. They have agreed to participate in the study.

Why have I been chosen?

We are approaching you because you have been identified as their friend or relative, and the person with stroke has agreed that we can contact you.

What will happen if they take part?

We will be arranging to see you relative/ friend at 3 months, 6 months and 12 months after the stroke. At these points we will be looking at any recovery in their arm and recording any pain, stiffness or perceived difficulties with care.

If you also agree to participate in the study we will ask you to complete 2 questionnaires at each of these assessments. The questionnaires record how difficult you feel it can be helping and supporting this person.

These assessments can be conducted at home or in the hospital- we will arrange to see your relative/friend where ever is most convenient for you both.

Towards the end of the first year after your friend's stroke, we will invite a small group of people involved in the study to attend either a focus group or an interview to discuss with us the experience of caring for the arm after stroke.

We will ask you to indicate if you would consider being involved in this part of the project, and if you do you will be able to decide if you would prefer to attend a focus group or interview. The focus group will involve about 4 other people and will last up to 3 hours. The interview is likely to be shorter and can take place in your own home. The focus groups and interviews will be audio-taped and then transcribed to enable us to consider participants responses in detail.

What are the possible benefits of taking part?

The information we get from this study may help us predict which people are most at risk of developing difficulty caring for the arm.

If you come to the hospital for the assessments, we will arrange transport for you. If, during an assessment we recognise that your relative/friend requires a further intervention for their arm, such as a splint we will arrange this for them.

What happens when the research stops?

At the end of the study we will send a summary of the results.

Will my taking part in the study be kept confidential?

All information collected as part of this study will be kept strictly confidential. The information provided will be analysed by the Chief Investigator, Rhoda Allison. Any information about your relative/friend will be given a unique number so that they cannot be recognised from it, when it is shown to other researchers. We will need to inform your relative/friend's GP of their participation in the study so as not to affect their current treatment.

What will happen to the results of the study?

It is planned to present the results at local and national conferences and publish them in journals that will be read by healthcare workers.

Who is organising the research?

Rhoda Allison, Consultant Therapist in Stroke will be running the study. The study is part of a piece of work towards a Doctorate in Clinical Research, being completed by Ms Allison as a student at the University of Exeter.

Who has reviewed the study?

The study has been reviewed by Research Ethics Committee.

Contact for further information?

Should you have any further questions please contact Rhoda Allison on 01626 324549 or 07973 445748, or Dr Debs Kelly on 01803 614567, who will be happy to discuss the study further.

Thank you for your time.

Appendix 7: Consent form for friends and relatives

Care of the arm after stroke

Consent Form for Relatives and friends

Researcher: Rhoda Allison

Please initial box

1. I confirm that I have read and understand the information sheet dated 15.07.11 (Version 2) for the above study and I have had the opportunity to ask questions.
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving reason, without my care or legal rights being affected.
3. I agree to take part in the above study.
4. Towards the end of the study, I would also like to attend a focus group or interview, and understand that these will be audiotaped and transcribed YES/ NO
5. I would like a short summary of the results of the study once it has finished.

Name of participant

Date

Signature

Researcher
(taking consent)

Date

Signature

1 for participant (relative or friend); 1 for researcher
1 for care record

Appendix 8: Example of pictographic resources used to support participants

<p>Hospital or home at 2-4 weeks</p>	
<p>3 months: at home</p> <p>Visit to ask you how the arm has recovered and look at the range of movement</p>	
<p>6 months: at home</p> <p>Visit to ask you how the arm has recovered and look at the range of movement</p>	
<p>12 months: at home</p> <p>Visit to ask you how the arm has recovered and look at the range of movement</p>	

Appendix 9: Information leaflet for consultees

Information leaflet for consultees

Care of the arm after stroke

Introduction

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research. To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn. If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way. If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend.

What is the purpose of the study?

Following a stroke, a large number of people have a very weak arm. Some people will recover some movement but not everyone will recover the full use of their arm. We currently do not really understand how recovery in the arm progresses for those people who have very little movement at the beginning.

Some people may develop stiff joints or muscles and may then find it difficult to wash or care for the hand or arm. We currently do not understand which people are most at risk of this occurring.

This research study will assess people at agreed times after the stroke over a period of up to 12 months to identify the natural course of change in the arm, and to identify if there are any simple tests that can predict which people are at risk of difficulty caring for the arm. The results of this research will increase our understanding of what happens with the weak arm after stroke. If we can identify which people are at risk of difficulty caring for the arm will we be able to test specific treatments in this group.

Why has my relative/ friend been approached?

We have approached your relative/friend because they have had a stroke in the past month and have a weak arm.

What will happen to them if they take part?

Initially they will have an initial assessment. This will look at the current movement in their arm, the flexibility, and the awareness of the arm. They will also be asked if they experience any pain in the arm. In total the assessment will usually take less than an hour, but if they need to rest it can be conducted over a longer period. Following the initial assessment the research team will arrange to see your relative/friend again at 3 months, 6 months and 12 months after the stroke. At each of these times they will assess the movement, and flexibility of the arm. They will use a simple questionnaire to establish if your relative/friend has developed any use of their arm, or if there is any difficulty caring for the arm. If possible, they will also use a questionnaire to assess quality of life. These assessments can be conducted at home or in the hospital- we will arrange to see your relative/friend where ever is most convenient for them. At each assessment we will also ask your relative/friend about any treatment or activities they are using for their arm, such as a splint.

What are the possible benefits of taking part?

The information we get from this study may help us predict which people are most at risk of developing difficulty caring for the arm.

If your relative/friend comes to the hospital for the assessments, we will arrange transport for them.

If, during an assessment we recognise that your relative/friend requires a further intervention for their arm, such as a splint we will arrange this for them.

What happens when the research stops?

At the end of the study we will send a summary of the results.

Will my taking part in the study be kept confidential?

All information collected as part of this study will be kept strictly confidential. The information provided will be analysed by the Chief Investigator, Rhoda Allison. Any information about your relative/friend will be given a unique number so that they cannot be recognised from it, when it is shown to other researchers. We will need to inform your relative/friend's GP of their participation in the study so as not to affect their current treatment.

What will happen to the results of the study?

It is planned to present the results at local and national conferences and publish them in journals that will be read by healthcare workers.

Who is organising the research?

Rhoda Allison, Consultant Therapist in Stroke will be running the study. The study is part of a piece of work towards a Doctorate in Clinical Research, being completed by Ms Allison as a student at the University of Exeter.

Who has reviewed the study?

The study has been reviewed by Research Ethics Committee.

Contact for further information?

Should you have any further questions please contact Rhoda Allison on 01626 324549 or 07973 445748 who will be happy to discuss the study further, or Dr Debs Kelly on 01803 614567.

Thank you for your time.

Appendix 11: Information leaflet for participants who regain capacity

Information leaflet for participants who regain capacity

Care of the arm after stroke

When you became ill, we felt you were unable to say whether or not you should join a research study we are conducting. We asked for his /her advice.

Now you are recovering, we want to ask if you would agree to continue in the study. You are free to withdraw from the study if you wish to.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear to you or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Following a stroke, a large number of people have a very weak arm. Some people will recover some movement but not everyone will recover the full use of their arm. We currently do not really understand how recovery in the arm progresses for those people who have very little movement at the beginning. Some people may develop stiff joints or muscles and may then find it difficult to wash or care for the hand or arm. We currently do not understand which people are most at risk of this occurring.

This research study will assess people at agreed times after the stroke over a period of up to 12 months to identify the natural course of change in the arm, and to identify if there are any simple tests that can predict which people are at risk of difficulty caring for the arm. The results of this research will increase our understanding of what happens with the weak arm after stroke. If we can identify which people are at risk of difficulty caring for the arm will we be able to test specific treatments in this group.

Why was I chosen?

We originally approached you because you had had a stroke and had a weak arm.

Do I have to continue to take part?

No. It is your decision whether you want to continue to take part or not. If you do decide to continue to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I continue to take part?

Initially you attended an initial assessment. At this assessment we measured the movement in your arm, the flexibility, and your awareness of the arm. You were asked if you experienced any pain in the arm.

Following the initial assessment we arranged to see you again at 3 months, 6 months and 12 months after the stroke. At each of these times we assess the movement, and flexibility of the arm. We use a simple questionnaire to establish if you have developed any use of your arm, or if there is any difficulty caring for the arm. We use a questionnaire to assess your quality of life. If you have a carer we also asked them if they would like to participate to give their views. These assessments can be conducted at home or in the hospital- this will be your choice. At each assessment we will also ask you about any treatment or activities you are using for your arm, such as a splint.

What are the possible benefits of taking part?

The information we get from this study may help us predict which people are most at risk of developing difficulty caring for the arm.

If you choose to come to the hospital for your assessments, we will arrange transport for you.

If, during an assessment we recognise that you require a further intervention for your arm, such as a splint we will arrange this for you.

What happens when the research stops?

At the end of the study we will send you a summary of the results.

Will my taking part in the study be kept confidential?

All information collected as part of this study will be kept strictly confidential. The information you provide will be analysed by the Chief Investigator, Rhoda Allison. Any information about you will be given a unique number so that you cannot be recognised from it, when it is shown to other researchers. We will need you to agree for us to inform your GP and of your participation in the study so as not to affect your current treatment.

What will happen to the results of the study?

It is planned to present the results at local and national conferences and publish them in journals that will be read by healthcare workers.

Who is organising the research?

Rhoda Allison, Consultant Therapist in Stroke will be running the study. The study is part of a piece of work towards a Doctorate in Clinical Research, being completed by Ms Allison as a student at the University of Exeter.

Who has reviewed the study?

The study has been reviewed by Research Ethics Committee.

Contact for further information?

Should you have any further questions please contact Rhoda Allison on 01626 324549 or 07973 445748 or Dr Debs Kelly on 01803 614567, who will be happy to discuss the study further.

Thank you for your time.

Appendix 12: Consent form for participants who regain capacity

Care of the arm after stroke

Consent Form for Participants with Stroke who regain capacity:

Researcher: Rhoda Allison

Please initial box

1. I confirm that I have read and understand the information sheet dated 15.07.11 (Version 2) for the above study and I have had the opportunity to ask questions.
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected.
3. I agree to take part in the above study.
4. Towards the end of the study, I would also like to attend a focus group or interview, and understand that these will be audiotaped and transcribed YES/ NO
5. I would like a short summary of the results of the study once it has finished.
6. I agree that my GP can be informed of my participation in the study

Name of participant

Date

Signature

Witness
(if participant unable to document)

Date

Signature

Researcher
(taking consent)

Date

Signature

1 for participant; 1 for researcher

1 for care record

Appendix 13: Letter to GPs informing them of persons participation

South Devon Healthcare 
NHS Foundation Trust


Torbay & Southern Devon Health &
Care Trust

Rhoda Allison
Consultant Therapist Stroke
Newton Abbot Hospital
Newton Abbot
TQ12 2SL

Date- to be completed

Dear Dr (To be completed)

Re your patient: (To be completed)

This patient has consented to participating in the Care of the Arm after Stroke Trial.

They were selected for the trial as, at this stage, we anticipate they will not regain the full use of their arm after their recent stroke. This trial is a longitudinal study of recovery in the profoundly affected arm after stroke.

During the study we will review each participant at 3 months, 6 months and 1 year post stroke to track the return of function and development of impairments such as spasticity or contracture in the arm. If it becomes apparent that a person is likely to benefit from a specific intervention such as a splint, we will make a referral for this to take place.

If you need any further information about the trial please do not hesitate to contact me.

Yours sincerely,

Rhoda Allison
Consultant Therapist Stroke

Appendix 14: Example of pictographic resources used to support participants- Assessing pain

PC-01

PAIN?



yes

no

Appendix 15: Final standardised protocol for measuring range of movement

Standard operating procedures

CAST Study

Photographic guide to goniometry in the arm

Participant is sitting. For each joint, the examiner moves the arm passively through the full range of movement available on three occasions.

On the fourth occasion, the examiner uses a goniometer positioned over the axis of the joint to measure the range of movement available, as shown in the photographic guide.

End of range occurs when the joint can not comfortably be moved further.

If using finger goniometers, be aware that scale of these is set to record amount of flexion at the joint, not extension (so needs to be corrected).

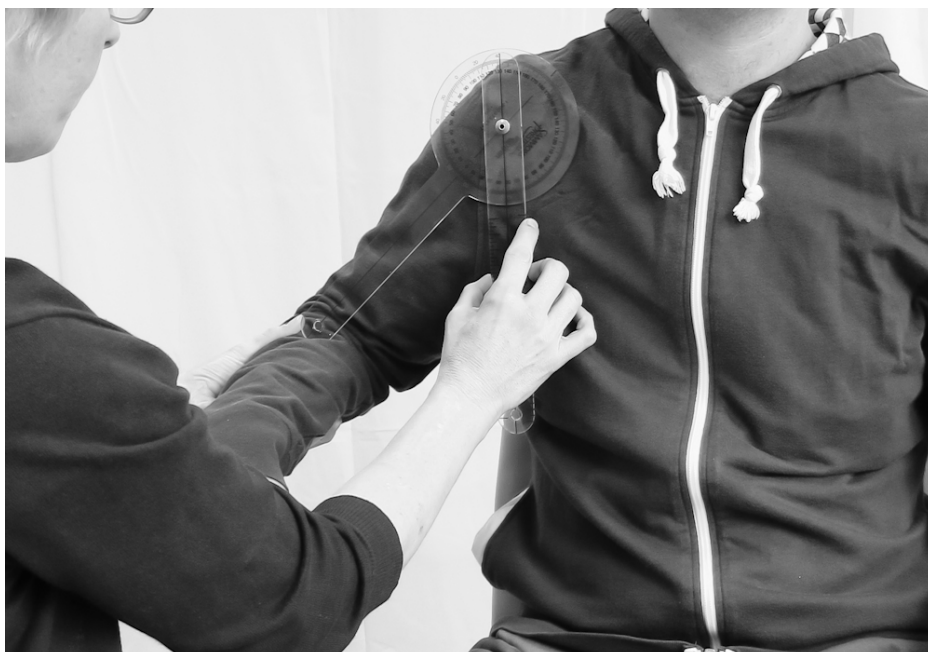
Shoulder flexion

Arm at side is 0 degrees



Shoulder abduction

Arm at side is 0 degrees



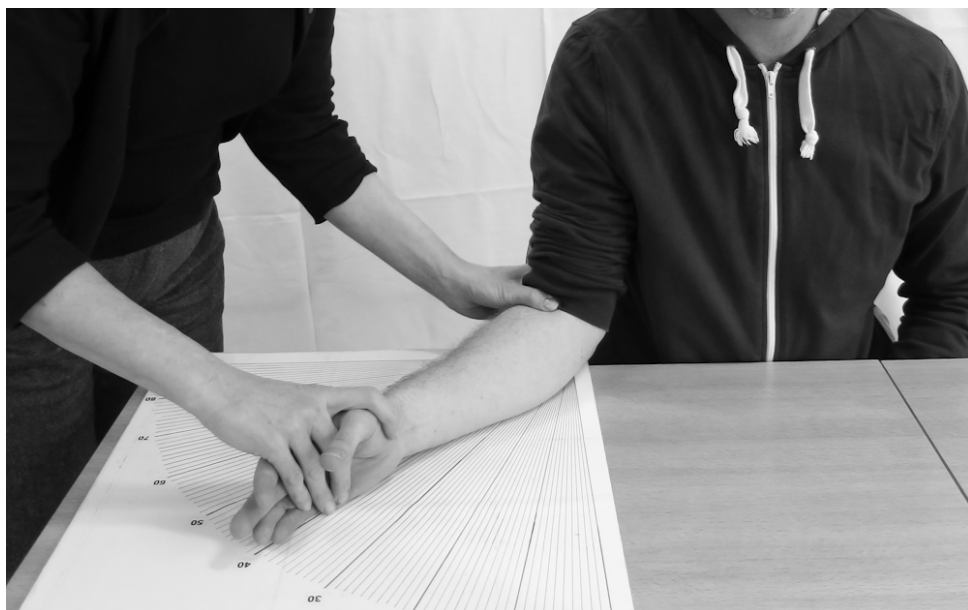
Shoulder external rotation

Neutral is 0 degrees

Step one: The participant sits with their arm resting on a table or tray. Position the elbow over the point of protractor as shown and allow 90 degrees elbow flexion



Step two: Laterally rotate the shoulder (forearm straight forward is 0 degrees)



If the participant is unable to achieve neutral, adjust the protractor to measure a negative value.

Elbow flexion

Full extension is 0 degrees



Elbow extension

Full extension is 180 degrees



Wrist extension

Neutral is 0 degrees

The participant sits with their forearm resting on a table or tray, with the fingers flexed



Finger MCP extension

Full extension is 180 degrees- this is the maximum recorded range



Finger PIP extension

Full extension is 180 degrees- this is the maximum recorded range



Finger DIP extension

Full extension is 180 degrees- this is the maximum recorded range



Thumb MCP extension

Full extension is 180 degrees- this is the maximum recorded range



Thumb IP extension

Full extension is 180 degrees- this is the maximum recorded range



Appendix 16: Workbook to record the predictor variables

1. PAIN

Ask the person do you have any pain in the arm at rest?

	MARK YES OR NO
PAIN AT REST	

2. INATTENTION AND SENSATION: FIND THE THUMB TEST

The examiner lifts the affected arm to eye level, and then places it back into the person's lap or equivalent resting position. The patient is then asked to grasp the thumb of the affected hand with their good hand. The examiner rates the response.

	MARK YOUR RATING HERE (0-2)
FIND THE THUMB TEST	

Rating scale:

No difficulty. The person is able to locate the affected thumb accurately.	0
Some impairment: the person is able to locate their affected lower arm (area below the elbow) but not their thumb.	1
Severe difficulty: the patient is unable to find his thumb or lower arm.	2

3. MOTOR CONTROL OF THE ARM: FUGL-MEYER

Refer to the attached guide to completing the Fugl-Meyer test. Each section is scored with 0, 1 or 2.

		MARK RATING HERE (0-2)
Shoulder / elbow / forearm		
1.1 Reflex activity	1.1.1 Flexors (biceps and finger flexors)	
	1.1.2 Extensors (triceps)	
1.2 Flexor synergy – volitional movement within synergy	1.2.1 Shoulder retraction	
	1.2.2 Shoulder elevation	
	1.2.3 Shoulder abduction	
	1.2.4 Shoulder external rotation	
	1.2.5 Elbow flexion	
	1.2.6 Forearm supination	
1.3 Extensor synergy – volitional movement within synergy	1.3.1 Shoulder adduction / internal rotation	
	1.3.2 Elbow extension	
	1.3.3 Forearm pronation	
1.4 Volitional movement mixing the dynamic flexor and extensor strategies	1.4.1 Hand on lumbar spine	
	1.4.2 Shoulder flexion	
	1.4.3 Forearm pronation / supination	
1.5 Volitional movements are performed with little or no synergy dependence	1.5.1 Shoulder abduction	
	1.5.2 Shoulder flexion	
	1.5.3 Forearm pronation-supination	
	1.6 Normal reflex activity	
2 Wrist	2.1 Wrist stability – elbow 90°	
	2.2 Wrist flexion/extension – elbow 90°	
	2.3 Wrist stability – elbow 0°	
	2.4 Wrist flexion/extension – elbow 0°	
	2.5 Circumduction	
3 Hand	3.1 Mass flexion	
	3.2 Mass extension	
	3.3 Grasp A – distal finger grasp	
	3.4 Grasp B – thumb adduction grasp	
	3.5 Grasp C – thumb to index finger grasp	
	3.6 Grasp D – cylinder grasp	
	3.7 Grasp E – spherical grasp	
4 Co-ordination/speed	4.1 Tremor	
	4.2 Dysmetria	
	4.3 Speed	
TOTAL SCORE:		

4. SPASTICITY: MODIFIED MODIFIED ASHWORTH SCALE

For each muscle group, the examiner moves the arm passive through the full range of movement available on three occasions. On the fourth occasion, the examiner rates the resistance felt to the passive movement using the rating scale given. Eg. To test shoulder adductors, passively abduct the shoulder on 3 occasions prior to rating the resistant felt to shoulder abduction.

	MARK YOUR RATING HERE (0-4)
SHOULDER ADDUCTORS	
SHOULDER INTERNAL ROTATORS	
ELBOW FLEXORS	
WRIST FLEXORS	
FINGER FLEXORS	

Rating scale:

No increase in tone	0
Slight increase in tone giving a catch when the limb was moved in flexion or extension	1
More marked increase in tone but limb easily flexed	2
Considerable increase in tone- passive movement difficult	3
Limb rigid in flexion or extension	4

5. PAIN

HAS THE PERSON HAD ANY PAIN IN THE ARM ON MOVEMENT DURING ANY PART OF THE PHYSICAL ASSESSMENT?

	MARK YES OR NO
PAIN ON MOVEMENT	

6. MOOD: THE STROKE APHASIC DEPRESSION QUESTIONNAIRE 10:

This should be completed with at least 2 members of the MDT. Please indicate on how many out of the last 7 days the patient has shown the following behaviours:

Behaviour	Days this week			
	Every day	4-6	1-4	Not at all
1. Did he/she have weeping spells?	3	2	1	0
2. Did he//she have restless disturbed nights?	3	2	1	0
3. Did he/she avoid eye contact when you spoke to him/her?	3	2	1	0
4. Did he/she burst into tears?	3	2	1	0
5. Did he/she complain of aches and pains?	3	2	1	0
6. Did he/she get angry?	3	2	1	0
7. Did he/she refuse to participate in social activities?	3	2	1	0
8. Is he/she restless and fidgety?	3	2	1	0
9. Did he/she sit without doing anything?	3	2	1	0
10. Did he/she keep him/herself occupied during the day?	0	1	2	3
TOTAL SCORE:				

Appendix 17: Workbook to record the outcome measures

1. Adverse events

Have you had any hospital admissions since you were last seen by the trial team?

Have you had any other significant ill health?

Details:

2. Ongoing treatment:

Have you had any of the following interventions in the past 3 months?

	Details
Formal therapy YES/NO	
Use of own exercise programme YES/NO	
Splinting YES/NO	(if so how long worn for)
Medications for analgesia (for arm) YES/NO	(if so which)
Medications for spasticity YES/NO	(if so which)
Botulinum toxin YES/NO	(if so was it shoulder, elbow, wrist, hand)
Formal care provision YES/NO	(how many carers, how frequently)
Any other intervention YES/NO	

3. DIFFICULTY CARING FOR THE ARM: LASIS

1. Investigator asks questions to the patient - responses noted on proforma. Each question should be qualified in terms of the usual level of difficulty when performing the task over the preceding 7 days.

2. The responses are chosen to the following the question “How difficult is this activity?” by the patient or carer from the rating chart (and scored for who does the activity)

3. If patients or carers have not performed a particular activity within last 7 days then leave blank

4. A summary score for patient disability is obtained by adding together all the patient scores and dividing this total by the number of questions on which responses were made.

PLEASE TICK HERE IF PERSON UNABLE TO COMPLETE	
--	--

1. Do you or your carer have difficulty cleaning the palm of your affected hand? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

2. Do you or your carer have difficulty cutting the fingernails of your affected hand? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

3. Do you or your carer have difficulty cleaning around the elbow of your affected arm? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

4. Do you or your carer have difficulty cleaning the armpit of your affected arm? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

5. Do you or your carer have difficulty cleaning the armpit of your unaffected arm? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

6. Do you or your carer have difficulty putting your arm through the sleeve of your coat? YES / NO					
Degree of difficulty experienced by patient	0	1	2	3	4

7. Do you have difficulty **putting a glove** on your affected hand?
YES / NO

Degree of difficulty experienced by patient 0 1 2 3 4

8. Do you have difficulty **rolling over in bed** because of tightness in your arm?
YES / NO

Degree of difficulty experienced by patient 0 1 2 3 4

9. Do you have difficulty **doing physiotherapy exercises** to your affected arm?
YES / NO

Degree of difficulty experienced by patient 0 1 2 3 4

10. Does the position of your affected arm cause difficulty in **balancing when you are standing by yourself**? **YES / NO**

Degree of difficulty experienced by patient 0 1 2 3 4

11. Does the position of your affected arm cause difficulty in **balancing when you are walking by yourself** (including use of walking aid) ? **YES / NO**

Degree of difficulty experienced by patient 0 1 2 3 4

12. Do you have difficulty using your affected arm to **hold objects steady while you use your unaffected arm**?
YES / NO

Degree of difficulty experienced by patient 0 1 2 3 4

How difficult is this activity ?

- 0 I HAVE NO DIFFICULTY
- 1 I HAVE A LITTLE DIFFICULTY
- 2 I HAVE MODERATE DIFFICULTY
- 3 I HAVE A GREAT DEAL OF DIFFICULTY
- 4 I CANNOT DO THIS ACTIVITY

PHYSICAL EXAMINATION

4. PAIN

Ask the person do you have any pain in the arm at rest?

	MARK YES OR NO
PAIN AT REST	

5. PASSIVE RANGE OF MOVEMENT

Participant is lying supine. For each joint, the examiner moves the arm passively through the full range of movement available on three occasions. On the fourth occasion, the examiner uses a goniometer positioned over the axis of the joint to measure the range of movement available, as shown in the photographic guide.

	RECORD THE RANGE HERE	
SHOULDER FLEXION		Arm at side is 0°
SHOULDER ABDUCTION		Arm at side is 0°
SHOULDER EXTERNAL ROTATION		Forearm straight up is 0°
ELBOW EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
ELBOW FLEXION		Full extension is 0°
WRIST EXTENSION		Neutral is 0°
INDEX FINGER MCP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
INDEX FINGER PIP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
INDEX FINGER DIP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
LITTLE FINGER MCP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
LITTLE FINGER PIP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
LITTLE FINGER DIP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
THUMB MCP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum
THUMB IP EXTENSION		Full extension is 180°. If hyperextends record 180° as maximum

6. SPASTICITY: MODIFIED MODIFIED ASHWORTH SCALE

Participant is lying supine. For each muscle group, the examiner moves the arm passive through the full range of movement available on three occasions. On the fourth occasion, the examiner rates the resistance felt to the passive movement using the rating scale given. Eg. To test shoulder adductors, passively abduct the shoulder on 3 occasions prior to rating the resistant felt to shoulder abduction.

	MARK YOUR RATING HERE (0-4)
SHOULDER ADDUCTORS	
SHOULDER INTERNAL ROTATORS	
ELBOW FLEXORS	
WRIST FLEXORS	
FINGER FLEXORS	

Rating scale:

No increase in tone	0
Slight increase in tone giving a catch when the limb was moved in flexion or extension	1
More marked increase in tone but limb easily flexed	2
Considerable increase in tone- passive movement difficult	3
Limb rigid in flexion or extension	4

7. SKIN CONDITION

OBSERVE SKIN IN HAND, ELBOW AND AXILLA- TICK MOST SEVERE CONDITION

CLEAN & DRY (1)	MACERATED (DAMP, SMELLY) (2)	BROKEN SKIN (3)

8. PAIN

HAS THE PERSON HAD ANY PAIN IN THE ARM ON MOVEMENT DURING ANY PART OF THE PHYSICAL ASSESSMENT?

	MARK YES OR NO
PAIN ON MOVEMENT	

9. ACTIVE USE OF THE ARM: MOTOR ACTIVITY LOG

Please rate how often you have used your affected arm for the following activities during the past week.

PLEASE TICK HERE IF PERSON UNABLE TO COMPLETE	
--	--

Putting arm through coat sleeve	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Steady myself while standing	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Carry an object from place to place	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Pick up fork of spoon, use for eating	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Comb hair	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Pick up cup by handle	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Hand craft/card playing	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this
Hold a book for reading	Never use the affected arm for this	0	1	2	3	4	5	Always use the affected arm for this

Use towel to dry face or other body part	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	
Pick up a glass	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	
Pick up toothbrush and brush teeth	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	
Shaving/make-up	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	
Use a key to open a door	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	
Letter writing/typing	Never use the affected arm for this						Always use the affected arm for this
	0	1	2	3	4	5	

10. Quality of life: SIPSO

Please answer all the questions

1. Since your stroke, how much difficulty do you have dressing yourself fully?

(Circle One Number)

No difficulty at all	4
Slight difficulty	3
Some difficulty	2
A lot of difficulty	1
I cannot dress myself fully	0

2. Since your stroke, how much difficulty do you have moving around *all* areas of the home? (Circle One Number)

No difficulty at all	4
Slight difficulty	3
Some difficulty	2
A lot of difficulty	1
I cannot move around all areas of the home	0

3. Since your stroke, how satisfied are you with your overall ability to perform daily activities *in and around the home*? (Circle One Number)

Completely satisfied	4
Mostly satisfied	3
Fairly satisfied	2
Not very satisfied	1
Completely dissatisfied	0

4. Since your stroke, how much difficulty do you have shopping for and carrying a few items (1 bag of shopping or less) when at the shops? (Circle One Number)

No difficulty at all	4
Slight difficulty	3
Some difficulty	2
A lot of difficulty	1
I cannot shop for and carry a few items	0

5. Since your stroke, how independent are you in your ability to move around your local neighbourhood? (Circle One Number)

I am completely independent	4
I prefer to have someone else with me	3
I need occasional assistance from someone	2
I need assistance much of the time	1
I am completely dependent on others	0

6. Since your stroke, how often do you feel bored with your free time at home?

(Circle One Number)

I am never bored with my free time	4
A little of my free time	3
Some of my free time	2
Most of my free time	1
All of my free time	0

7. Since your stroke, how would you describe the amount of communication between you and your friends/associates? (Circle One Number)

A great deal	4
Quite a lot	3
Some	2
A little bit	1
None	0

8. Since your stroke, how satisfied are you with the level of interests and activities you share with your friends/associates? (Circle One Number)

Completely satisfied	4
Mostly satisfied	3
Fairly satisfied	2
Not very satisfied	1
Completely dissatisfied	0

9. Since your stroke, how often do you visit friends/others?

(Circle One Number)

Most days	4
At least once a week	3
At least once a fortnight	2
Once a month or less	1
Never	0

10. Since your stroke, how do you feel about your appearance when out in public?

(Circle One Number)

Perfectly happy	4
Slightly self-conscious	3
Fairly self-conscious	2
Very self-conscious	1
I try to avoid going out in public	0

Appendix 18: Worksheet for collecting data on carer outcomes

Carer burden: Self-rated burden (SRB)

If the person has a carer, ask the carer to rate how burdensome caring for their partner is.

On the scale below '0' means that you feel that caring for or accompanying your partner at the moment is not hard at all; '100' means that you feel that caring for or accompanying your partner at the moment is much too hard.

Please indicate with an 'X' on the scale how burdensome you feel caring for or accompanying your partner is at the moment.

Not at all
straining

Much too
straining

0	10	20	30	40	50	60	70	80	90	100

Appendix 19: Topic guide for focus groups and interviews

1. How has the recovery and movement in your arm changed since your stroke?
2. What do you find particularly difficult in relation to your arm?
3. Have you experienced any difficulty looking after your arm? If so can you describe this. (prompts regards washing, dressing, cutting nails)
4. Have you experienced any difficulty with pain?
5. How do you feel about the about the appearance of the arm?
6. What treatments were you offered to help your arm?
Did you find any of these helpful?
7. What did you think of the measures that were used in the study? (Self reported measures will be available and interviewer will ask participants about each item of LASIS etc)
8. Are there other aspects of the arm after stroke that we should consider including in the measures?
9. How did you find being involved in the research process? Is there anything we should change?
10. How was it, being approached about involvement in the research so early after the stroke?
11. Did you have longer term need for support? If so can you describe /expand on how were these met?

Appendix 20: Letters of ethical approval



National Research Ethics Service NRES Committee South West – Frenchay

South West Research Ethics Centre
Level 3, Block B
Whitefriars
Lewins Mead,
Bristol
BS1 2NT

Telephone: 0117 342 1334/ 0117 342 1382
Facsimile: 0117 342 0445

21 July 2011

Ms Rhoda Allison
Consultant Therapist in Stroke
Torbay Care Trust
Stroke Unit
Newton Abbot Hospital
Devon
TQ12 2SL

Dear Ms Allison

Study title: Predicting difficulty in caring for the arm after stroke
and developing a longitudinal profile of impairment and
disability
REC reference: 11/SW/0149

Thank you for your letter of 16th July 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		07 June 2011
Covering Letter		16 July 2011
GP/Consultant Information Sheets	1	03 June 2011
Interview Schedules/Topic Guides	1	03 May 2011
Interview Schedules/Topic Guides	1	03 May 2011
Investigator CV		
Other: CV Ian Frampton		
Other: Letter from funder		06 June 2011
Other: Carer burden scale		
Participant Consent Form	2	15 July 2011
Participant Consent Form: Friends and relatives	2	15 July 2011
Participant Consent Form: Consultee declaration form	2	15 July 2011
Participant Consent Form: Participant who regains capacity	2	15 July 2011
Participant Information Sheet	2	15 July 2011
Participant Information Sheet: Friend/relative	2	15 July 2011
Participant Information Sheet: Consultee	2	15 July 2011
Participant Information Sheet: Participant who regains capacity	2	15 July 2011
Protocol	2.0	03 June 2011
Questionnaire: Leeds spasticity impact scale		
Questionnaire: Motor activity log		

REC application		09 June 2011
Referees or other scientific critique report		12 April 2011
Response to Request for Further Information		
Summary/Synopsis	1	03 June 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/SW/0149

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely


Dr Mike Shere
Chair

Email: ubh-tr.SouthWest5@nhs.net

Enclosures: "After ethical review – guidance for researchers" – sent via e-mail

Copy to: *Iain Lang, NHS Devon*
Ms Reshma Raycoba, PenCLRN

References

Ada, L., O'Dwyer, N. & O'Neill, E. (2006). Relation between spasticity, weakness and contracture of the elbow flexors and upper limb activity after stroke: An observational study. *Disability and Rehabilitation*, 28, 13, 891–897.

Adams W.C. & Imans F.J. (1983). Resting blood flow in the paretic and nonparetic lower legs of hemiplegic persons: Relation to local skin temperature. *Archives of Physical Medicine and Rehabilitation*, 64, 9, 423-428.

Alexander, S.J. (2010). 'As long as it helps somebody': why vulnerable people participate in research. *International Journal of Palliative Nursing*, 16, 4, 174–179.

Allison, R., Shenton, L., Bamforth, K., Richards, D. & Kilbride, C. (in submission). Incidence, time course and predictors of impairments relating to caring for the profoundly affected arm after stroke: A systematic review.

Allison, R., Kilbride, C., Frampton, I., Shenton, L., Marsden, J. & Picken, J. (in submission). Development and preliminary evaluation of a standard assessment for monitoring changes in impairment and disability in the profoundly-affected arm after stroke in research and clinical practice.

Allison, R., Kilbride, C., Frampton, I., Picken, J. & Marsden, J. (2013). Involving people with severe communication disability and cognitive impairment in stroke research. *Cerebrovascular Diseases*, 35, 3, 214.

Allison, R., Bailey, C., Kilbride, C., Frampton, I., Marsden, J. & Picken, J. (2012). Care of the Arm after Stroke (CAST): Developing a systematic battery of assessments for measuring impairment and disability in the non-functional arm. *Proceedings of the UK Stroke Forum Conference*. UKSF.

Allison, R. & Shenton, L. (2011a). Can we predict which patients will have difficulty caring for the profoundly-affected arm after stroke? *Journal of Rehabilitation Medicine*, 43, S51, 67.

Allison, R. & Shenton, L. (2011b). Identifying the course of impairments and predicting difficulty caring for the profoundly-affected arm after stroke: a systematic review. *Proceedings of the World Confederation of Physical Therapy Congress*. Retrieved from: www.wcpt.org/posters_and_ppts.

Allison, R., Evans, P., Kilbride, C., & Campbell, J. (2008). Secondary prevention of stroke: Using the experiences of patients and carers to inform the development of an educational resource. *Family Practice*, 25, 5, 355-361.

Altman, D. (1991). *Practical statistics for medical research*. London: Chapman and Hall.

American Academy of Orthopaedic Surgeons. (1965). *Joint motion: method of measuring and recording*. Chicago: American Academy of Orthopaedic Surgeons.

Andrews, A.W. & Bohannon, R.W. (2001). Discharge function and length of stay for patients with stroke are predicted by lower extremity muscle force on admission to rehabilitation. *Neurorehabilitation and Neural Repair*, 15, 2, 93-97.

Andrews, A.W. & Bohannon, R.W. (1989). Decreased shoulder range of motion on paretic side after stroke. *Physical Therapy*, 69, 9, 768-772.

Ansari, N.N., Naghdi, S., Hasson, S., Mousakhani, A., Nouriyar, A. & Omidvar, Z. (2009). Inter-rater reliability of the Modified Modified Ashworth Scale as a clinical tool in measurements of post-stroke elbow flexor spasticity. *NeuroRehabilitation*, 24, 3, 225–229.

Ansari, N.N., Naghdi, S., Hasson, S., Azarsa, M.H. & Azarnia, S. (2008). The Modified Tardieu Scale for the measurement of elbow flexor spasticity in adult patients with hemiplegia. *Brain Injury*, 22, 13, 1007-1012.

Ansari, N.N., Naghdi, S., Moammeri, H. & Jalaie, S. (2006). Ashworth Scales are unreliable for the assessment of muscle spasticity. *Physiotherapy Theory and Practice*, 22, 3, 119-125.

Appelros, P. (2006). Prevalence and predictors of pain and fatigue after stroke: a population-based study. *International Journal of Rehabilitation Research*, 29, 4, 329-33.

Aras, M.D., Gokkaya, N.K.O., Comert, D., Kaya, A. & Cakci, A. (2004). Shoulder pain in hemiplegia: results from a national rehabilitation hospital in Turkey. *American Journal of Physical Medicine & Rehabilitation*, 83, 9, 713-719.

Ashford, S., Turner-Stokes, L. & Slade, M. (2010). Psychometric evaluation of the Arm Activity measure (ArmA) – a measure of active and passive function in the hemiparetic arm. *American Academy of Physical Medicine and Rehabilitation*. Seattle USA, November 5.

Ashford, S. & Turner-Stokes, L. (2009). Management of shoulder and proximal upper limb spasticity using botulinum toxin and concurrent therapy interventions: A preliminary analysis of goals and outcomes. *Disability and Rehabilitation*, 31, 4, 220-226.

Ashford, S., Slade, M., Malaprade, F. & Turner-Stokes, L. (2008). Evaluation of functional outcome measures for the hemiparetic upper limb: a systematic review. *Journal of Rehabilitation Medicine*, 40, 10, 787–795.

Ashford, S. & Turner-Stokes, L. (2006). Goal attainment for spasticity management using botulinum toxin. *Physiotherapy Research International*, 11, 1, 24–34.

Ashworth B. (1964). Preliminary trial of carisoprodol in multiple sclerosis. *Practitioner*, 192, 540–2.

Atkinson, M.J., Gillard, P., Dunning, K., D'Ambrosio, L., Varon, S.F., Zorowitz, R.D. & Kissela, B. (2012). PCV84 A comparison of clinician and patient views on symptoms and impact of post-stroke spasticity. *Value in Health*, 15, 4, 127.

Bakheit, A.M., Fheodoroff, K. & Molteni, F. (2011). Spasticity or reversible muscle hypertonia? *Journal of Rehabilitation Medicine*, 43, 6, 556–557.

Bakheit, A.M.O., Thilmann, A.F., Ward, A.B., Poewe, W., Wissel, J., Muller, J., Benecke, R., Collin, C., Muller, F., Ward, C.D. & Neumann, C. (2000). A randomized, double-blind, placebo-controlled, dose-ranging study to compare the efficacy and safety of three doses of botulinum toxin type A (Dysport) with placebo in upper limb spasticity after stroke. *Stroke*, 31, 10, 2402-2406.

Bakke, F. (1995). The acute treatment of stroke. In Harrison, M.A. (Ed.), *Physiotherapy in stroke management* (pp215-222). London: Churchill Livingstone.

Bamford, J., Sandercock, P., Dennis, M., Burn, J. & Warlow, C. (1991). Classification and natural history of clinically identifiable subtypes of cerebral infarction. *The Lancet*, 337, 8756, 1521-6.

Barnes, M.P. (2008). An overview of the clinical management of spasticity. In Barnes, M.P. & Johnson, G.R. (Eds.), *Upper Motor Neurone Syndrome and Spasticity: Clinical Management and Neurophysiology* (2nd Edition) (pp1-8). Cambridge: Cambridge University Press.

Barnes, M.P. & Ward, A.B. (2000). *Textbook of rehabilitation medicine*. Oxford: Oxford University Press.

Barnes, M.P. (1998). Management of spasticity. *Age and Ageing*, 27, 239-245.

Barnes, S., Gregson, J., Leathley, M., Smith, T., Sharma, A. & Watkins, C. (1999). Development and inter-rater reliability of an assessment tool for measuring muscle tone in people with hemiplegia after a stroke. *Physiotherapy*, 85, 8, 405-409.

Benaim, C., Froger, J., Cazottes, C., Gueben, D., Porte, M., Desnuelle, C. & Pelissier J.Y. (2007). Use of the Faces Pain Scale by left and right hemispheric stroke patients. *Pain*, 128, 1-2, 52-58.

Bennett, H.E. & Lincoln, N.B. (2006). Potential screening measures for depression and anxiety after stroke. *International Journal of Therapy and Rehabilitation*, 13, 9, 401-406.

Berglund, A. & Ericsson, K. (2003). Different meanings of quality of life: a comparison between what elderly persons and geriatric staff believe is of importance. *International Journal of Nursing Practice*, 9, 2, 112-119.

Bhakta, B.B. (2000). Management of spasticity in stroke. *British Medical Bulletin*, 56, 2, 476-485.

Bhakta, B.B., Cozens, J.A., Chamberlain, M.A. & Bamford, J.M. (2000). Impact of botulinum toxin type A on disability and carer burden due to arm spasticity after stroke: a randomised double blind placebo controlled trial. *Journal of Neurology, Neurosurgery and Psychiatry*, 69, 2, 217-221.

Bhakta, B.B., Cozens, J.A., Chamberlain, M.A. & Bamford, J.M. (1996). Use of botulinum toxin in stroke patients with severe upper limb spasticity. *Journal of Neurology, Neurosurgery and Psychiatry*, 61, 1, 30-35.

Bisiach, E., Perani, D., Vallar, G. & Berti, A. (1986). Unilateral neglect: personal and extra-personal. *Neuropsychologia*, 24, 6, 759-767.

Blackburn, M., van Vliet, P. & Mockett, S.P. (2002). Reliability of measurements obtained with the modified Ashworth scale in the lower extremities of people with stroke. *Physical Therapy*, 82, 1, 25.

Bohannon, R.W. (2003). Evaluation and treatment of sensory and perceptual impairments following stroke. *Topics in Geriatric Rehabilitation*, 19, 2, 87-97.

Bohannon, R.W. (1988). Relationship between shoulder pain and selected variables in patients with hemiplegia. *Clinical Rehabilitation*, 2, 2, 111-117.

Bohannon, R.W. & Smith, M.B. (1987). Inter rater reliability of a modified Ashworth Scale of muscle spasticity. *Physical Therapy*, 67, 2, 206-207.

Boschelman-Morrin, J. & Conolly, W.B. (2001). *The hand: Fundamentals of therapy* (3rd ed). Oxford: Butterworth Heinemann.

Bot, S.D., Terwee, C.B., van der Windt, D.A., Bouter, L.M. & deVet, H.C.W. (2004). Clinimetric evaluation of shoulder disability questionnaires: a systematic review of the literature. *Annals of Rheumatic Diseases*, 63, 4, 335-341.

Bovend'Eerd, T., Newman, M., Barker, K., Dawes, H., Sackley, C., Minelli, C. & Wade, D. (2008). The effects of stretching in spasticity – a systematic review. *Archives of Physical Medicine and Rehabilitation*, 89, 7, 1395-1406.

Bowen, A., McKenna, K. & Tallis, R. (1999). Reasons for the variability in the reported rate of occurrence of unilateral spatial neglect following stroke. *Stroke*, 30, 6, 1196-202.

Bowling, A. (2001). *Measuring disease: A review of disease-specific quality of life measurement scales*. (2nd ed). Buckingham: Open University Press.

Boyd, E.A. & Torrance, G.M. (1992). Clinical measures of shoulder subluxation: their reliability. *Canadian Journal of Public Health*, 83, 2, S24-S28.

Brady, M.C., Fredrick, A. & Williams, B. (2013). People with aphasia: capacity to consent, research participation and intervention inequalities. *International Journal of Stroke*, 8, 3, 193-6.

Brashear, A., R. Zafonte, Corcoran, M., Galvez-Jimenez, N., Gracies, J.M. & Gordon, M.F. (2002a). Inter- and intrarater reliability of the Ashworth Scale and the Disability Assessment Scale in patients with upper-limb poststroke spasticity. *Archives of Physical Medicine and Rehabilitation*, 83, 10, 1349-1354.

Brashear, A., Gordon, M.F., Elovic, E., Kasscieh, V.D., Marciniak, Do, M., Lee, C., Jenkins, S. & Turkel, C. (2002b). Intramuscular injection of botulinum toxin for the treatment of wrist and finger spasticity after a stroke. *New England Journal of Medicine*, 347, 6, 395-400.

Brocklehurst, J.C., Morris, P. & Andrews, K. (1981). Social effects of stroke. *Social Science and Medicine*, 15, 1, 35-39.

Buck, D., Jacoby, A., Massey, A. & Ford, G. (2000). Evaluation of measures used to assess quality of life after stroke. *Stroke*, 31, 8, 2004-2010.

Bykov, Y. (2012). Gabapentin in the treatment of patients with neuropathic pain after stroke. *Neurology*, 78, 1, 1.

Cash, T.F., Fleming, E.C., Alindogan, J., Steadman, L. & Whitehead, A. (2002). Beyond body image as a trait: The development and validation of the Body Image States Scale. *Eating Disorders: The Journal of Treatment & Prevention*, 10, 2, 103-113.

Chang J.H., Shin M.J., Cha Y.S. & Park J.H. (2012). Upper extremity coldness in acute or subacute stroke patients. *Brain Injury*, 26, 4, 584.

Cheng, P.T., Lee, C.E., Liaw, M.Y., Wong, M.K. & Hsueh, T.C. (1995). Risk factors of hemiplegic shoulder pain in stroke patients. *Journal of Musculoskeletal Pain*, 3, 3, 59-73.

Chisholm, D., Knapp, M.R.J., Knudsen, H.C., Amaddeo, F., Gaitte, L. & van Wijngaarden, B. (2000). Client Socio-Demographic and Service Receipt Inventory - European Version : development of an instrument for international research : EPSILON Study 5. *British Journal of Psychiatry*, 177, 39, s28-s33.

Choi-Kwon, S., Choi, J.M., Kwon, S.U., Kang, D.W. & Kim, J.S. (2006). Factors that affect the quality of life at 3 years post-stroke. *Journal of Clinical Neurology*, 2, 1, 34-41.

Cicchetti, D.V. (1994). Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment*, 6, 4, 284-290.

- Connell, L., Lincoln, N.B. & Radford, K. (2008). Somatosensory impairment after stroke: frequency of different deficits and their recovery. *Clinical Rehabilitation*, 22, 8, 758-767.
- Connell, L.A. (2007) *Sensory impairment and recovery after stroke*. PhD thesis, University of Nottingham.
- Constraint-Induced Movement Therapy Research Group. (2004). *Manual: Upper Extremity Motor Activity Log*. University of Alabama: Birmingham, USA.
- Craig, P., Dieppe, P., MacIntyre, S., Michie, S., Nazareth, I. & Petticrew, M. (2008). *Developing and evaluating complex interventions: new guidance*. London: Medical Research Council.
- Dalemans, R., Wade, D.T., van den Heuvel W.J.A. & de Witte L.P. (2009). Facilitating the participation of people with aphasia in research: a description of strategies. *Clinical Rehabilitation*, 23, 10, 948–959.
- de Jong, L.D., Hoonhurst, M.H., Stuive, I. & Dijkstra, P.U. (2011). Arm motor control as predictor for hypertonia after stroke: a prospective cohort study. *Archives of Physical Medicine and Rehabilitation*, 92, 9, 1411-1417.
- de Jong, L.D., Nieuwboer, A. & Aufdemkampe, G. (2006). Contracture preventive positioning of the hemiplegic arm in subacute stroke patients: A pilot randomized controlled trial. *Clinical Rehabilitation*, 20, 8, 656-667.
- Deakin, A., Hill, H. & Pomeroy, V.M. (2003). Rough guide to the Fugl-Meyer assessment: upper limb section. *Physiotherapy*, 89, 12, 751-763.
- Decq, P., Filipetti, P. & Lefaucheur, J.P. (2005). Evaluation of spasticity in adults . *Operative Techniques in Neurosurgery*, 7, 3, 100-108.
- Department of Health. (2008). *Guidance on nominating a consultee for research involving adults who lack capacity to consent*. London: DH.
- Department of Health. (2007). *National stroke strategy*. London: DH.
- Department of Health. (2005). *Mental capacity act*. Retrieved from <http://www.legislation.gov.uk/ukpga/2005/9/section/3>
- de Winter, A.F., Heemskerk, M.A., Terwee, C.B., Jans, M.P., Devillé, W., van Schaardenburg, D.J., Scholten, R.J. & Bouter, L.M. (2004). Inter-observer reproducibility of measurements of range of motion in patients with shoulder pain using a digital inclinometer. *BMC Musculoskeletal Disorders*, 14, 5, 18.
- Doan, Q.V., Brashear, A., Gillard, P.J., Varon, S.F., Vandenburg, A.M., Turkel, C.C. & Elovic E.P. (2012). Relationship between disability and health-related quality of life and caregiver burden in patients with upper limb poststroke spasticity. *Physical Medicine and Rehabilitation*, 4, 1, 4-10.

Dolan, B. & Birtchnell, S. (1997). Measuring body image. In Salter, M. (Ed.), *Altered body image: The nurses role* (2nd Ed.) (pp51-74). Bridgend: Balliere Tindall.

Douai, A., Rudd, A.G. & Wolfe, C.D. (2013). Prevalence of post-stroke cognitive impairment: South London stroke register 1995-2010. *Stroke*, 44, 1, 138-45.

Doyle, S., Bennett, S., Fasoli, S.E. & McKenna, K.T. (2010). Interventions for sensory impairment in the upper limb after stroke. *Cochrane Database of Systematic Reviews*, 6, 1361-6137.

Duncan, P.W., Lai, S.M., Tyler, D., Perera, S., Reker, D.M. & Studenski, S. (2002). Evaluation of proxy responses to the Stroke Impact Scale. *Stroke*, 33, 11, 2593-9.

Duncan, P.W., Wallace, D., Lai, S.M., Johnson, D., Embretson, S. & Laster, L.J. (1999). The Stroke Impact Scale version 2.0: evaluation of reliability, validity, and sensitivity to change. *Stroke*, 30, 10, 2131-40.

Dunn, L.B., Lindamer, L.A., Palmer, B.W., Schneiderman, L.J. & Jeste, D.V. (2001). Enhancing comprehension of consent for research in older patients with psychosis: a randomized study of a novel consent procedure. *American Journal of Psychiatry*, 158, 11, 1911–1913.

Effective Public Health Practice Project. (2008). *Quality assessment tool for quantitative studies*. Retrieved from <http://www.ehpp.ca/Tools.htm>

Elkins, J.S., Khatabi, T., Fung, L., Rootenberg, J. & Claiborne Johnston, S. (2006). Recruiting subjects for acute stroke trials : a meta-analysis. *Stroke*, 37, 1, 123-128.

Ellis, B. & Bruton, A. (2002). A study to compare the reliability of composite finger flexion with goniometry for measurement of range of motion in the hand. *Clinical Rehabilitation*, 16, 5, 562-570.

Elo, S. & Kyngas, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, 62, 1, 107–115.

European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. (2009). *Treatment of pressure ulcers: Quick Reference Guide*. Washington DC: National Pressure Ulcer Advisory Panel.

EuroQol Group. (1990). EuroQol: a new facility for the measurement of health-related quality of life. *Health Policy*, 16, 3, 199-208.

Faria-Fortini, I., Michaelsen, S.M., Cassiano, J.G. & Teixeira-Salmela, L.F. (2011). Upper extremity function in stroke subjects: relationships between the International classification of functioning, disability, and health domains. *Journal of Hand Therapy*, 24, 3, 257-265.

Fearon, P., Langhorne, P. & Early Supported Discharge Trialists . (2012). *Services for reducing duration of hospital care for acute stroke patients*. Cochrane Database of Systematic Reviews, 9. Art. No.: CD000443. DOI: 10.1002/14651858.CD000443.pub3

Fergusson, D., Hutton, B. & Drodge, A. (2007). The epidemiology of major joint contractures: A systematic review of the literature. *Clinical Orthopaedics & Related Research*, 456, 22-29.

Feys, H., de Weerdt, W., Nuyens, G. & van de Wickel, A. (2000). Predicting motor recovery of the upper limb after stroke rehabilitation. *Physiotherapy Research International*, 5, 1, 1-18.

Fleuren, J.F.M., Voerman, G.E., Erren-Wolters, C.V., Snoek, G.J., Rietman, J.S., Hermens, H.J. & Nene, A.V. (2010). Stop using the Ashworth Scale for the assessment of spasticity. *Journal of Neurology, Neurosurgery and Psychiatry*, 81, 1, 46–53.

Fleuren, J.F.M. (2009). *Assessment of spasticity: from EMG to patients' perception*. Enschede, Netherlands: Gildeprint Drukkerijen. ISBN 978-90-365-2869-6.

Foerch, C., Misselwitz, B., Sitzer, M., Berger, K., Steinmetz, H. & Neumann-Haefelin, T. (2005). Difference in recognition of right and left hemispheric stroke. *The Lancet*, 366, 9483, 392-393.

Forster, A. (2007). TRaining Caregivers after Stroke (TRACS): A cluster randomised controlled trial of structured training programme for caregivers of in-patients after stroke. *UK Stroke Forum Conference*: Harrogate.

Forster, A., Young, J., Kalra, L., Smithard, D., Knapp, M., Patel, A., Farrin, A., Breen, R. & Nixon, J. (2006). *TRACS: Training caregivers after stroke: Protocol Version 1.0*. Leeds, UK: Academic Unit of Elderly Care and Rehabilitation.

Forster, A. & Young, J. (1995). Incidence and consequences of falls due to stroke: A systematic inquiry. *British Medical Journal*, 311, 6997, 83–86.

Fotiadis, F., Grouios, G., Ypsilanti, A. & Hatzinikolaou, K. (2005). Hemiplegic shoulder syndrome: possible underlying neurophysiological mechanisms. *Physical Therapy Reviews*, 10, 1, 51–8.

Fuchs-Lacelle, S. & Hadjistavropoulos, T. (2004). Development and preliminary validation of the pain assessment checklist for seniors with limited ability to communicate (PACSLAC). *Pain Management Nursing*, 5, 1, 37-49.

Gaber, T.A., Parsons, F. & Gautam, V. (2011). Validation of the language component of the Addenbrooke's Cognitive Examination-Revised (ACE-R) as a screening tool for aphasia in stroke patients. *Australasian Journal on Ageing*, 30, 3, 156-8.

Gajdosik, R.L. & Bohannon, R.W. (1987). Clinical measurement of range of motion: review of goniometry emphasizing reliability and validity. *Physical Therapy*, 67, 12, 1867-1872.

Galasko, D., Klauber, M.R., Hofstetter, C.R., Salmon, P., Lasker, B. & Thal, L.J. (1990). The Mini-Mental State Examination in the early diagnosis of Alzheimer's disease. *Archives of Neurology*, 47, 1, 49-52.

Gamble, G.E., Barberan, E., Laasch, H.U., Bowsher, D., Tyrrell, P.J. & Jones, A.K.P. (2002). Poststroke shoulder pain: A prospective study of the association and risk factors in 152 patients from a consecutive cohort of 205 patients presenting with stroke. *European Journal of Pain*, 6, 6, 467-474.

Gamble, G.E., Barberan, E., Bowsher, D., Tyrrell, P.J. & Jones, A.K. (2000). Post stroke shoulder pain: more common than previously realized. *European Journal of Pain*, 4, 3, 313-5.

Garrison, F.H. (1969). *History of Neurology*. Springfield, Illinois: Charles C Thomas Publishing.

General Medical Council. (2010). *Consent to research*. London: GMC.

Geyh, S., Cieza, A., Schouten, J., Dickson, H., Frommelt, P., Omar, Z., Kostanjsek, N., Ring, H. & Stucki, G. (2004). ICF core sets for stroke. *Journal of Rehabilitation Medicine*, 36, S44, 135-141.

Gigliacca, N.S., Penalva, M.C, Molina, S.C., Voos, J.A. & Vigliecca, M.R. (2012). Is the Folstein's Mini-Mental-Test an aphasia test? *Applied Neuropsychology*, 19, 3, 221-228.

Gilham, S. & Clark, L. (2011). *Psychological care after stroke: Improving stroke services for people with cognitive and mood disorders*. Leicester: NHS Improvement.

Gracies, J.M. (2001). Evaluation de la spasticité. Apport de l'échelle de Tardieu. *Motricité Cérébrale*, 22, 1-16.

Graneheim, U.H. & Lundman, B. (2004). Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today*, 24, 2, 105-112.

Green, J. & Thorogood, N. (2004). *Qualitative Methods for Health Research*. London: Sage Publications.

Gregory, R., Roked, F., Jones, L. & Patel, A. (2007). Is the degree of cognitive impairment in patients with Alzheimer's disease related to their capacity to appoint an enduring power of attorney? *Age and Ageing*, 36, 5, 527- 531.

Gregson, B.A., Smith, M., Lecouturier, J., Rousseau, N., Rodgers, H. & Bond, J. (1997). Issues of recruitment and maintaining high response rates in a longitudinal study of older hospital patients in England--pathways through care study. *Journal of Epidemiology & Community Health*, 51, 5, 541-8.

Gregson, J.M., Leathley, M., Moore, A.P., Sharma, A.K., Smith, T.L. & Watkins, C.L. (1999). Reliability of the tone assessment scale and the Modified Ashworth Scale as clinical tools for assessing poststroke spasticity. *Archives of Physical Medicine & Rehabilitation*, 80, 9, 1013-1016.

Griffin, A. & Bernhardt, J. (2006). Strapping the hemiplegic shoulder prevents development of pain during rehabilitation: a randomized controlled trial. *Clinical Rehabilitation*, 20, 4, 287-295.

Gunendi, Z., Gogus, F., Keles, Z. & Ture, D. (2010). Compliance of rheumatoid arthritis patients with resting hand splint. *Turkiye Klinikleri Journal of Medical Sciences*, 30, 1, 213-217.

Gustafsson, S., Sunnerhagen, K.S. & Dahlin-Ivanoff, S. (2004). Occupational therapists' and patients' perceptions of ABILHAND, a new assessment tool for measuring manual ability. *Scandinavian Journal of Occupational Therapy*, 11, 3, 107-117.

Hacker, V.L., Stark, D. & Thomas, S. (2010). Validation of the Stroke Aphasic Depression Questionnaire using the brief assessment schedule depression cards in an acute stroke sample. *British Journal of Clinical Psychology*, 49, 1, 123-127.

Hadianfard, H. & Hadianfard, M.J. (2008). Predictor factors of hemiplegic shoulder pain in a group of stroke patients. *Iranian Red Crescent Medical*, 10, 3, 215-219.

Hagbarth, K.E., Hägglund, J.V., Nordin, M., & Wallin, E.U. (1985). Thixotropic behaviour of human finger flexor muscles with accompanying changes in spindle and reflex responses to stretch. *Journal of Physiology*, 368, 323-42.

Hall, J., Dudgeon, B. & Guthrie, M. (1995). Validity of clinical measures of shoulder subluxation in adults with poststroke hemiplegia. *American Journal of Occupational Therapy*, 49, 6, 526-533.

Hanley, B., Bradburn, J., Barnes, M., Evans, C., Goodare, H., Kelson, M., Kent, A., Oliver, S., Thomas, S. & Wallcraft, J. (2003). *Involving the public in NHS, public health, and social care research: Briefing notes for researchers*. London: INVOLVE.

Harwood, T.G., & Garry, T. (2003). An overview of content analysis. *The Marketing Review*, 3, 4, 479-498.

Heinrich, S., Deister, A., Birker, T., Hierholzer, C., Weigelt, I., Zeichner, D., Angermeyer, M.C., Roick, C. & König, H.H. (2011). Accuracy of self-reports of mental health care utilization and calculated costs compared to hospital records. *Psychiatry Research*, 185, 1, 261-8.

Heller, A., Wade, D.T., Wood, V.A., Sunderland, A., Hower, R.L. & Ward, E. (1987). Arm function after stroke: Measurement and recovery over the first three months. *Journal of Neurology, Neurosurgery and Psychiatry*, 50, 6, 714-719.

Herr, K., Bursch, H., Ersek, M., Miller, L.L. & Swafford, K. (2010). Use of pain-behavioral assessment tools in the nursing home: expert consensus recommendations for practice. *Journal of Gerontological Nursing*, 36, 3, 18-31.

Hesse, S., Mach, H., Frohlich, S., Behrend, S., Werner, C. & Melzer, I. (2012). An early botulinum toxin A treatment in subacute stroke patients may prevent a disabling finger flexor stiffness six months later: a randomized controlled trial. *Clinical Rehabilitation*, 26, 3, 237-245.

Hirayama, K., Fukutake, T. & Kawamura, M. (1999). 'Thumb localizing test' for detecting a lesion in the posterior column-medial lemniscal system. *Journal of the Neurological Sciences*, 167, 1, 45-49.

Hobart, J.C., Cano, S.J., Zajicek, J.P. & Thompson, A.J. (2007). Rating scales as outcome measures for clinical trials in neurology: problems, solutions, and recommendations. *Lancet Neurology*, 6, 12, 1094-105.

Holmes, J.M., Lytle, L.A., Gross, C.R., Ahmed, R.L. Troxel, A.B. & Schmitz, K.H., (2008). The body image and relationships scale: development and validation of a measure of body image in female breast cancer survivors. *Journal of Clinical Oncology*, 10, 26, 1269-74.

Hsieh, Y.W., Wu, C.Y., Lin, K.C., Chang, Y.F., Chen, C.L., & Liu, J.S. (2009). Responsiveness and validity of three outcome measures of motor function after stroke rehabilitation. *Stroke*, 40, 4, 1386-1391.

Hunter, S.M. & Crome, P. (2002). Hand function and stroke. *Reviews in Clinical Gerontology*, 12, 1, 68-81.

Intercollegiate Stroke Working Party (2012). *National Clinical Guideline for Stroke*. (4th Ed). London: Royal College of Physicians.

International Association for the Study of Pain. (2012) *Pain taxonomy*. Retrieved from <http://www.iasp-pain.org/Content/NavigationMenu/GeneralResourceLinks/PainDefinitions/default.htm>; 12th July 2012.

Institute for Innovation & Improvement. (2013). *Care outside hospital programme: Bring care closer to home*. Retrieved from http://www.institute.nhs.uk/news/care_outside_hospitals_-_banner_image/care_outside_hospital_programme.html; 31st March 2013.

Involve (2010). *Payment for involvement: A guide for making payments to members of the public actively involved in NHS, public health and social care research guidance*. London: Involve.

Johnson, G.R. & Pandyan, A.D. (2008). The measurement of spasticity. In Barnes, M.P. & Johnson, G.R. (Eds.), *Upper motor neurone syndrome and spasticity: clinical management and neurophysiology* (2nd Edition) (pp.64-78). Cambridge: Cambridge University Press.

Kalra, L., Perez, I., Gupta, S. & Wittink, M. (1997). The influence of visual neglect on stroke rehabilitation. *Stroke*, 28, 7, 1386-91.

Kavanaugh, K., Moro, T.T., Savage, T. & Mehendale, R. (2006). Enacting a theory of caring to recruit and retain vulnerable participants for sensitive research. *Research in Nursing & Health*, 29, 3, 244-252.

Keenan, M.A.E. (1988). Management of the spastic upper extremity in the neurologically impaired adult. *Clinical Orthopaedics and Related Research*, 233, 116-125.

Keklicek, H. & Uygur, F. (2012). Effects of hand taping on upper extremity function in children with cerebral palsy. *Neurorehabilitation and Neural Repair*, 26, 6, NP7-NP8.

Keppel, C.C. & Crowe, S.F. (2000). Changes to body image and self-esteem following stroke in young adults. *Neuropsychological Rehabilitation: An International Journal*, 10, 1, 15-31.

Kilbride, C., Allison, R. & Evans, P. (2011). What do stroke survivors think about the evidence based stroke care they receive? Learning from insights at the "periphery". *International Journal of Person Centered Medicine* 1, 2, 254-259.

Kolominsky-Rabas, P.L., Weber, M., Gefeller, O., Neundoerfer, B. & Heuschmann, P.U. (2001). Epidemiology of ischemic stroke subtypes according to TOAST criteria : Incidence, recurrence, and long-term survival in ischemic stroke subtypes: a population-based study. *Stroke*, 32, 12, 2735-2740.

Kong, K.H., Lee, J. & Chua, K.S. (2012). Occurrence and temporal evolution of upper limb spasticity in stroke patients admitted to a rehabilitation unit. *Archives of Physical Medicine and Rehabilitation*, 93, 1, 143-148.

Kong, K., Chua, K.S.G. & Lee, J. (2010). Symptomatic upper limb spasticity in patients with chronic stroke attending a rehabilitation clinic: frequency, clinical correlates and predictors. *Journal of Rehabilitation Medicine*, 42, 5, 453-457.

Korner-Bitensky, N., Kehayia, E., Tremblay, N., Mazer, B., Singer, F. & Tarasuk, J. (2006). Eliciting information on differential sensation of heat in those with and without poststroke aphasia using a visual analogue scale. *Stroke*, 37, 2, 471-475.

Korpelainen, J.T., Sotaniemi, K.A. & Myllyla, V.V. (1995). Asymmetrical skin temperature in ischemic stroke. *Stroke*, 26, 9, 1543-7.

Kumar, P., Bradley, M., Gray, S. & Swinkels, A. (2011). Reliability and validity of ultrasonographic measurements of acromion-greater tuberosity distance in poststroke hemiplegia. *Archives of Physical Medicine & Rehabilitation*, 92, 5, 731-736.

Kumar, P. & Swinkels, A. (2009). A critical review of shoulder subluxation and its association with other post stroke complications. *Physical Therapy Reviews*, 14, 1, 13-25.

Kvigne, K. & Kirkevold, M. (2003). Living with bodily strangeness: women's experiences of their changing and unpredictable body following a stroke. *Qualitative Health Research*, 13, 9, 1291-1310.

Kwah, L.K., Harvey, L.A., Diong, J.H.L. & Herbert, R.D. (2012). Half of the adults who present to hospital with stroke develop at least one contracture within six months: an observational study. *Journal of Physiotherapy*, 58, 1, 41-47.

Kwakkel, G., Kollen, B.J., van der Grond, J. & Prevo, A.J.H. (2003). Probability of regaining dexterity in the flaccid upper limb: Impact of severity of paresis and time since onset in acute stroke. *Stroke*, 34, 9, 2181-2186.

Lam, K., Lau, K.K., So, K.K., Tam, C.K., Wu, Y.M., Cheung, G., Liang, K.S., Yeung, K.M., Lam, K.Y., Yui, S. & Leung, C. (2012). Can botulinum toxin decrease carer burden in long term care residents with upper limb spasticity? A randomized controlled study. *Journal of the American Medical Directors Association*, 13, 5, 477-84.

Lam, D.H., McCrone, P., Wright, K. & Kerr, N. (2005). Cost-effectiveness of relapse-prevention cognitive therapy for bipolar disorder: 30-Month study. *British Journal of Psychiatry*, 186, 500-506.

Lance, J.W. (1980). Symposium synopsis. In Feldman, R.G., Young, R.R. & Koella, W.P. (Eds.), *Spasticity: Disordered Motor Control*. Chicago: Yearbook Medical Publishers.

Langhorne, P., Stott, D.J., Robertson, L., McDonald, J., Jones, L., McAlpine, C., Dick, F., Taylor, G.S. & Murray, G. (2000). Medical complications after stroke: a multicenter study. *Stroke*, 31, 6, 1223-9.

Lannin, N.A., Cusick, A., McCluskey, A. & Herbert, R.D. (2007). Effects of splinting on wrist contracture after stroke: a randomized controlled trial. *Stroke*, 38, 1, 111-116.

Lannin, N.A. & Herbert, R.D. (2003). Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research. *Clinical Rehabilitation*, 17, 8, 807-816.

Lathlean J. (2006). Qualitative analysis. In Gerrish K, Lacey A (eds). *The Research Process in Nursing*, Oxford: Blackwell Publishing, 417–433.

Leathley, M.J., Gregson, J.M., Moore, A.P., Smith, T.L., Sharma, A.K. & Watkins, C.L. (2004). Predicting spasticity after stroke in those surviving to 12 months. *Clinical Rehabilitation*, 18, 4, 438-43.

Leeds, L., Meera, R.J. & Hobson, J.F. (2004) The utility of the Stroke Aphasic Depression Questionnaire in a stroke rehabilitation unit. *Clinical Rehabilitation*, 18, 2, 228-31.

Liberati, A., Altman, D.G., Tetzlaff, J., Mulrow, C., Gøtzsche, P.C., Ioannidis, J.P.A., Clarke, M., Devereaux, P.J., Kleijnen, J. & Moher, D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Plosmedicine*, 6, 7. Retrieved from <http://www.plosmedicine.org>. Accessed 2011 May 07.

Lin, J.H., Hsu, M.J., Sheu, C.F., Wu, T.S., Lin, R.T., Chen, C.H., Hsieh, C.L. (2009). Psychometric comparisons of 4 measures for assessing upper-extremity function in people with stroke. *Physical Therapy*, 89, 8, 840-850.

Lincoln, N.B., Jackson, J.M. & Adams, S.A. (1998). Reliability and revision of the Nottingham Sensory Assessment for stroke patients. *Physiotherapy*, 84, 8, 358-365.

Lindgren, I., Lexell, J., Jonsson, A.C. & Brogardh, C. (2012). Left sided hemiparesis, pain frequency, and decreases shoulder range of abduction are predictors of long-lasting shoulder pain. *Physical Medicine and Rehabilitation*, 4, 8, 561-8.

Lindgren, I., Jonsson, A.C., Norrving, B. & Lindgren, A. (2007). Shoulder pain after stroke: a prospective population-based study. *Stroke*, 38, 2, 343- 348.

Lindsay, M. (1997). A neurological perspective. In Salter, M. (Ed.), *Altered body image: The nurses role* (2nd Ed) (pp248-266). Bridgend: Balliere Tindall.

Lord, S., Langhorne, P. & Quinn, T.J. (2010). Validity of standard pain assessment tools in a stroke rehabilitation unit. *International Journal of Stroke*, 5, 26, 1747.

Lundstrom, E., Smits, A., Terent, A. & Borg, J. (2010). Time-course and determinants of spasticity during the first six months following first-ever stroke. *Journal of Rehabilitation Medicine*, 42, 4, 296-301.

Lundström, E., Smits, A., Borg, J., & Terént, A. (2010). Four-fold increase in direct costs of stroke survivors with spasticity compared with stroke survivors without spasticity: the first year after the event. *Stroke*, 41, 2, 319-324.

Lundstrom, E., Smits, A., Terent, A. & Borg, J. (2009). Risk factors for stroke-related pain 1 year after first-ever stroke. *European Journal of Neurology*, 16, 2, 188-193.

Lundstrom, E., Terent, A. & Borg, J. (2008). Prevalence of disabling spasticity 1 year after first-ever stroke. *European Journal of Neurology*, 15, 6, 533–539.

Mackenzie, A. & Greenwood, N. (2012). Positive experiences of caregiving in stroke: a systematic review. *Disability and Rehabilitation*, 34, 17, 1413–1422.

Malhotra, S., Pandyan, A.D., Rosewilliam, S., Roffe, C. & Hermens Roessingh, H. (2011). Spasticity and contractures at the wrist after stroke: time course of development and their association with functional recovery of the upper limb. *Clinical Rehabilitation*, 25, 2, 184–191.

Manigandan, C. & Charles, J. (2007). Effect of hand splinting: isn't temporality crucial? *Stroke*, 38, 11, 146.

Markgraf, T.S., Wharton, W., Cleary, C., Lorenze, K., Zeisse, M., Daun, M., Gleason, C.E., Erwin, K., Carlsson, C.M., Johnson, S.C., Sager, M.A. & Asthana S. (2009). Recruiting for Alzheimer's disease research: A systematic review of recruitment techniques and challenges among NIH-funded ADRCs. *Alzheimer's and Dementia*, 5, 4, S1, 242-243.

Mastwyk, M., Ritchie, C.W., LoGiudice, D., Sullivan, K.A., Macfarlane S.D., Sullivan, K.A. & Macfarlane, S. (2002). Carer impressions of participation in Alzheimer's disease clinical trials: what are their hopes? And is it worth it? *International Psychogeriatrics*, 14, 1, 39-45.

Masuca, S.R., Das, D.S., Delano, D., Irani, M., Pandurengan, R., Barreto, A.D., Ifejika-Jones, N., Misra, V., Bursaw, A., Peng, H., Rahbar, M.H., Savitz, S.I., Grotta, J. & Gonzales, N.R. (2012). Barriers to obtaining informed consent in acute stroke clinical trials. *Stroke*, 43, A3769, 2.

Mawson, S., Datta, D., Clarke, A. & Harris, I. (2007). Investigating the effects of botulinum toxin injections and physiotherapy on upper limb function for stroke patients: a randomised controlled trial. *Physiotherapy*, 93, S1, 564.

McNaughton, H., Weatherall, M., Taylor, W. & McPherson, K. (2001). Factors influencing rate of Barthel Index change in hospital following stroke. *Clinical Rehabilitation*, 15, 4, 422–427.

Monaghan, J., Forster, A., Young, J., Kalra, L., Knapp, M., Patel, A., Smithard, D., Anwar, S., Efthymiou, M., Farrin, A. & Nixon, J. (2009). Recruitment to cluster randomised stroke rehabilitation trials: Experiences from the TRACS trial. *Cerebrovascular Diseases*, 27, 4, 148.

Moura, R., Fukujima, M.M., Aguiar, A.S., Fontes, S.V., Dauar, R.F. & do Prado, G.F. (2009). Predictive factors for spasticity among ischemic stroke patients. *Arquivos de Neuro-Psiquiatria*, 67, 4, 1029-36.

Moseley, G.L. (2007). Reconceptualising pain according to modern pain science. *Physical Therapy Reviews*, 12, 3, 169–178.

Murray, C.J. & Lopez, A.D. (1997). Global mortality, disability, and the contribution of risk factors: global burden of disease study. *Lancet*, 17, 349, 1436–1442.

Naghdi, S., Ebrahimi, I., Asgari, A., Olyaei, G.R., Kazemnejad, A., Mansouri, K. & Ansari, N.N. (2007). A preliminary study into the criterion validity of the Modified Modified Ashworth Scale using the new measure of the alpha motoneuron excitability in spastic hemiplegia. *Electromyography & Clinical Neurophysiology*, 47, 3, 187-92.

National Audit Office. (2010). *Progress in improving stroke care*. London: NAO.

National Institute for Health Research. (2012). *Feasibility and pilot studies*. (Retrieved from: <http://www.netscc.ac.uk/glossary/#glos6>, 23rd January 2012).

National Institutes of Health National Cancer Institute Working Group on Enhancing Recruitment to Early Phase Cancer Clinical Trials. (2004). *Enhancing recruitment to early phase cancer clinical trials: literature review*. Bethesda, MD.

National Institutes of Health National Cancer Institute Office of Communications. (1996). *Cancer clinical treatment trials: informational preferences of patients and their families*. Bethesda, MD.

Nystuen, P. & Hagen, K.B. (2004). Telephone reminders are effective in recruiting nonresponding patients to randomized controlled trials. *Journal of Clinical Epidemiology*, 57, 8, 773–776.

O'Dwyer, N.J., Ada, L. & Neilson, P.D. (1996). Spasticity and muscle contractures following stroke. *Brain: A Journal of Neurology*, 119, 5, 1737-1749.

Open University. (2012). *Care: A loaded word*. Retrieved from <http://www.open.edu/openlearn/body-mind/social-care/caring-family-affair/content-section-3.1> on 15 Dec 2012.

Paci, M., Nannetti, L., Taiti, P., Baccini, M., Pasquini, J. & Rinaldi, L. (2007). Shoulder subluxation after stroke: relationships with pain and motor recovery. *Physiotherapy Research International*, 12, 2, 95-104.

Pandyan, A.D., Gregoric, M., Barnes, M.P., Wood, D., Van Wijck, F., Burrige, J., Hermens, H. & Johnson, G.R. (2005). Spasticity: Clinical perceptions, neurological realities and meaningful measurement. *Disability and Rehabilitation*, 27, 1-2, 2-6.

Pandyan, A.D., Price, C.I.M., Barnes, M.P. & Johnson, G.R. (2003a). A biomechanical investigation into the validity of the modified Ashworth Scale as a measure of elbow spasticity. *Clinical Rehabilitation*, 17, 3, 290-293.

Pandyan, A.D., Cameron, M., Powell, J., Stott, D.J. & Granat, M.H. (2003b). Contractures in the post-stroke wrist: a pilot study of its time course of development and its association with upper limb recovery. *Clinical Rehabilitation*, 17, 1, 88-95.

Pandyan, A.D., Johnson, G.R., Price, C.I.M., Curless, R.H., Barnes, M.P. & Rodgers, H. (1999). A review of the properties and limitations of the Ashworth and modified Ashworth Scales as measures of spasticity. *Clinical Rehabilitation*, 13, 5, 373-383.

Pappas, N., Baldwin, K. & Keenan, M.A. (2011). Treatment of the non-functional contracted hand. *University of Pennsylvania Orthopaedic Journal*, 21, 90-92.

Park, S., Wolf, S.L., Blanton, S., Winstein, C. & Nichols-Larsen, D.S. (2008). The EXCITE trial: predicting a clinically meaningful motor activity log outcome. *Neurorehabilitation & Neural Repair*, 22, 5, 486-493.

Parry, R.H., Lincoln, N.B. & Vass, C.D. (1999). Effect of severity of arm impairment on response to additional physiotherapy early after stroke. *Clinical Rehabilitation*, 13, 3, 187-198.

Patel, M.D., Tilling, K., Lawrence, E., Rudd, A.G., Wolfe, C.D.A. & McKevitt, C. (2006). Relationships between long-term stroke disability, handicap and health-related quality of life. *Age and Ageing*, 35, 3, 273-279.

Patient Reported Health Instruments Group. (2006). *A structured review of patient-reported measures in relation to selected chronic conditions, perceptions of quality of care and carer impact*. Oxford: University of Oxford.

Patrick, D. & Guyatt, G. (2013). Patient reported outcomes. Downloaded at http://www.esourceresearch.org/Portals/0/Uploads/Documents/Public/Patrick_FullChapter.pdf 30th April 2013.

Patrick, E. & Ada, L. (2006). The Tardieu Scale differentiates contracture from spasticity whereas the Ashworth Scale is confounded by it. *Clinical Rehabilitation*, 20, 2, 173-182.

Patten, C., Lexell, J., & Brown, H.E. (2004). Weakness and strength training in persons with poststroke hemiplegia: rationale, method, and efficacy. *Journal of Rehabilitation research and Development*, 41, 3A, 293-312.

Pedersen, P.M., Jorgensen, H.S., Nakayama, H., Raaschou, H.O. & Olsen, T.S. (1996). General cognitive function in acute stroke: the Copenhagen stroke study. *Journal of Neurologic Rehabilitation*, 10, 3, 153-158.

Pendlebury, S.T., Mariz, J., Bull, L., Mehta, Z. & Rothwell, P.M. (2012). MoCA, ACE-R, and MMSE versus the National Institute of Neurological Disorders and Stroke-Canadian Stroke Network Vascular Cognitive Impairment Harmonization Standards Neuropsychological Battery after TIA and stroke. *Stroke*, 43, 2, 464-9.

Penta, M., Tesio, L., Arnould, C., Zancan, A. & Thonnard, J.L. (2001). The ABILHAND questionnaire as a measure of manual ability in chronic stroke patients: Rasch-based validation and relationship to upper limb impairment. *Stroke*, 32, 7, 1627-1634.

Pickering, R.M., Kunkel, D., Fitton, C., Ashburn, A., & Jenkinson, D. on behalf of the Stroke Association Rehabilitation and Research Centre Team (2010) In-hospital recruitment to observational studies of stroke. *International Journal of Rehabilitation Research*, 33, 1, 56-63.

Platz, T., Vuadens, P., Eickhof, C., Arnold, P., Van Kaick, S. & Heise, K. (2008). REPAS, a summary rating scale for resistance to passive movement: item selection, reliability and validity. *Disability and Rehabilitation*, 30, 1, 44-53.

Pomeroy, V.M., Frames, C., Faragher, E.B., Hesketh, A., Hill, E., Watson, P. & Main, C.J. (2000). Reliability of a measure of post-stroke shoulder pain in patients with and without aphasia and /or unilateral spatial neglect. *Clinical Rehabilitation*, 14, 6, 584-591.

Pomerance, J.F. & Keenan, M.A. (1996). Correction of severe spastic flexion contractures in the nonfunctional hand. *Journal of Hand Surgery - American Volume*, 21, 5, 828-33.

Popkess-Vawter, S. & Banks, N. (1992). Body image measurement in overweight females. *Clinical Nursing Research*, 1, 4, 402-17.

Portelli, R., Lowe, D., Irwin, P., Pearson, M. & Rudd, A.G. (2005). Institutionalization after stroke. *Clinical Rehabilitation*, 19, 1, 97-108.

Poulin de Courval, L., Barsauskas, A., Berenbaum, B., Dehaut, F., Dussault, R., Fontaine, F.S., Labrecque, R., Leclerc, C. & Giroux, F. (1990). Painful shoulder in the hemiplegic and unilateral neglect. *Archives of Physical Medicine and Rehabilitation*, 71, 9, 673-676.

Prescott, R.J., Garraway, W.M. & Akhtar, A.J. (1982). Predicting functional outcome following acute stroke using a standard clinical examination. *Stroke*, 13, 5, 641-647.

Price, C.I., Curless, R.H. & Rodgers, H. (1999). Can stroke patients use visual analogue scales? *Stroke*, 30, 7, 1357-1361.

Pringle, J., Hendry, C., McLafferty, E. & Drummond, J. (2010). Stroke survivors with aphasia: personal experiences of coming home. *British Journal of Community Nursing*, 15, 5, 241-247.

Pringle, J., Hendry, C., & McLafferty, E. (2008). A review of the early discharge experiences of stroke survivors and their carers. *Journal of Clinical Nursing, 17*, 18, 2384-2397.

Rabadi, M.H. & Rabadi, F.M. (2006). Comparison of the action research arm test and the Fugl-Meyer assessment as measures of upper-extremity motor weakness after stroke. *Archives of Physical Medicine & Rehabilitation, 87*, 7, 962-6.

Rajaratnam, B.S., Venketasubramanian, N., Kumar, P.V., Goh, J.C. & Chan, Y.H. (2007). Predictability of simple clinical tests to identify shoulder pain after stroke. *Archives of Physical Medicine & Rehabilitation, 88*, 8, 1016-21.

Ratnasabapathy, Y., Broad, J., Baskett, J., Pledger, M., Marshall, J. & Bonita, R. (2003). Shoulder pain in people with a stroke: a population based study. *Clinical Rehabilitation, 17*, 3, 304-11.

Reynolds, E.H. & Kinnier Wilson, J.V. (2004). Stroke in Babylonia. *Archives of Neurology, 61*, 4, 597-601.

Reynolds, P.S., Crenshaw, C.T., Lefkowitz, D.S., Shelton, B.J., Preisser, J.S. & Tegeler, C.H. (2001). A practical stroke severity scale predicts hospital outcomes. *Journal of Stroke & Cerebrovascular Diseases, 10*, 5, 231-235.

Rodgers, H., Atkinson, C., Bond, S., Suddes, M., Dobson, R. & Curless, R. (1999). Randomized controlled trial of a comprehensive stroke education program for patients and caregivers. *Stroke, 30*, 12, 2585-2591.

Rodriguez-Hernandez, S.A., Kroon, A.A., van Boxtel, M.P.J., Mess, W.H., Lodder, J., Jolles, J. & de Leeuw, P.W. (2003). Is there a side predilection for cerebrovascular disease? *Hypertension, 42*, 1, 56-60.

Roosink, M., Renzenbrink, G.J., Buitenweg, J.R., Van Dongen, R.T., Geurts, A.C. & Ijerman, M.J. (2011). Persistent shoulder pain in the first 6 months after stroke: results of a prospective cohort study. *Archives of Physical Medicine and Rehabilitation, 92*, 7, 1139-1145.

Rose, D.Z. & Kasner, S.E. (2011). Informed consent: the rate-limiting step in acute stroke trials. *Frontiers in Neurology, 2*, 65, 1-9.

Royal College of Physicians. (2012). *Sentinel Stroke National Audit Programme (SSNAP) : Acute Organisational Audit Report*. London: RCP.

Royal College of Physicians. (2011). *National Sentinel stroke clinical audit 2010, Round 7: Public report for England, Wales and Northern Ireland*. London: RCP.

Royal College Physicians. (2009). *Spasticity in adults: Management using botulinum toxin: National Guidelines*. London: RCP.

Rudd, T. (2009). *Stroke*. *British Geriatrics Society*. cited 2011 Mar 18]; Retrieved from: http://www.bgs.org.uk/index.php?option=com_content&view=article&id=378:stroke&catid=12:goodpractice&Itemid=106

Rudd, T. & Matchar, D.B. (2004). Health policy and outcome research in stroke. *Stroke*, 35, 2, 397-400.

Sackley, C., Brittle, N., Patel, S., Ellins, J., Scott, M., Wright, C. & Dewey, M.E. (2008). The prevalence of joint contractures, pressure sores, painful shoulder, other pain, falls, and depression in the year after a severely disabling stroke. *Stroke*, 39, 12, 3329-3334.

Sapkota, B., Chaudhry, S., Rodriguez, G., Suri, M. & Qureshi, A. (2012). Discharge destination as a surrogate for modified rankin scale defined outcomes at 3 and 12 months among stroke survivors. *Neurology*, 78, E11, 1.

Sawaki, L., Wu, C.W., Kaelin-Lang, A. & Cohen, L.G. (2006). Effects of somatosensory stimulation on use-dependent plasticity in chronic stroke. *Stroke*, 37, 1, 246-247.

Shai, G., Ring, H., Costeff, H. & Solzi, P. (1984). Glenohumeral malalignment in the hemiplegic shoulder: An early radiologic sign. *Scandinavian Journal of Rehabilitation Medicine*, 16, 3, 133-6.

Shaw, L., Rodgers, H., Price, C., van Wijck, F., Shackley, P., Steen, N., Barnes, M., Ford, G. & Graham, L., on behalf of the BoTULS investigators. (2010). BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. *Health Technology Assessment*, 14, 26.

Sheean, G. (2001). Botulinum treatment of spasticity: Why is it difficult to show a functional benefit? *Current Opinion in Neurology*, 4, 6, 771-6.

Shepherd, R.B. & Carr, J.H. (1998). The shoulder following stroke: Preserving musculoskeletal integrity for function. *Topics in Stroke Rehabilitation*, 4, 35-53.

Singh, P., Joshua, A., Ganeshan, S. & Suresh, S. (2011). Intra-rater reliability of the modified Tardieu scale to quantify spasticity in elbow flexors and ankle plantar flexors in adult stroke subjects. *Annals of Indian Academy of Neurology*, 14, 1, 23-26.

Smith, L.N., Lawrence, M., Kerr, S.M., Langhorne, P. & Lees, K.R. (2004). Informal carers' experience of caring for stroke survivors. *Journal of Advanced Nursing*, 46, 3, 235-244.

Sneeuw, K.C.A, Aaronson, N.K., de Haan, R.J. & Limburg, M. (1997). Assessing quality of life after stroke: the value and limitations of proxy ratings. *Stroke*, 28, 8, 1541-1549.

Sommerfeld, D.K. & Welmer, A.K. (2012). Pain following stroke, initially and at 3 and 18 months after stroke, and it's association with other disabilities. *European Journal of Neurology*, 19, 10, 1325-1330.

Sommerfeld, D.K., Eek, E.U.B., Svensson, A.K., Holmqvist, L.W. & von Arbin, M.H. (2004). Spasticity after stroke: its occurrence and association with motor impairments and activity limitations. *Stroke*, 35, 1, 134-140.

Sprigg, N., Gray, L.J., Bath, P.M., Lindenstrom, E., Boysen, G., De Deyn, P.P., Friis, P., Leys, D., Marttila, R., Olsson, J.E., O'Neill, D., Ringelstein, E.B., van der Sande, J.J., Turpie, A.G. & TAIST Investigators. (2007). Stroke severity, early recovery and outcome are each related with clinical classification of stroke: data from the 'Tinzaparin in Acute Ischaemic Stroke Trial' (TAIST). *Journal of the Neurological Sciences*, 15, 254, 1, 54-9.

Stampacchia, G., Bradaschia, E. & Rossi, B. (2004). Change of stretch reflex threshold in spasticity: effect of botulinum toxin injection. *Archives Italiennes de Biologie*, 142, 3, 265-7.

Starrost, K., Geyh, S., Trautwein, A., Grunow, J., Ceballos-Baumann, A., Prosiegel, M., Stucki, G. & Cieza A. (2008). Interrater reliability of the extended ICF core set for stroke applied by physical therapists. *Physical Therapy*, 88, 7, 841-851.

Stein, J. & Wagner, L.C.B. (2006). Is informed consent a "yes or no" response? Enhancing the shared decision-making process for persons with aphasia. *Topics in Stroke Rehabilitation*, 13, 4, 42-46.

Stephenson, R., Edwards, S. & Freeman J. (1998). Associated reactions: their value in clinical practice? *Physiotherapy Research International*, 3, 2, 151-152.

Stroke Unit Trialists' Collaboration . (2007). *Organised inpatient (stroke unit) care for stroke*. Cochrane Database of Systematic Reviews, 4. Art. No.: CD000197. DOI: 10.1002/14651858.CD000197.pub2

Stroup, D. F., Berlin, J. A., Morton, S. C., Olkin, I., Williamson, G. D., Rennie, D., Moher, D., Becker, B.J., Sipe, T.A. & Thacker, S.B. for the MOOSE Group. (2000). Meta-analysis of observational studies in epidemiology: A proposal for reporting. Meta-analysis of Observational Studies in Epidemiology (MOOSE) group. *Journal of the American Medical Association*, 283, 15, 2008–12.

Suethanapornkul, S., Kuptniratsaikul, P.S., Kupt niratsaikul, V., Uthensut, P., Dajpratha, P. & Wongwisethkarn, J. (2008). Post stroke shoulder sublaxation and shoulder pain: a cohort multicentre study. *Journal of the Medical Association of Thailand*, 91, 12, 1885-92.

Sullivan, J., Hurley, D. & Hedman, L.D. (2012). Afferent stimulation provided by glove electrode during task-specific arm exercise following stroke. *Clinical Rehabilitation*, 26, 11, 1010-1020.

Sutcliffe, L.M. & Lincoln, N.B. (1998) The assessment of depression in aphasic stroke patients: the development of the Stroke Aphasic Depression Questionnaire. *Clinical Rehabilitation*, 12, 6, 506-13.

Taub, E., Miller, N.E., Novack, T.A., Cook, E.W., Fleming, W.C., Nepomuceno, C.S., Connell, J.S. & Crago, J.E. (1993). Technique to improve chronic motor deficit after stroke. *Archives of Physical Medicine and Rehabilitation*, 37, 4, 347-354.

Teixeira-Salmela, L.F., Neto, M.G., Magalhaes, L.C., Lima, R.C. & Faria, C.D.C.M. (2009). Content comparisons of stroke-specific quality of life based upon the international classification of functioning, disability, and health. *Quality of Life Research*, 18, 6, 765-773.

Terwee, C.B., Bot, S.D., de Boer, M.R., van der Windt, D.A., Knol, D.L. & Dekker, J.H. (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of Clinical Epidemiology*, 60, 1, 34-42.

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L. & Goldsmith, C.H. (2010). A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology*, 10, 1, <http://www.biomedcentral.com/1471-2288/10/1>

Thommessen, B., Wyller, T.B., Bautz-Holter, E. & Laake, K. (2001). Acute phase predictors of subsequent psychosocial burden in carers of elderly stroke patients. *Cerebrovascular Diseases*, 11, 3, 201-206.

Thompson, J.E. (1996). The evolution of surgery for the treatment and prevention of stroke: The Willis Lecture. *Stroke*, 27, 8, 1427-1434.

Tombaugh, T.N. & McIntyre, N.J. (1992). The mini-mental state examination: a comprehensive review. *Journal of the American Geriatric Society*, 40, 9, 922-35.

Townend, E., Brady, M. & McLaughlan, K. (2007). Exclusion and inclusion criteria for people with aphasia in studies of depression after stroke: a systematic review and future recommendations. *Neuroepidemiology*, 29, 1, 1-17.

Trigg, R. & Wood, V.A. (2003). The validation of the Subjective Index of Physical and Social Outcome (SIPSO) *Clinical Rehabilitation*, 17, 7, 283-289.

Trigg, R. & Wood, V.A. (2000). The Subjective Index of Physical and Social Outcome (SIPSO): a new measure for use with stroke patients. *Clinical Rehabilitation*, 14, 3, 288-299.

Truelsen, T., Bonita, R. & Jamrozik, K. (2001). Surveillance of stroke: a global perspective. *International Journal of Epidemiology*, 30, 1, S11-16.

Tseng, M.C. & Chang, K.C. (2006). Stroke severity and early recovery after first-ever ischemic stroke: Results of a hospital-based study in Taiwan. *Health Policy*, 79, 1, 73-78.

Turton, A.J. & Britten, E. (2005). A pilot randomized controlled trial of a daily muscle stretch regime to prevent contractures in the arm after stroke. *Clinical Rehabilitation*, 19, 6, 600-612.

Tyson, S.F., Hanley, M., Chillala, J., Selley, A.B. & Tallis, R.C. (2008). Sensory loss in hospital-admitted people with stroke: Characteristics, associated factors, and relationship with function. *Neurorehabilitation and Neural Repair*, 22, 2, 166-172.

Urban, P.P., Wolf, T., Uebele, M., Marx, J.J., Vogt, T., Stoeter, P., Bauermann, T., Weibrich, C., Vucurevic, G.D., Schneider, A. & Wissel, J. (2010). Occurrence and clinical predictors of spasticity after ischemic stroke. *Stroke*, 41, 9, 2016-2020.

Uswatte, G., Taub, E., Morris, D., Vignolo, M. & McCulloch, K. (2005). Reliability and validity of the upper-extremity motor activity log-14 for measuring real-world arm use. *Stroke*, 36, 11, 2496-2499.

van Exel, N.J.A., Scholte op Reimer, W.J.M., Brouwer, W.B.F., van den Berg, B., Koopmanschap, M.A., & van den Bos, G.A.M. (2004). Instruments for assessing the burden of informal caregiving for stroke patients in clinical practice: a comparison of CSI, CRA, SCQ and self-rated burden. *Clinical Rehabilitation*, 18, 2, 203–214.

van Kuijk, A.A., Hendricks, H.T., Pasman, J.W., Kremer, B.H. & Geurts, A.C. (2007). Are clinical characteristics associated with upper-extremity hypertonia in severe ischaemic supratentorial stroke? *Journal of Rehabilitation Medicine*, 39, 1, 33-37.

van Ouwenaller, C., Laplace, P.M. & Chantraine, A. (1986). Painful shoulder in hemiplegia. *Archives of Physical Medicine and Rehabilitation*, 67, 1, 23–6.

Vataja, R., Leppavuori, A., Pohjasvaara, T., Mantyla, R., Aronen, H.J., Salonen, O., Kaste, M. & Erkinjuntti, T. (2004). Post stroke depression and lesion location revisited. *Journal of Neuropsychiatry and Clinical Neuroscience*, 16, 2, 156-62.

Vattanasilp, W., Ada, L. & Crosbie, J. (2000). Contribution of thixotropy, spasticity, and contracture to ankle stiffness after stroke. *Journal of Neurology, Neurosurgery & Psychiatry*, 69, 1, 34-9.

Venables, G. (2008). Translating research into practice: Lessons from trials of thrombolysis in acute stroke. *Annals of Indian Academy of Neurology*, 11, 4, 203–206.

Vincenta, C., Desrosier, J., Landreville, P., Demers, L., & BRAD group. (2009). Burden of caregivers of people with stroke: evolution and predictors. *Cerebrovascular Diseases*, 27, 5, 456–464.

Visser-Meily, J.M.A., Post, M.W.M., Riphagen, I.I. & Lindeman, E. (2004). Measures used to assess burden among caregivers of stroke patients: a review. *Clinical Rehabilitation*, 18, 6, 601-623.

Wang, T.N., Lin, K.C., Wu, C.Y., Chung, C.Y., Pei, Y.C. & Teng, Y.K. (2011). Validity, responsiveness, and clinically important difference of the abihand questionnaire in patients with stroke. *Archives of Physical Medicine and Rehabilitation*, 92, 7, 1086-1091.

Wanklyn, P., Forster, A. & Young, J. (1996). Hemiplegic shoulder pain (HSP): natural history and investigation of associated features. *Disability & Rehabilitation*, 18, 10, 497-501.

Warden, V., Hurley, A.C. & Volicer, L. (2003). Development and psychometric evaluation of the pain assessment in advanced dementia (PAINAD) scale. *Journal of the American Medical Directors Association*, 4, 1, 9-15.

Ware, J.E. (1997). *SF-36 Health Survey: Manual and Interpretation Guide*. (2nd Ed). The Health Institute, New England Medical Centre. Boston, MA. Nimrod Press.

Watkins, C.L., Leathley, M.J., Gregson, J.M., Moore, A.P., Smith, T.L. & Sharma, A.K. (2002). Prevalence of spasticity post stroke. *Clinical Rehabilitation*, 16, 5, 515-522.

Welmer, K.A., Holmqvist, L.W. & Sommerfeld, D.K. (2008). Limited fine hand use after stroke and its association with other disabilities. *Journal of Rehabilitation Medicine*, 40, 8, 603–608.

Whelan, P.J.P., Oleszek, J., Macdonald, A., & Gaughran, F. (2009). The utility of the Mini-mental State Examination in guiding assessment of capacity to consent to research. *International Psychogeriatrics*, 21, 2, 338–344.

Williams, L.S., Bakas, T., Brizendine, E., Plue, L., Tu, W., Hendrie, H. & Kroenke, K. (2006). How valid are family proxy assessments of stroke patients' health-related quality of life? *Stroke*, 37, 8, 2081-2085.

Wirshing, D.A., Wirshing, W.C., Marder, S.R., Liberman, R.P. & Mintz, J. (1998). Informed consent: assessment of comprehension. *American Journal of Psychiatry*, 155, 11, 1508-11.

World Health Organisation. (2001). *International Classification of Functioning, Disability and Health*. Geneva: World Health Organisation.

World Health Organisation. (2005). *WHO STEPS Stroke Manual: the WHO STEPwise approach to stroke surveillance*. Geneva: World Health Organisation.

Wound UK. (2006). *Best Practice Statement: Care of the Older Person's Skin*. London: Wound UK.

Wright, A. (2012). *A Criticism of the IASP's Definition of Pain*. Retrieved from:
http://bham.academia.edu/AndrewWright/Papers/1434374/A_Criticism_of_the_IASPs_Definition_of_Pain; 12th July 2012.

Wyatt, K.M., Lloyd, J.J., Creanor, S. & Logan, S. (2011). The development, feasibility and acceptability of a school-based obesity prevention programme: results from three phases of piloting. *British Medical Journal Open*, 1: e000026. doi:10.1136/bmjopen-2010-000026

Wyke, A., Barby, A., Buckley, B., Cowper, A., Lilleystone, J., Staniszewska, S. & Williams, S. (2008). What is 'quality of life' for patients? *British Journal of Healthcare Management*, 14, 7, 280-287.

Wyller, T.B. & Kirkevold, M. (1999). How does a cerebral stroke affect quality of life? Towards an adequate theoretical account. *Disability and Rehabilitation*, 21, 4, 152-61.

Youdas, J.W., Bogard, C.L. & Suman, V.J. (1993). Reliability of goniometric measurements and visual estimates of ankle joint active range of motion obtained in a clinical setting. *Archives of Physical Medicine and Rehabilitation*, 74, 10, 1113-1118.

Zackowski, K.M., Dromerick, A.W., Sahrman, S.A., Thach, W.T. & Bastian, A.J. (2004). How do strength, sensation, spasticity and joint individuation relate to the reaching deficits of people with chronic hemiparesis? *Brain*, 127, 1035-1046.

Zorowitz, R.D., Hughes, M.B., Idank, D., Ikai, T. & Johnston, M.V. (1996). Shoulder pain and subluxation after stroke: correlation or coincidence? *American Journal of Occupational Therapy*, 50, 3, 194-201.