

# **A Programme of Mixed Methods Research to Develop and Evaluate an Optimized, Fit-For Purpose Person-Centred Intervention to Improve Mental Health and Reduce Antipsychotics amongst People with Dementia in Care Homes (WHELD)**

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### **Competing Interests**

Prof Ballard reports grants from Novo Nordisk pharmaceutical company, grants and personal fees from Acadia pharmaceutical company, grants and personal fees from Lundbeck pharmaceutical company, personal fees from Pfizer pharmaceutical company, personal fees from Roche pharmaceutical company, personal fees from Lilly pharmaceutical company, personal fees from Heptares pharmaceutical company, personal fees from Otsuka pharmaceutical company, personal fees from Novartis pharmaceutical company and personal fees from Allergan pharmaceutical company, outside the submitted work. Esme Moniz-Cook held NIHR funding for a programme grant during this period (RP-PG-0606-106). Dr Corbett reports personal fees from Lundbeck, personal fees from Novartis, personal fees from Bial, personal fees from Acadia, outside the submitted work, and an NIHR Programme Development Grant held during the study period (RP-DG-1212-10004). Dr Aarsland has received research support and/or honoraria from Astra-Zeneca, H. Lundbeck, Novartis Pharmaceuticals and GE Health, and serves as paid consultant for H. Lundbeck and Axovant. Dr Fossey reports a grant from the Alzheimer's Society. Zoe Hoare reports associate membership of the HS and DR board. All other authors have no conflicts of interest to declare.

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## **Abstract**

**(Word count = 750)**

**Background:** The effective management of agitation and other neuropsychiatric and behavioural symptoms in people with dementia is a major challenge, particularly in care home settings where dementia severity is higher and there is limited training and support for care staff. There is evidence for the value of staff training and the use of psychosocial approaches, although no intervention currently exists to combine these elements into an intervention that is fit for purpose and effective in these settings based on RCT evidence.

**Objective:** To develop and evaluate a complex intervention to improve the well-being, reduce antipsychotic use and improve quality of life in people with dementia in care homes through person-centred care, management of agitation and non-drug approaches.

**Design:** Five-year programme consisting of six work packages (WP). WP1 consisted of two systematic reviews of personalised psychosocial interventions for behavioural and psychological symptoms for people with dementia in care homes. WP2 consisted of a meta-synthesis of studies examining implementation of psychosocial interventions, in addition to developing a draft WHELD intervention. WP3 consisted of a factorial study of elements of the draft WHELD intervention in 16 care homes. WP4 involved optimisation of the WHELD intervention based on WP3 data. WP5 involved a multicentre RCT in 69 care homes which evaluated the impact of the optimised

WHELD intervention on quality of life, agitation and overall neuropsychiatric symptoms in people with dementia. WP6 focussed on dissemination of the programme.

**Setting:** Care homes in the UK.

**Participants:** People with dementia living in care homes, and the health and care professionals providing treatment and care in these settings.

**Results:**

WP1: Reviews demonstrated RCT and qualitative evidence supporting the use of psychosocial approaches to manage behavioural symptoms, but highlighted a concerning lack of evidence-based training manuals in current use.

WP2: The meta-analysis identified key issues in promoting use of interventions in care homes. The WHELD intervention was developed through adaptation of published approaches.

WP3: The factorial trial showed that antipsychotic review alone significantly reduced antipsychotic use by 50% (odds ratio 0.17, 95% confidence interval [CI] 0.05 to 0.60). antipsychotic review plus social interaction significantly reduced mortality (odds ratio 0.36, 95% CI 0.23 to 0.57) but showed significantly worse outcome in BPSD compared with the group receiving neither antipsychotic review nor social interaction (mean difference +7.37, 95% CI 1.53 to 13.22). This detrimental impact was reduced when combined with social interaction (-0.44, 95% CI -4.39 to 3.52) but with no significant benefits for agitation. The exercise intervention significantly improved neuropsychiatric symptoms (-3.58, 95%CI -7.08 to -0.09) but not depression (-1.21, CI -4.35 to 1.93). Qualitative work with care staff provided additional insights into acceptability and feasibility of the intervention.

WP4: Optimisation of the WHELD intervention led to final version which combined person-centred care training with social interaction and pleasant activities. The intervention was adapted for delivery through a 'Champion' model.

WP5: The large-scale multicentre RCT in 69 care homes showed significant benefit to quality of life, agitation and overall neuropsychiatric symptoms, at reduced overall cost compared to treatment as usual. The intervention conferred a statistically significant improvement in QoL (DEMQOL-Proxy Z score 2.82,  $p = 0.0042$ ; mean difference 2.54, SEM 0.88; 95% CI 0.81, 4.28; Cohen's  $D$  effect size 0.24). There were also statistically significant benefits in agitation (CMAI Z score 2.68,  $p = 0.0076$ ; mean difference 4.27, SEM 1.59; 95% CI -7.39, -1.15; Cohen's  $D$  0.23) and overall neuropsychiatric symptoms (NPI-NH Z score 3.52,  $p < 0.001$ ; mean difference 4.55, SEM 1.28; 95% CI -7.07, -2.02; Cohen's  $D$  0.30). The WHELD intervention contributed to significantly lower health and social care costs compared to treatment as usual (- £4740 ,95%CI -6129 to -3156). Focus groups were conducted with 47 staff, up to 12 months after the end of WP5, demonstrating sustained benefits.

WP6: The outputs of the programme were translated into GP workshops and a British Medical Journal e-learning module, an updated national best practice guideline and a portfolio of lay and care home outreach activities.

### **Limitations**

Residents with dementia were not involved in qualitative work

### **Conclusions:**

The WHELD intervention is effective in improving quality of life and reducing both agitation and overall neuropsychiatric symptoms in people with dementia in care homes. It provides a structured training and support intervention for care staff with lower overall costs for resident care than treatment as usual.

**Future work:** It will be important to consider the long-term sustainability of the WHELD intervention and cost-effective means of long-term implementation.

**Study registration:** ISRCTN Refs: 40313497 & 62237498

**Funding details:** National Institute of Health Research (UK)

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## List of Abbreviations

AD	Alzheimer's Disease
ANCOVA	Analysis of covariance
AR	Antipsychotic Review
BEHAV-AD	Behaviour in Alzheimer's Disease Scale
BMJ	British Medical Journal
BPSD	Behavioural and Psychological Symptoms of Dementia
CANE	Camberwell Assessment of Need in the Elderly
CDR	Clinical Dementia Rating
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CMAI	Cohen Mansfield Agitation Inventory
CSRI	Client Service Receipt Inventory
DCM	Dementia Care Mapping
DEMqoL	Dementia Quality of Life Scale
ES	Effect Size
FAST	Functional Assessment Staging
GP	General Practitioner
IoPPN	Institute of Psychiatry, Psychology and Neuroscience
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health Research
NPI (NH)	Neuropsychiatric Inventory (Nursing Home version)
NVQ	National Vocational Qualification
OR	Odds Ratio
PMG	Programme Management Group
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUIS	Quality of Interactions Scale
RCT	Randomised controlled trial
SD	Standard Deviation

SE ..... Standard Error  
TAU ..... Treatment As Usual  
UK ..... United Kingdom  
US ..... United States  
WHELD ..... A Programme of Research to Develop and Evaluate an Optimized,  
Fit-For-Purpose, Person-Centred Intervention to Improve Mental Health and Reduce  
Antipsychotics amongst People with Dementia in Care Homes  
WP ..... Work Package

## **Plain English Summary**

**(Word count = 297)**

The programme addressed antipsychotic drug use and behavioural symptoms in people with dementia living in care homes,

Firstly, we published literature reviews and focus group work supporting non-drug approaches to improve behavioural and psychological symptoms. Previous studies highlighted the potential value of personalised activities, social interaction and exercise. A review of available training manuals showed a concerning lack of evidence for current training packages, with only 4 out of 170 manuals showing benefit for residents with dementia in clinical trials.

We conducted a clinical trial to see whether training in person-centred care could be enhanced through review of antipsychotic prescriptions, promotion of social interaction/ personalised activities or exercise. Combining personalised activities with a review of antipsychotic medication led to both a 50% reduction in antipsychotic use and significant improvement in some aspects of quality of life for residents with dementia. There was also a significant reduction in mortality. There were improvements in symptoms of agitation for people receiving the exercise intervention. We then developed an optimised version of WHELD combining the effective elements. This was tested in a large randomised clinical trial involving 69 care homes and 847 residents over 9 months. The results demonstrated benefits in quality of life, a reduction in agitation and improvement in quality of care for residents in those homes receiving the WHELD intervention, at a reduced cost compared to usual care.

The findings have been disseminated in numerous publications, a series of GP outreach activities (workshops and online learning), and an update to national best practice guidelines, in addition to workshops with care home staff. The WHELD programme has provided important new information about the best way to provide training and support to empower and enable care home staff to substantially improve care for people with dementia.

## **Scientific summary**

### **(Word count= 2289)**

#### **Background**

Neuropsychiatric symptoms, often referred to by consensus as behavioural and psychological symptoms of dementia (BPSD), represent a major challenge to the treatment and care. They impact on mortality, quality of life and antipsychotic use. Two major elements of treatment and care are known to be critical to improving this aspect of service provision. Firstly, the development of safe and effective psychosocial interventions for BPSD, as a safe and effective alternative to antipsychotic medication. Since the millennium, there has been a growing focus on a personalized approach to delivering these interventions. Secondly, high quality training and skills development for staff to enable them to provide the best possible care, in addition to effective support for clinicians working with people in care home settings. These requirements are highlighted in government directives worldwide. Person-centred care is recognized as a gold standard in care provision in dementia, yet there are no standardized programmes to support implementation in care homes.

#### **Objectives**

To improve mental health and reduce the prescription of antipsychotic drugs for people with dementia in care homes, by developing and evaluating an optimized intervention based upon the most effective currently available therapies that can provide a broad range of benefits and which can be routinely implemented as part of NHS care. We will also determine whether the intervention improves quality of life (QOL).

This was achieved through addressing the following research questions through six Work Packages (WP):

What is the evidence supporting the use of psychosocial interventions for BPSD and staff training programmes in person-centred care in improving BPSD and antipsychotic use? (WP1)

What factors influence implementation of psychosocial interventions in care home settings? (WP2)

What is the effectiveness and feasibility of person-centred care training for care staff alone and in combination with antipsychotic review, social interaction and exercise interventions? (WP3)

What adaptations are required to optimise the effectiveness and implementation of the WHELD intervention? (WP4)

What is the effectiveness and cost-effectiveness of the optimised WHELD intervention? (WP5)

How can the WHELD intervention be effectively disseminated in order to maximise impact on care practice and future research? (WP6)

## **Methods**

WP1: The two systematic reviews utilised broad searches of electronic databases including MEDLINE, PsychInfo, Embase, Web of Science, Clinical Trials, British Nursing Index and Cochrane Library to identify relevant publications relating to psychosocial interventions, and a broader search of online search engines to identify existing person-centred care training manuals. Following protocolized review procedures, quality criteria were applied to published studies. In the training manuals review the efficacy of manuals was also considered.

WP2: A meta-synthesis approach was used to conduct a review of studies examining the implementation of psychosocial interventions in care homes. Eligible studies were coded and data extracted for thematic analysis. Themes were combined using an interpretive method of meta-data synthesis grouping themes where they had greatest explanatory power. WP2 also involved a series of intervention development steps with a Therapy Development Group to create and protocolize an initial WHELD intervention package.

WP3: A cluster-randomized factorial controlled trial of the WHELD intervention was conducted in people with dementia in 16 care homes. All homes received person-centred care training and weekly visits from a research therapist. Eight were randomly assigned to antipsychotic review, social interaction or exercise for nine months, with most homes assigned to more than one intervention. Primary outcome measure was antipsychotic use. Secondary outcome measures were agitation, depression, overall

BPSD, quality of life and mortality. WP3 also involved focus group discussions with care home staff from all participating homes to discuss expectations of the study and its implementation, and a cost function analysis conducted with the baseline data from the factorial study. The analysis utilized data from demographics, medical history, clinical assessment of BPSD and assessment of unmet needs to define costs of care and associated variables for people with dementia in care homes.

WP4: This WP consisted of a series of review and consultation steps leading to optimisation of the WHELD intervention. This included (i) Review of the outcomes of WP3 with expert and governance groups, (ii) Review of study materials and their usage with WHELD therapists, and (iii) Focus group discussions with 41 care staff involved in the factorial trial in WP3 to understand their experience of involvement in research and use of the WHELD intervention. The intervention was then refined according to the outputs.

WP5: A randomised controlled cluster trial with an embedded cost-effectiveness study was conducted in people with dementia in 69 care homes comparing the WHELD intervention with treatment as usual. The primary outcome measure was quality of life (DEMqoL-proxy). Secondary outcome measures included agitation (Cohen Mansfield Agitation Inventory), BPSD (NPI-NH), antipsychotic use and pain (Abbey Pain Scale). Staffing inputs and service use data (CSRI) were collected for use in the cost-effectiveness analysis. Focus group discussions were held with 12 therapists and supervisors to discuss the sustainability of the intervention in care homes. Additionally, a focus group was conducted nine to 12 months after the end of WP5 with care staff from nine homes that had received the intervention to understand factors related to the sustainability of the intervention beyond the research implementation period.

WP6: This dedicated dissemination phase involved a series of tailored activities to maximise the impact of the WHELD programme. Work included academic publication and presentations, outreach to GPs through regional workshops and the development of a British Medical Journal e-learning module, updating of national best practice guidelines and additional events for care homes.

## Results

WP1: The systematic review of psychosocial interventions identified 40 studies, and highlighted the evidence supporting the use of reminiscence therapy (Effect Size-ES 0.33), personalised pleasant activities (ES 0.46) and training in person-centred care, with less consistent benefit for personalised music, exercise and validation therapy. A lack of large-scale RCTs was identified. The efficacy and quality review of person-centred care training manuals for staff identified 30 available manuals, of which only four were supported by RCT evidence. Of these, studies reported benefit to agitation, depression, overall BPSD and antipsychotic use. These were the Focussed Intervention for Training of Staff, N.E.S.T, Dementia Care Mapping and Improving Dementia Care manuals.

WP2: The meta-synthesis on psychosocial implementation revealed key issues in promoting use of interventions in care homes, including the core involvement of staff, buy-in by family members, flexibility to home structures and working arrangements, ongoing training, supervision and support for staff and the need for cultural change. These findings were combined with WP1 to inform intervention development. The WHELD intervention involved four key elements: person-centred care training based on adapted versions of published manuals, Antipsychotic Review by GPs based on national best practice guidelines, Social Interaction and Exercise, both adapted from published interventions.

WP3: In the factorial trial, antipsychotic review significantly reduced antipsychotic use by 50% (odds ratio 0.17, 95% confidence interval [CI] 0.05 to 0.60). antipsychotic review plus social interaction significantly reduced mortality (odds ratio 0.36, 95% CI 0.23 to 0.57) but showed significantly worse outcome in BPSD compared with the group receiving neither antipsychotic review nor social interaction (mean difference +7.37, 95% CI 1.53 to 13.22). This detrimental impact was mitigated by concurrent delivery of social interaction (-0.44, 95% CI -4.39 to 3.52) n. The exercise intervention significantly improved neuropsychiatric symptoms (-3.58, 95% CI -7.08 to -0.09) but not depression (-1.21, CI -4.35 to 1.93). The focus group discussions findings highlighted that successful training and support interventions must acknowledge and respond to

“whole home” issues. Three overarching themes emerged as influential: the need to be attentive in addressing staff expectations and perceived value of the proposed interventions, the value of sustained relationships and recognition of good practice.

WP4: Review of the WHELD intervention and materials based on therapist records, focus groups with 41 staff from six participating homes and consultation with the expert and therapy development group led to a number of key changes to the intervention. The optimized intervention therefore consisted of the person-centred care and social interaction interventions, with activities elements from the exercise package and a revised version of the antipsychotic review intervention in which staff prompted GPs for review. The delivery model was adapted for implementation and cost-effectiveness, replacing intensive therapist time with a champions’ model in which nominated care staff took ownership for interventions in their home. Focus group discussions outcomes relating to both the overall research experience and the use of WHELD materials reported a generally positive experience for staff, although there were issues with extra burden of data collection and the time factors in homes.

WP5: In all, 847 people were randomised to WHELD or TAU, of whom 553 completed the 9-month randomised controlled trial. The intervention conferred a statistically significant improvement in QoL (DEMQOL-Proxy  $Z$  score 2.82,  $p = 0.0042$ ; mean difference 2.54, SEM 0.88; 95% CI 0.81, 4.28; Cohen’s  $D$  effect size 0.24). There were also statistically significant benefits in agitation (CMAI  $Z$  score 2.68,  $p = 0.0076$ ; mean difference 4.27, SEM 1.59; 95% CI -7.39, -1.15; Cohen’s  $D$  0.23) and overall neuropsychiatric symptoms (NPI-NH  $Z$  score 3.52,  $p < 0.001$ ; mean difference 4.55, SEM 1.28; 95% CI -7.07, -2.02; Cohen’s  $D$  0.30). There was a statistically significant benefit in positive care interactions measured by QUIS (19.7% improvement, SEM 8.94, 95% CI 2.12, 37.16,  $p = 0.03$ , Cohen’s  $D$  0.55). In an additional exploratory analysis, overall benefits were greatest in people with moderately severe dementia. The WHELD intervention contributed to significantly lower health and social care costs compared to treatment as usual (- £4740, 95% CI -6129 to -3156). Focus group discussions with 12 WHELD therapists highlighted a number of perceptions of the knowledge and skills required for delivering the intervention. A flexible approach to working with homes was a key factor, and therapists reported that supervision and skills development was critical to their role. They also reported that the champions

model, whilst helpful, required considerable input to support staff in developing confidence in cascading information to their colleagues. Focus groups with 47 staff from nine participating homes took place nine to twelve months following the end of the trial and were analysed using thematic analysis. A number of sustained benefits and practices and contributing organizational factors in the homes were identified

WP6: Dissemination activities were successfully completed. Key activities included regional workshops for GPs which received excellent feedback and response, and the creation of an e-learning module for GPs with the BMJ Learning portal. The national guidelines on behavioural and psychological symptoms of dementia management were updated and endorsed by NHS England. Additional events and workshops were held with care home staff, and investigators presented the findings at numerous national and international conferences. All findings were prepared for publication in peer-reviewed journals.

## **Conclusions**

The WHELD programme successfully optimized a person-centred care training package by augmenting the intervention with person-centred pleasant activities and antipsychotic review. This gave additional tangible benefits and made the programme more pragmatic – an essential component for successful implementation. The definitive RCT conducted in WP5 provides an evidence-based platform to enable effective implementation in care home settings for people with dementia.

The results of WP3 suggest the need for some caution when reviewing antipsychotic medications in people with dementia, and highlight the importance of providing an evidence-based non-pharmacological intervention in parallel with antipsychotic discontinuation to maximize benefit for people with dementia. Of note, combining antipsychotic review with social intervention did not just result in the reduction of antipsychotics without worsening of BPSD, but also led to significant improvement in quality of life and a significant 30% reduction in mortality.

The intervention in WP5 was optimized not just for efficacy, but also to design an intervention that was more suitable for practical implementation in real world settings.

The intervention conferred significant benefits on quality of life, agitation and overall neuropsychiatric symptoms. The standardised effect sizes (Cohen's D) for quality of life, agitation and neuropsychiatric symptoms were all between 0.23 and 0.3. These would usually be considered as a small effect size. For context the effect size for treating agitation is more favourable than has been demonstrated in other studies using antipsychotic medication and very few studies have demonstrated any impact on quality of life for residents with dementia. It should also be noted that the intervention targeted all residents with dementia and is therefore difficult to compare with an intervention delivered to a population with clinically significant symptoms.

As part of the adaptation of the intervention there was a less proactive approach to GP education as part of antipsychotic review and the modified WHELD intervention did not achieve an overall reduction in antipsychotic use in this RCT. The GP intervention has however been developed as a BMJ educational module, and in practice it should therefore be possible to implement the WHELD intervention directly in care homes and promote the GP educational component in parallel.

Therefore, in summary, WHELD has provided clear evidence to inform clinical and care practice for people with dementia living in care homes.

Firstly, with regard to antipsychotic use, the clinical trials in the programme provide evidence that advocates the continued judicious prescribing of antipsychotics that follows the changing landscape of their use in the UK and worldwide. Given the findings related to antipsychotic review, it is critical that prescribers consider the potential impacts of antipsychotic withdrawal and carefully balance the harm to benefit ratio associated with antipsychotics.

Secondly, the programme has clearly demonstrated the value of social interaction and individualised pleasant activities as part of person-centred care in the treatment and care of people with dementia.

Finally, the qualitative work conducted in this programme has highlighted opportunities and challenges in implementation of psychosocial approaches in care homes. One

that is of particular importance is the need for ongoing training and support for care home staff to enable and empower them in their role.

**Study registration:** ISRCTN Refs: 40313497 & 62237498

**Funding details:** National Institute of Health Research (UK)

## **Programme Synopsis**

### **Background**

Dementia is characterised by the progressive loss of cognition and function, leading to loss of independence and communication ability, and eventually to death. Dementia exerts an enormous impact on the individuals affected, as well as their families, many of whom provide informal care for long periods of time. In the context of an ageing population dementia is also a critical public health issue, with considerable financial implications at a societal level. There are 46 million people with dementia worldwide, including 850,000 in the UK, of whom an estimated 250,000 live in care homes <sup>1 2</sup>. In the US 64% of people receiving Medicare in nursing homes have dementia <sup>3</sup>. Care homes provide fulltime residential and nursing care, and represent a unique challenge for healthcare. There is an increasing focus in research and policy on the improvement of institutionalised care, and the need for evidence-based interventions for people with dementia that are tailored to this setting.

### **Dementia in healthcare provision and policy**

Dementia has a vast impact on health and social care services in the UK. The direct cost of dementia is £42 billion per year <sup>1</sup>, greater than stroke, heart disease and cancer combined. This was the basis of the UK National Dementia Strategy for England, developed by the Department of Health in partnership with stakeholder organisations such as the Alzheimer's Society <sup>4,5</sup>. The strategy laid out a unique vision for people with dementia and provided a five year plan to “develop services for people with dementia and their carers that are fit for the 21st century and that meet the needs of everyone”.

The strategy included two key objectives with particular relevance to care home settings, with strategies to achieve them. “Improving the quality of care for people with dementia in care homes” (Objective 11), involved a government directive to include specialist mental health teams in dementia care, within a range of other measures. “The development of an informed and effective workforce for people with dementia” (Objective 13) aimed to provide training and skills for health and social care staff to enable them to deliver the best care.

The importance of providing high quality care for people with dementia living in residential and nursing homes has received less focus within the subsequent Prime Minister's challenge on dementia 2020 <sup>5</sup> and the related implementation plan <sup>6</sup> . However, the value of an adequately trained workforce and the provision of evidence-based training was highlighted, and the focus on minimizing unnecessary prescribing of antipsychotic medications to people with dementia was maintained <sup>6</sup>, in line with international recommendations <sup>7</sup>. A subsequent report from the King's Fund "Social care for older people: Home truths" has highlighted the substantial pressures facing the care home sector, and the urgent need to use limited resources more effectively to achieve high quality care <sup>8</sup>.

People with dementia have complex care needs, particularly those residing in care homes. The majority of these individuals have moderate or severe dementia and their care needs are influenced by a combination of cognitive, functional and communication impairments, and medical comorbidities, and a high frequency of BPSD<sup>3,7,9</sup>. The NHS provides for these complex health needs largely through primary care and specialist service consultancy. Some specialist teams have introduced more proactive liaison services, but these are not widespread. An effective solution is needed to enable consistent and effective NHS support for people with dementia and staff, particularly in care home settings where specialist staff are rarely available. Such an NHS service would need to improve the general quality of care, the skill base of care staff, and the availability of non-pharmacological interventions and reduce the frequency of potentially harmful antipsychotic prescribing to improve health and quality of life for people with dementia in care homes.

The WHELD Programme Grant was run in parallel with National Dementia Strategy for England and the Prime Minister's challenge on dementia implementation activities, and within the context of a national drive to improve healthcare service provision and care home services for people with dementia. It represents an important example of the development of a robust evidence-base for dementia care and the improvement of services in care homes.

## **Behavioural and psychological symptoms in dementia**

Neuropsychiatric symptoms, often referred to by consensus as behavioural and psychological symptoms in dementia (BPSD), include aggression, agitation and restlessness, psychosis, depression, anxiety, elation, disinhibition, sleep disturbance and apathy. BPSD affects 90% of people with dementia at some point during the course of their condition<sup>10</sup>. These BPSD are critical indicators of quality of life and well-being, and have clinically significant impacts on their individual and their caregivers. They present a substantial challenge for health and care professionals as there are limited treatment options.<sup>10</sup>

Current best practice guidelines promote non-pharmacological interventions as the first-line approach for the treatment of BPSD and there is a growing evidence-base to support the value of this approach<sup>11</sup>. However, there is little guidance on how to implement non-drug treatments, and no structured framework for their widespread use in practice.

### **The use of antipsychotics in people with dementia**

Current best practice guidance limits the use of antipsychotics to short-term prescription (up to 12 weeks) of risperidone in intractable cases that are causing risk to the person or others.

#### *Clinical effectiveness of antipsychotic medications*

Systematic reviews have analysed the clinical effectiveness of antipsychotics in people with dementia. Most studies have focused on the treatment of agitation, aggression, psychosis or overall BPSD<sup>12,13</sup>. These analyses are based on 18 placebo controlled randomised trials, most of which were conducted over a 10-13 week period. However, many of these trials have not been published in full. The best evidence base exists for risperidone, with five fully published good quality randomised controlled trials (RCTs) and a total of 1761 participants<sup>12, 13</sup>. Adverse events were comprehensively reported in all five studies<sup>12,13</sup>. A meta-analysis reported a significant advantage for risperidone in the treatment of aggression (−0.84 points on the BEHAV-AD rating scale (95% confidence interval −1.28 to 0.40) at a dose of 1 mg and −1.5 points (−2.05 to

-0.95) at 2 mg)<sup>12</sup>. This threshold of change indicates a statistically significant difference but only borderline clinically meaningful benefit at the 2 mg dose. Evidence of clinically meaningful benefit is restricted to aggression; none was seen for non-aggressive symptoms of agitation. Effectiveness is even more limited for the treatment of psychosis. Statistically significant benefit but no clinically meaningful benefit has been reported in one trial only at 1 mg risperidone (BEHAV-AD mean difference -0.14, -0.25 to -0.03)<sup>12,13</sup>.

There are important issues to highlight in the evidence-base relating to antipsychotic use in dementia. Firstly, the evidence for benefit is not equal for all antipsychotics. For example, a meta-analysis of published trials found no evidence that quetiapine confers benefit in the treatment of behavioural and psychological symptoms of dementia<sup>13</sup>. A meta-analysis of risperidone studies indicates statistically significant benefit, but with a small effect size (Cohen's D effect size of 0.18 for the treatment of psychosis and 0.2 for treating aggression)<sup>12,13</sup>. Olanzapine and aripiprazole appear to have similar effect sizes, but based on a smaller number of studies. Other atypical antipsychotics have not been evaluated in RCTs. Secondly, all published antipsychotic trials have reported a high placebo response rate (e.g. 45% v 55% for risperidone), indicating that benefit is often related to the general benefits of good clinical practice.

#### *Safety concerns for antipsychotics*

The evidence of modest clinical effectiveness of antipsychotics must be balanced against the considerable risk of adverse events. There are established safety concerns associated with these medications including worsening of cognitive decline, cerebrovascular events, sedation, falls and increased risk of mortality<sup>17</sup>. In a systematic review of 15 RCTs of antipsychotics in people with Alzheimer's disease reported a 1% attributable risk of mortality over 12 weeks of treatment (risk difference 0.01, 0.004 to 0.02; P=0.01). A 12 month double blind RCT examining antipsychotic discontinuation in people with Alzheimer's disease, with a follow-up of participants for up to five years, found a significant reduction in mortality associated with discontinuation (hazard ratio 0.58, 0.36 to 0.92), with a risk difference in mortality of 29% after 36 months<sup>18</sup>. A subsequent meta-analysis of all 18 RCTs of atypical antipsychotics for the treatment of behavioural and psychological symptoms of dementia also found a clinically significant acceleration of cognitive decline in people

taking antipsychotics (mini-mental state examination mean difference 0.73 points, 0.38 to 1.09;  $P < 0.0001$ ) over 12 weeks.

Reporting of adverse events is most complete for risperidone. Full data are not available for other antipsychotics due to the large number of unpublished studies. Of particular concern, meta-analyses have established a threefold increased risk of cerebrovascular events in people with Alzheimer's disease who take risperidone compared with those taking placebo (odds ratio 3.43, 1.60 to 7.32;  $Z = 3.18$ ;  $P = 0.001$ ), with a risk difference of 3.1% versus 1.0% in a pooled analysis<sup>11</sup>. Another important risk is an increased frequency of extrapyramidal symptoms (risk difference by meta-analysis 0.06, 0.03 to 0.09 over 12 weeks). Peripheral oedema, sedation, prolonged Q-Tc interval, infections, and abnormal gait have also been highlighted as potential problems<sup>198</sup>. None of the RCTs of antipsychotic treatment for people with Alzheimer's Disease reported the impact on well-being or quality of life. However, the relationship between the prescription of antipsychotics and well-being has been examined in one cohort study of 209 people suggesting lower well-being in people taking these medications in an analysis controlling for BPSD<sup>20</sup>.

#### *Long-term use of antipsychotics*

Although more limited, evidence on the long term use of antipsychotic drugs is also beginning to emerge. Only three trials have evaluated a range of atypical antipsychotic drugs over periods of six months and longer. Adverse events are more marked with longer term use, with one RCT reporting 59% mortality compared with 30% in a placebo group after 36 months<sup>18</sup>. In another nine month RCT of 421 people with Alzheimer's disease, 18% of patients receiving risperidone withdrew from the trial owing to adverse events compared with 5% of those receiving placebo<sup>12</sup>. Only one RCT has directly evaluated the impact of an antipsychotic (quetiapine), on agitation, reporting no benefit compared with placebo over six months<sup>21</sup>. Overall, these studies have reported no benefit or very modest benefit in the treatment of the behavioural and psychological symptoms of dementia over six to 12 months. The exception is one recent trial that compared the impact of withdrawal versus continuation of haloperidol, and which indicated ongoing benefit of continuation in people who had initially responded to haloperidol treatment<sup>22</sup>. A Cochrane review of nine randomised placebo

controlled trials concludes that long term prescriptions of antipsychotics can be discontinued without a detrimental effect on BPSD <sup>23</sup>.

### *The changing landscape of antipsychotic use*

The lack of efficacy and the established safety concerns associated with antipsychotics is the basis of recommendations that these drugs are not to be used in people with Alzheimer's disease. Only risperidone is licensed for use in this patient group, in cases of severe BPSD that are causing significant distress or risk to the individual and where other treatment approaches have failed <sup>7</sup>. Despite this, antipsychotic prescribing has been very common due to the lack of other treatments and the considerable pressure to prescribe experienced by health professionals. To address this issue, many governments and health authorities have promoted initiatives to reduce the unnecessary prescribing of antipsychotics, including the National Dementia Strategy for England <sup>7, 24, 25</sup>. These initiatives were supported by evidence showing no detrimental effects of withdrawing prescriptions on BPSD <sup>23</sup>. As a result there has been a marked reduction in antipsychotic use in people with AD and dementia. An audit conducted in the UK in 2012 showed a 50% reduction in use, with 16% of people with dementia continuing to receive antipsychotics<sup>26</sup>. Similar trends have been documented across Europe and the US<sup>27-29</sup>. It will now be imperative for authorities to support this success in reducing unnecessary prescribing by adapting and updating guidance to reflect the altered landscape of antipsychotic use in dementia. For example, automatic withdrawal of antipsychotics may not be the best course of action since the larger proportion of existing prescriptions may be appropriate for the individuals. Instead, it will be essential for guidance to focus on continued review of prescriptions and careful monitoring. The change in policy and pressure to reduce prescriptions also highlights the importance of training for staff in care home settings and the need to enable their access to other effective therapies.

### **Non-pharmacological treatments for BPSD**

All best practice guidance for the management of BPSD recommend the first-line use of non-pharmacological approaches unless the symptoms are so severe that they are causing great distress or risk. The exceptions to this are cases where symptoms are

causing significant risk or extreme distress<sup>11</sup>. Although more severe and challenging agitation and aggression often requires pharmacological intervention, this level of BPSD does also respond to intense psychological approaches when tailored to the individual.

### *Person-centred care*

Person-Centred Care dictates that all care planning and therapies are embedded within a framework that is tailored to the needs and wishes of each individual. This personalized approach involves taking a full history and record of the person's interests, preferences and abilities, including their hobbies, culture and religious beliefs, previous employment and their medical and physical status. When working with people with dementia it is important to involve family members or close friends in discussions about the person to ensure a rich life history is created. Person-centred care also requires comprehensive medical review to ensure the care and treatment is appropriate to their current and ongoing status (see review by Fazio et al 2018 for an excellent overview of Person Centred Care)<sup>30</sup>. The value of a person-centred care approach is clearly established in the literature<sup>31-34</sup>. However, a systematic review has highlighted a critical issue in how person-centred care is delivered. Of the 170 identified person-centred care training manuals available for use in care settings, only 30 met quality criteria and of these only four were supported by evidence of their effectiveness<sup>35</sup>. This disconnect between available programmes and evidence is concerning and emphasizes the importance of a standardized approach to person-centredness and the use of non-pharmacological approaches. Of the person-centred care training programmes that do carry a robust evidence-base, each reported an improvement in outcomes related to BPSD. One RCT of an intensive nine-month training programme, the Focussed Intervention for Training of Staff showed a significant 50% reduction in antipsychotic prescriptions without worsening of behavioural and psychological symptoms in dementia in 347 care home residents<sup>31</sup>. A trial of Dementia Care Mapping, an in-depth care planning approach that is based on observation of care followed by planning to optimise it, reported improvements in agitation (Cohen's D effect size >0.5) but no reduction in antipsychotic use in 298 residents with dementia in 15 care homes<sup>33</sup>. Finally, a cluster RCT of an enriched person-centred care programme focusing on improving quality of life for care home

residents with dementia reported significant improvements in mood and numerical benefit in QOL which did not reach statistical significance in more than 200 residents in ten care homes<sup>36</sup>. The evidence-base also supports the use of focused interventions using an ‘antecedent, behaviour, consequence’ (ABC) approach to create individualized charts for care. These are usually delivered by a clinical psychologist<sup>37</sup>. A meta-analysis of these studies highlighted significant improvements in agitation and a significant reduction in antipsychotic use but no overall significant benefit in mood or quality of life<sup>35</sup>

### *Specific non-pharmacological interventions*

In addition to these training interventions, which promote a holistic approach to person-centred care, there are a number of simple approaches available that can be used by health and care professionals, or even family members. These include The Seattle Protocols, an approach which focuses on increasing physical and cognitive activities for people with dementia, such as balance exercises, gardening or walking<sup>38</sup>, Personalized Social Interaction, which aims to ensure each individual has dedicated time when they are interacting with other people through a personalised programme and Simulated Presence Therapy which uses recordings of conversations or events to promote conversation. More complex approaches include the Needs, Environment, Stimulation, and Techniques (N.E.S.T) intervention, usually delivered by a Recreational Therapist, and the Brief Psychosocial Treatment, an approach that creates a tailored programme of social interaction which has been used as a lead-in phase in a clinical trial to effectively reduce placebo response to a drug treatment<sup>32</sup>,<sup>39</sup>.

Non-drug approaches to improve well-being are frequently used as part of a person’s care plan. When used within a person-centred care framework these interventions provide an effective means to control for any unmet need which may lead to BPSD. Some specific interventions have also been evaluated for their effect on BPSD. Most focus on promoting ‘pleasant activities’, either with or without elements of social interaction. The majority of trials of these approaches have shown improvements in both agitation and depression<sup>40-44</sup>. For example, reminiscence therapy involves working with an individual to recall life events and memories, often through the use of props such as photographs or mementoes. It may also be enhanced through the use

of audio or video recordings of events or family members, as in the Simulated Presence Therapy described above <sup>45</sup>. As such, this approach also involves a great deal of social interaction. There is good evidence to support this approach in addressing symptoms of depression, with six out of seven published studies showing benefit <sup>46</sup>. A similar approach is used in Validation therapy, although the evidence-base for this is more limited. However, two small trials have reported beneficial effects on behaviour, including agitation, apathy and sleep disturbance <sup>47</sup>. The effect on other BPSD is less clear. The use of music in the care of people with dementia has been used with some success in a number of trials which report improvements in both agitation and anxiety, but not depression<sup>46,48,49</sup>. A number of studies have also examined the use of physical exercise, although few have reported significant improvement in BPSD <sup>47</sup>.

This emerging evidence base suggests that a number of interventions confer some benefit, but no single intervention has achieved improvement of mental health and reduction of antipsychotic use; and none of the interventions conferred a direct benefit to the quality of life of people with dementia in care homes.

### **Rationale for the WHELD programme**

Key NHS priorities include improving mental health and the treatment of mental health problems, further reducing antipsychotic use and improving the quality of life for people with dementia in care home settings. There is strong evidence that a number of specific Person-Centred Care interventions confer some benefit, but no single intervention has achieved both an improvement of mental health and a reduction of psychotropic drugs in people with dementia. Furthermore, none of the interventions evaluated prior to this programme conferred a direct benefit to the quality of life for people with dementia living in care homes. Most importantly none of these interventions have achieved widespread implementation in a clinical or care setting as part of routine NHS practice.

Further research is therefore urgently needed to address these key issues. Such research will need to develop an optimized therapy combining the most effective

elements of currently available evidence-based interventions to maximize the breadth of benefit. The intervention needs to be conceptually integrated, practical to implement in an NHS and care home setting and be cost effective.

To achieve these objectives will require an integrated programme of research. We tackled this using the MRC framework for complex interventions to model, develop, adapt, evaluate and disseminate the intervention.

The final stage of the MRC pathway, overcoming the barriers to enable widespread implementation is also a major challenge, which cannot be overstated, as this has never been achieved for any therapy in a care home setting. Research is needed to tailor an optimized therapy to the needs of NHS staff, care home staff and people with dementia living in care homes and their families. In addition, research is also imperative to understand and overcome the potential obstacles to implementation and to refine the intervention model through an extensive period of testing in the field. Although much is known about the effectiveness of interventions, which benefit specific aspects of health and mental health, any intervention is of limited value unless it is practical and can be implemented routinely in clinical practice. A comprehensive programme of research is essential to overcome the barriers and develop and implement an effective intervention which can be rolled out nationally as an NHS service to people with dementia in care homes, conferring the benefits to real people in everyday care settings. This is the basis for the design and delivery of the WHELD Programme, funded by the NIHR Programme Grants for Applied Research in 2012.

### **Aims and Objectives**

The overarching aim of the WHELD programme was to improve mental health and reduce the prescription of antipsychotic drugs for people with dementia in care homes, by developing and evaluating an optimized intervention based upon the most effective currently available therapies that can provide a broad range of benefits and which can be routinely implemented as part of NHS care. We will also determine whether the intervention improves quality of life (QOL).

To achieve these aim, the specific objectives for the WHELD Programme were:

To update current systematic reviews regarding the most effective interventions to reduce behavioural and psychological symptoms experienced by people with dementia in care homes

To optimize the most promising interventions and adapt them for an NHS and care home context through expert consensus and consultation with health and care professionals

To determine the specific benefits of the interventions in incremental evaluation studies

To develop an optimised intervention supported by an operationalized manual, with the specific aim of maximizing the breadth of benefit whilst remaining practical and cost-effective

To evaluate the optimised intervention and determine the cost effectiveness in a well-powered cluster randomised controlled trial

To understand the factors that contribute to feasible implementation and sustainability through consultation with study participants, and to field test the intervention in order to customize it as a practical NHS intervention

To proactively disseminate the findings and intervention to enable widespread implementation

Additionally, the WHELD programme aimed to support capacity development within dementia research by providing research training to post-doctoral researchers to enable them to develop careers as independent researchers, and to build skills and knowledge amongst NHS care staff through study participation.

### **Guiding principles for the design of the WHELD programme**

The design and approach taken for the WHELD programme followed a number of guiding principles in order to maximise the impact and relevance of the research to current practice and evidence. These were:

Development of interventions: It would have been inefficient and unnecessary to develop new interventions to promote mental health from basic principles as effective interventions already existed at the commencement of the programme. However,

these interventions required adaption for a UK NHS and care home setting and optimization to improve the breadth of benefit.

Evaluation of quality of life: Previous trials had not been able to demonstrate improvement of care home residents' quality of life. The WHELD programme was therefore adequately designed and powered for such an effect to be demonstrated.

Meaningful evaluation of interventions: Prior to a large RCT, incremental evaluation was prioritised as a means of determining the effective elements within the overall WHELD intervention, how these elements improve the breadth of benefits and which of these key elements deliver value for money.

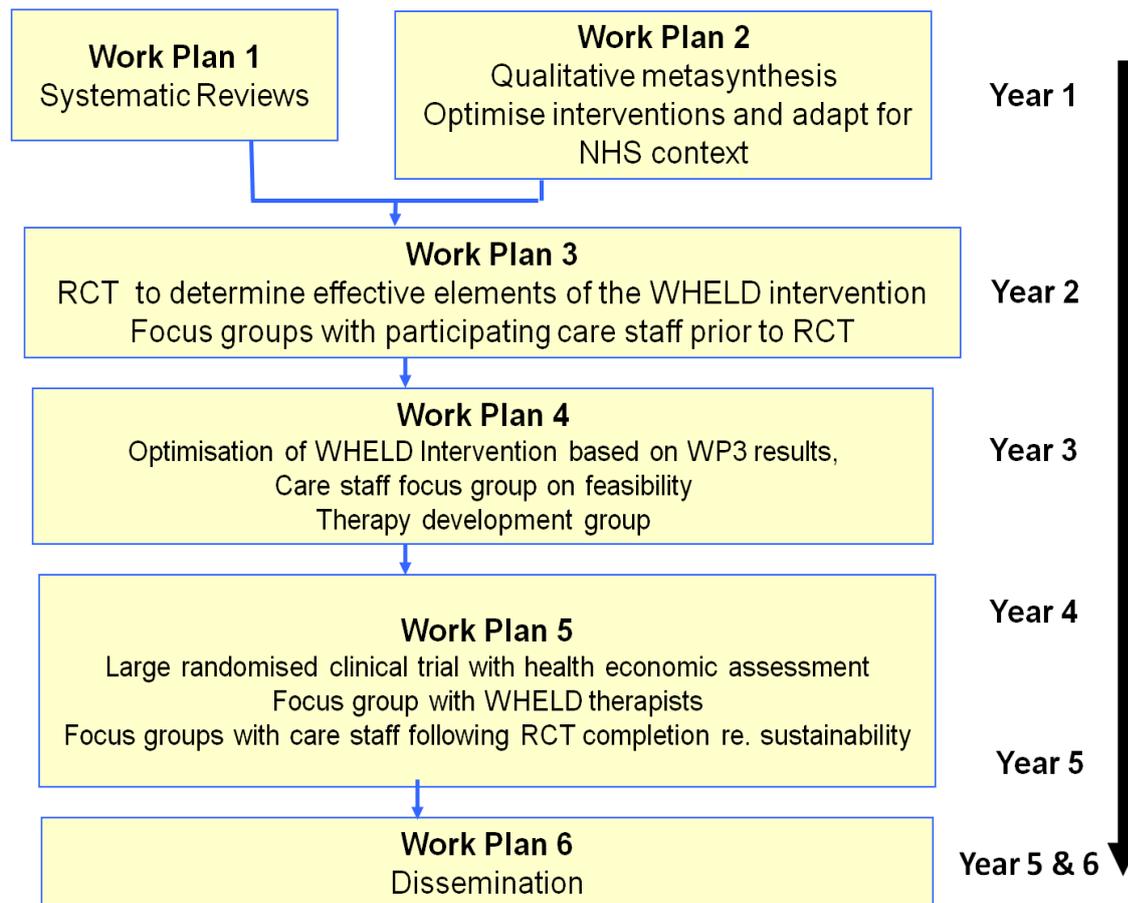
Importance of field testing: It was deemed essential to undertake an extensive period of field testing to ensure that the WHELD intervention was fully tailored to the needs of the NHS and the care home sector and to deliver an intervention that can be a nationally implemented cornerstone of NHS treatment for people with dementia residing in care homes. This was particularly important as it has not previously been possible to achieve widespread implementation of any intervention in a care home setting.

Dovetailing with national strategy and ongoing research: WHELD recognises the need to work within the dynamic climate in UK healthcare provision and alongside ongoing complementary research. The programme was designed to address the priorities published in the National Dementia Strategy for England and dovetails with studies examining specialist approaches for the psychological and pharmacological management of BPSD and other physical and mental health problems.

## **Work Plan**

The WHELD programme followed a pathway through modelling, feasibility, evaluation, dissemination and implementation as illustrated in the MRC framework for complex interventions. The programme, which involved six work packages, is summarised in the research pathway diagram below :

**Figure 1: Research Pathway Diagram**



Work Package 1: Update and publish a systematic review to highlight the service models and interventions for people with dementia living in care homes with the best available evidence base

Work Package 2: Model and adapt existing effective interventions to a UK NHS context

Work Package 3: Evaluation of the breadth of benefits in an incremental design to establish the most effective and most cost-effective combination of intervention elements (Factorial Study)

Work Package 4: Development of an optimized intervention (WHELD), “welding together” the most effective elements of the best available interventions, and developing a standardized manual and training programme for care staff

Work Package 5: Evaluation of the full breadth of benefit conferred by the intervention through a large cluster RCT with parallel cost-effectiveness and process evaluations.

Work Package 6: Dissemination of the findings and WHELD intervention to enable widespread national implementation

### **Limitations in Design**

In designing the study we were mindful of the challenges of measuring quality of life in people with moderate- severe dementia and therefore relied predominantly on a proxy measure. Within any randomised control trial of a non-pharmacological intervention it is a difficult decision whether to opt for treatment as usual or an active control in the comparison arm. We used an active control (person centred care) in work package 3 involving 16 care homes but opted for a treatment as usual control in work package 5 due to the scale of the study in 69 care homes. This may have inflated the magnitude of observed benefits with the WHELD intervention in work package 5.

The training and supervision in the intervention was delivered directly to care staff who participated in qualitative work . However, we recognise that residents with dementia who received the intervention delivered by the staff were not included in the qualitative studies and could provide a valuable perspective.

The details of each Work Package are discussed in the following sections.

**Improving person-centred care for people with  
dementia in care homes (NIHR WHELD)**

**Work Package 1**

**Systematic reviews of psychosocial and person-  
centred care interventions for people with dementia  
living in care homes**

## **Abstract**

**Objectives:** WP1 sought to ask two specific research questions: (i) What is the evidence supporting the use of psychosocial interventions for BPSD? (ii) What is the quality and efficacy of existing psychosocial interventions and staff training programmes in person-centred care in improving BPSD and antipsychotic use?

**Methods:** Two systematic reviews were conducted. One examined publications relating to psychosocial interventions. The second conducted a search to identify person-centred care training manuals. Quality criteria were applied and the efficacy of manuals was considered.

**Results:** The systematic review of psychosocial interventions identified 40 studies, and highlighted the evidence supporting the use of reminiscence therapy (Effect Size 0.33), personalised pleasant activities (ES 0.46) and training in person-centred care. The modest number of adequately powered RCTs was highlighted. The efficacy and quality review identified 30 manuals meeting the quality criteria, of which only four were supported by RCT evidence. Of these, studies reported benefit to agitation, depression, overall BPSD and antipsychotic use.

**Conclusions:** The reviews highlighted the limitations of the evidence-based related to person-centred care training, but the combined reviews indicate that there are some benefits in the use of psychosocial interventions for people with dementia living in care homes.

## **Background**

BPSD represent a major challenge to dementia care, and are associated with important clinical outcomes<sup>15,17</sup>. There is a high level of unmet need, particularly for individuals living in care homes<sup>2</sup>.

A major element of dementia care is the development of safe, effective psychosocial interventions which improve residents' care, reduces behavioural and psychological symptoms in people with dementia and offers an alternative to antipsychotic medication. There is a growing focus on a personalized approach to these interventions. A second element is the need for high quality training, in addition to effective support for clinicians. These requirements are highlighted in government directives worldwide<sup>7,25,50</sup>.

As the starting point for WHELD, WP1 aimed to synthesise the landscape of non-pharmacological treatment approaches and the resources that are currently available. This work directly informed decisions regarding the design and delivery of the WHELD intervention.

## **Aims & Objectives**

The aim was to address and update gaps in the evidence base to inform the development of the WHELD intervention.

The two major objectives were:

To update a systematic review highlighting service models and interventions for people with dementia living in care homes

To conduct a two-pronged systematic review of quality and efficacy of existing person-centred care interventions, with a focus on impact on BPSD and antipsychotic use.

# **Systematic Review of psychosocial interventions to address behavioural and psychological symptoms experienced by people with dementia living in care homes**

## **Rationale**

The literature has consistently shown substantial numbers of studies investigating treatment approaches for BPSD. However, the majority focus on pharmacological intervention and of those evaluating psychosocial approaches only a fraction use robust, good quality methodology to investigate effectiveness<sup>51,52,53,54</sup>. Of the recent systematic reviews only O'Neil<sup>55</sup> focussed on the treatment of individual BPSD, and none focused on the benefits of personalized psychosocial interventions. Despite the high profile of antipsychotic use as an issue in clinical practice, no systematic reviews have considered this outcome<sup>31</sup>. A considerable number of new studies have been published since the most recent systematic reviews, which include studies published before 2009<sup>55</sup>.

## **Methods**

The work followed a systematic review protocol (<sup>46</sup>/<http://dx.doi.org/10.1017/S1041610214000131> - abstract; link to full Author Accepted Manuscript (AAM) in Appendix 1), and focused on studies published from 1<sup>st</sup> January 2012 to 31<sup>st</sup> December 2012. .

### *Development of Review Criteria*

A preliminary search was undertaken to identify studies examine the impact on psychosocial interventions on BPSD and antipsychotic use in people with dementia living in care homes. The search was subsequently refined by a specialist panel to focus on personalized psychosocial interventions.

### *Selection of Included Studies*

A qualified librarian and one investigator performed the initial search. Two investigators examined these results and excluded irrelevant articles. Personalized psychosocial interventions were grouped into six categories of interventions.

#### *Quality of included studies*

A traffic light system was used to describe a risk of bias analysis, using an adaptation of the Cochrane review 2008 framework (reported in Corbett et al 2012<sup>56</sup>). The 6 criteria (adequate sequence selection, allocation concealment, Blinding, Incomplete outcome data. Free of selective reporting, free of other bias) were each rated as green, amber or red to produce an overall rating.

#### *Data analysis*

Quality assessment used operationalised Cochrane criteria<sup>56</sup> and PRISMA guidance. A descriptive summary was developed for the impact of each type of intervention. Where available the effect size was included.

## **Results**

#### *Studies included in the review*

641 studies were identified in the initial search, of which 597 were excluded. 40 studies were included. Of these nine were rated *green*, eight *amber* and 23 *red*. None of the included studies contained a health economic analysis.

#### *Description of studies*

The 40 studies included 26 RCTs and 14 studies with quasi-experimental designs. The studies were performed in 13 different countries, using 66 different outcome measures. 20 (50%) were published in the last four years. The studies were distributed into the six categories, the number of papers in each category being show in brackets: Reminiscence (6), Personalized music (7), Personalized pleasant activities with or without social interaction (10), Validation therapy (2), Personalized exercise/physical activities (12) and person-centred care training and practice development (3).

#### Reminiscence

Six studies<sup>57-60</sup> evaluated reminiscence. Two had a parallel group RCT design<sup>57,60,61</sup>. There was substantial variability within sample size (range 30-115 participants, median 67), duration (range between three and eight weeks, median seven), frequency of intervention and session length (30–60 minutes). Results consistently showed significant benefit to depression (Effect size 0.33)<sup>58-61</sup>. Other outcomes were less consistently evaluated, and benefit was variable. One of two studies examining BPSD reported benefit<sup>62</sup>. None evaluated agitation.

### Personalized Music

Personalized music was examined in seven studies<sup>49, 63-67</sup> including four parallel group RCTs<sup>48, 49, 63, 67</sup>. The studies included 20-104 participants (median 55.5), lasting four-42 weeks (median six), with variable frequency and session length (30–50 minutes). Benefit was identified in three studies examining agitation<sup>48,49,66</sup>, including two RCTs. There was no difference in treatment “dose”. The effect size of personalized music on agitation ranged from 0.43 (in favour of control) to 0.66 (median 0.21). There was some evidence of benefit to overall BPSD<sup>49</sup> and anxiety<sup>48</sup> but not depression<sup>49</sup>. Subsequent work has suggested a possible impact on depression<sup>68</sup>.

### Personalized activities

Ten studies were included<sup>40-42,44,69-74</sup>, of which seven were RCTs. The studies had 37-231 participants (median 147.5), lasting one-36 weeks (median 4), varying in frequency and length (30-240 minutes). Four studies<sup>40-42, 69</sup> reported benefit to agitation (Effect Size 0.24 – 0.91, median 0.46). One study reported benefit to depression<sup>44</sup> and four studies<sup>40,41,71,73</sup> reported benefit to mood.

### Validation therapy

Two studies analysed validation therapy<sup>47,75</sup>. One 12-week trial of 30 patients (45-60 minutes) showed benefit to BPSD in combination with reminiscence therapy<sup>75</sup>. Another 16-week trial of 50 patients also saw benefit to agitation, apathy, irritability and night-time behaviour<sup>47</sup>.

### Personalized exercise

12 trials of exercise interventions were identified<sup>76-87</sup>, including 11 RCTs. Only four<sup>76, 78, 80, 84</sup> met criteria for personalized approaches, involving 56-682 participants (median

205) over five-weeks (median 15), varying in frequency and session length (30-60 minutes), and showing limited benefit.

#### Person-centred care training and practice development

Three cluster-RCTs focused on person-centred care training<sup>31,33,36</sup>, with 289-349 participants (median 293), lasting four-18 months. Two evaluated the impact on antipsychotic use, with one indicating a significant reduction<sup>31</sup>. One study reported benefit to agitation<sup>33</sup>. All examined mood, but only one reported significant benefit<sup>36</sup>.

Further evaluations were undertaken for interventions showing significant benefit to explore factors associated with favourable treatment response, defined as at least four studies examining the same outcome, with more than 50% of studies indicating benefit. Reminiscence had a beneficial impact on mood in all studies, indicating a broad spectrum of benefit, but further work is needed to clarify whether reminiscence benefits people living at home, younger individuals and those with severe dementia. Studies of personalized pleasant activities with or without social interaction indicated significant benefit for people with moderate-severe dementia living in nursing homes. Further work is needed to clarify whether there are benefits in other settings, in people with severe dementia or in younger individuals.

## Discussion

This Work Package successfully completed and published a systematic review of the evidence supporting the use of psychosocial interventions for BPSD in care home settings.

This review has progressed understanding of the potential differential benefits of interventions on specific BPSD, in particular through reminiscence on mood and depression (Effect size 0.33)<sup>57-59</sup> and personalized pleasant activities on agitation (Effect size 0.46)<sup>40-42, 69</sup>. This provides valuable new evidence on the best use of psychosocial interventions for BPSD.

Only three RCTs were identified which evaluated person-centred care training interventions<sup>31,33,36</sup>. Although all three reported benefit in at least one key outcome, benefits were inconsistent. One reported reduced antipsychotic use<sup>31</sup>, one improved agitation<sup>33</sup> and one improved mood<sup>36</sup>. Further work is needed to optimize these interventions. Evidence regarding personalized music was inconsistent and mainly focused on the treatment of agitation, although interpretation was challenging, and further work is needed. Despite larger evidence base for exercise, only four studies focused on personalized approaches to exercise and impact on BPSD, showing limited benefit. Importantly, there is no evidence that any of the interventions specifically conferred benefit to psychosis.

### *Limitations*

The outcome measures and trial duration in included studies varied considerably, precluding a meta-analysis. We also did not examine health economic outcomes. Only one study examined continued benefit beyond the period of the intervention, which is a key consideration for the WHELD protocol development.

It should also be noted that the study limited the period of inclusion to studies published since 2000 to focus on more recent and relevant studies. However, pre-2000 studies were consistent with our conclusions, for example benefits were reported from social interaction<sup>88</sup>, personalized pleasant activities without social interaction<sup>88</sup>, personalized physical activity<sup>89</sup>, an educational program<sup>90</sup> and reminiscence<sup>91</sup>.

An additional limitation is variety in theoretical frameworks underpinning the interventions, and their frequency, session length and duration. Despite this, the review presents clear information to inform clinical practice and the next phases of the programme. This work is valuable in improving the targeting of individual BPSD with specific personalized psychosocial interventions, and in driving key research questions.

### **Implications for delivery of the WHELD programme**

This review highlighted valuable differential effects between different personalized psychosocial interventions that could have implications for the tailoring of care packages according to symptoms. It highlighted the importance of person-centred care interventions, pleasant activities for the treatment of agitation, and the use of reminiscence therapy for mood. These findings were pulled through to WP2 and directly informed the development of the WHELD intervention.

In addition, the review indicated areas of need for the design of the WHELD intervention and protocol, including the need to focus on health economics, to improve understanding of the impact of duration and frequency of specific interventions on effect size, and to develop a more detailed understanding of the impact of the conceptual frameworks on outcome, and whether this can be used to optimize interventions. It also highlighted the importance of understanding of the level of care staff education needed to deliver specific interventions effectively, and the impact of the care environment and leadership on implementation.

The review was conducted based on a literature search up to December 2012 as part of the WHELD programme and to inform therapy development. A rapid updating search in October 2019 and citation tracking from out published papers did not identify any relevant new studies that would change our conclusions.

# **Systematic Review of person-centred interventions and training manuals for care home staff working with people with dementia**

## **Rationale**

Global government initiatives emphasise the importance of training for care staff and the need to improve access to effective psychosocial therapies for people with dementia<sup>5-7,50</sup>. These recommendations have resulted in a proliferation of training programmes that are promoted to care providers. However, the evidence to support their effectiveness is unclear.

Increasing the skills of the workforce through training in the UK would cost an estimated £546,000,000. It is therefore vital to have a clear understanding of the available training courses and their evidence base to support clinical and care interventions.

In line with the overall WHELD objectives we focussed on the implications for BPSD and antipsychotic use for this element of WP1.

## **Methods**

Full methodology is in Appendix 1<sup>35</sup>/<http://dx.doi.org/10.1002/gps.4072> - abstract, link to full AAM in Appendix 1.

The review had two objectives:

Quality review: To review the quality of available training manuals for person-centred care of people with dementia

Efficacy review: To undertake a systematic review of RCTs delivering training interventions to improve Person-Centred Care

### *Quality review*

Manuals and training packages were identified through electronic searches, screened for eligibility and scored for comprehensiveness and degree of operationalisation. Studies scoring three or more for both criteria were deemed to provide broad person-

centred interventions to address BPSD and/or antipsychotic use and were suitable for implementation. All papers and manuals published up to 30<sup>th</sup> June 2012 were included.

Data were extracted and manuals separated into categories according to the type of intervention or training. They were rated independently by three investigators. The type of research evidence available was noted and summarised as anecdotal, qualitative study, open trials, quasi-experimental and RCTs.

### *Efficacy review*

All RCT and quasi-experimental studies with a control group which addressed BPSD and/or antipsychotic use were included in the efficacy review. The methodological quality of studies was assessed applying the Cochrane system<sup>56</sup>.

Data pertaining to BPSD or antipsychotic prescribing were extracted for meta-analysis. Meta-analysis was undertaken with the Comprehensive Meta-analysis (v2 Hewlett Packard) package for key outcomes (agitation, depression, total neuropsychiatric inventory) reporting standardized mean differences with 95% confidence intervals and for antipsychotic drugs when data were available from two or more studies.

## **Results**

### *Quality Review*

170 packages were identified. 63 met the screening criteria and 30 were shortlisted, having obtained sufficient criteria scores. Of these four were supported by RCT evidence.

### *Efficacy Review*

Seven studies were identified<sup>31,33,40,92-95</sup>. Five were parallel group RCTs. Three evaluated the impact of person-centred care training on antipsychotic use, with two indicating significant reductions of 12.8%<sup>95</sup> and 21.5%<sup>31</sup>, which was confirmed by a meta-analysis (Standard difference in means 1.08, z 2.97, p=0.003) Quantitative evaluation of agitation was available for four studies<sup>31, 33, 40, 94</sup> with an overall significant

benefit. Benefit to depression was reported in assisted living environments, but not in care home settings. One trial reported global impact on BPSD, showing a significant 8.7-point improvement. All six studies received a 'Green' score for quality and risk of bias using the Cochrane quality review process<sup>56</sup>.

### *Excluded studies*

Several other interventions did not meet inclusion criteria, including Reducing Disability in Alzheimer's Disease (RDAD)<sup>34</sup> and Cognitive Stimulation Therapy<sup>96</sup>. Reasons for exclusion included focussing on specific domains, not focussing on BPSD or antipsychotic use, non-care home settings or interventions delivered directly to people.

### *Outcome of Combined Quality and Efficacy Review*

Only four manuals met the quality criteria and had published clinical trial evidence of efficacy:

Focussed Intervention of Training for Staff<sup>31, 97</sup> a ten-month person-centred care training package delivered by a mental health professional, conferring a 19.1% reduction in antipsychotic use (95%CI 0.5%-37.7%).

A collection of evidence-based protocols for non-drug strategies, N.E.S.T<sup>32, 93</sup>, **Error! Reference source not found.** and the manual, 'Simple Pleasures', conferring improvements in agitation (CMAI  $p=0.01$ ) and depression (GDS;  $p=0.001$ )<sup>93</sup>.

Dementia Care Mapping, a detailed observational and care planning approach for care homes, showing a significant reduction in agitation (CMAI  $p=0.01$ ) and falls ( $p=0.02$ )<sup>33</sup>

Improving Dementia Care<sup>98</sup>, a practical training and staff development resource, showing a reduction in agitation although the outcomes varied between sites (CMAI;  $p=0.01$ )<sup>33</sup>.

## **Discussion**

This review identified evidence demonstrating the benefits of person-centred care interventions on agitation and antipsychotic use in people with dementia living in care homes. However, this was based on intervention studies performed on only a fraction of the training programmes that are currently available. Only 30 (18%) of the manuals

followed good educational and person-centred care principles and only four (2.3%) had clinical trial evidence. Thus, over 80% of available training packages are of variable quality and 98% are not evidence based. This is extremely concerning. Healthcare and care home sectors are investing in training following government directives, yet this is being spent largely on programmes that carry no evidence of benefit. If the UK is to meet the imperative of providing better social and medical care, evidence-based intervention training must be a priority. Of note, interventions for which there is evidence of benefit were delivered over a period of at least four months and involve ongoing clinical supervision or support to embed implementation into care home practice. This suggests that one-off training packages or classroom-based training is likely to be ineffective.

The literature does not currently provide any evidence for effectiveness on psychosis, depression and quality of life. This is an important priority for further research, as highlighted by the Department of Health<sup>99</sup>.

### *Limitations*

Although the review incorporated national and international manuals, the review was limited to English language. The search for published manuals was complemented by a search for RCTs, focussing on training and activity-based, thereby mitigating the limitations and ensuring a broad international perspective. In addition, training programmes without available manuals were excluded. Several manuals had a broader framework for care delivery than a specific focus on BPSD. It is therefore likely that wider benefits were not captured.

### **Implications for delivery of the WHELD Programme**

This review highlighted the major disconnect between interventions that are routinely available and commissioned, and the evidence base. This added further weight to the overall rationale of the WHELD programme.

The review provided key indicators of elements for a successful person-centred intervention, including the importance of consistent, long-term support for staff. It

indicated the need to evaluate effectiveness on psychosis, depression and quality of life in addition to agitation and antipsychotic use.

The limited number of available training manuals without direct clinical trial evidence of benefit for people with dementia is alarming and emphasizes the importance of a feasible, effective training programme.

## **Concluding Remarks from WP1**

WP1 successfully delivered the objectives of updating the current evidence base with systematic reviews. It highlighted pleasant activities and social intervention as priority areas for addressing agitation, and reinforced our view that augmentation of existing interventions was needed to deliver comprehensive benefit and improve quality of life.

Finally, WP1 identified an alarming number of available training manuals that are not evidence-based, and strongly emphasized the need for an evidence-based manual. These findings were taken forward by the Therapy Development Group in WP2.

## **Major Outputs from WP1**

### **Publications**

Available in Appendix 1

WP1a) Testad I, Corbett A, Aarsland D, Lexow KO, Fossey J, Woods B, *et al.* The value of personalized psychosocial interventions to address behavioural and psychological symptoms in people with dementia living in care home settings: a systematic review. *International Psychogeriatrics / IPA* 2014;**26**:1083-98.

<http://dx.doi.org/10.1017/S1041610214000131> - abstract, link to full AAM in

Appendix 1

WP1b) Fossey J, Masson S, Stafford J, Lawrence V, Corbett A, Ballard C. The disconnect between evidence and practice: a systematic review of person-centred interventions and training manuals for care home staff working with people with dementia. *International journal of geriatric psychiatry* 2014;**29**:797-807.

<http://dx.doi.org/10.1002/gps.4072>- abstract, link to full AAM in Appendix 1

**Improving person-centred care for people with dementia in  
care homes (NIHR WHELD)**

**Work Package 2**

**Modelling and adaptation of interventions for use within an  
NHS context**

## **Abstract**

**Objectives:** WP2 sought to identify the factors that influence implementation of psychosocial interventions in care home settings and to develop the WHELD intervention for evaluation based on these outputs and findings from WP1.

**Methods:** A meta-synthesis approach was used to conduct a review of studies examining the implementation of psychosocial interventions in care homes. Data was analysed by thematic analysis using an interpretive method of meta-data synthesis, grouping themes where they had greatest explanatory power. These findings and WP1 results were used by a Therapy Development Group to create and protocolize a WHELD intervention package.

**Results:** The meta-analysis revealed key issues in promoting use of interventions in care homes, including the core involvement of staff, buy-in by family members, flexibility of care home working arrangements, training, supervision and support for staff and the need for cultural change. These findings combined with WP1 informed intervention development. The WHELD intervention involved four key elements: person-centred care training based on adapted versions of published manuals, Antipsychotic Review by GPs based on national best practice guidelines, Social Interaction and Exercise, both adapted from published interventions.

**Conclusions:** The work completed in WP2 follows a clear pathway from theoretical basis, through conceptual framework to a tangible operational intervention. The WHELD intervention represents a synthesis of knowledge drawn from clinical trial data, existing resources and qualitative analysis, and collated for use by a broad expert consensus process.

## **Background and Rationale**

WP1 illustrated the strength of evidence for several psychosocial interventions and manualised person-centred care programmes that confer benefit on mental health and antipsychotic medication use for people with dementia living in care homes. Promising interventions were identified, including staff training, person-centred care and structured social interaction approaches and exercise. Importantly, none of the interventions directly improved quality of life for care home residents nor achieved widespread implementation as part of routine care practice. WP1 also highlighted the lack of evidence-based training programmes and the importance of an integrated approach to ongoing support for care staff.

This pointed towards the need for a whole-systems approach to improve person-centeredness in care homes with integration of the most effective individual interventions and to develop an understanding of the factors that influence implementation.

WP2 therefore encompassed a further review to gather qualitative data on aspects of psychosocial intervention design, followed by a series of therapy development steps to adapt and combine the key components of established effective interventions.

### **Aims & Objectives**

The overall aim of WP2 was to create a conceptually integrated evidence based intervention that and practical to implement in UK care home setting.

The objectives of WP2 were to:

Conduct a systematic review and meta-synthesis of qualitative research to identify factors influencing the implementation of psychosocial interventions

Conduct a series of expert panel and Therapy Development Group (TDG) sessions to develop a person-centred care intervention by combining the best elements of existing interventions in a way which is both conceptually integrated and practical.

# **Implementation of Psychosocial Interventions: Systematic Review and Meta-analysis**

## **Rationale**

Qualitative methods are the most appropriate approach for addressing complex questions regarding implementation and acceptability of psychosocial interventions in care homes. Individual studies provide insight into how different psychosocial interventions are used and experienced within residential settings. Integrating these findings in a qualitative meta-synthesis promises to enhance their implementation and impact upon health policy and clinical practice<sup>100, 101</sup>. WP2 used this approach to help to understand and overcome the potential obstacles to implementing psychosocial interventions as part of routine practice. To our knowledge this is the first systematic review and meta-synthesis of the qualitative evidence in this field.

## **Methods**

Full details of the methodology are provided in Appendix 1<sup>102</sup>/<http://dx.doi.org/10.1192/bjp.bp.111.101402>. Systematic review methodology was used to identify relevant research regarding the use and effectiveness of psychosocial interventions designed to improve outcomes for people with dementia in care homes, from the perspective of people with dementia, relatives or care staff<sup>103</sup>. Papers published between 1<sup>st</sup> January 1995 and 31<sup>st</sup> January 2011 were included in the review.

Two investigators independently assessed relevant papers for methodological quality using the critical appraisal skills programme checklist<sup>104</sup>. We opted for an inclusive strategy<sup>105</sup> and, in common with other synthesis<sup>101</sup>, the quality appraisal process was used as a criterion to judge the value of papers with respect to their contribution to the synthesis. Themes were included in the meta-synthesis if they were supported by data from at least one article judged to be of reasonable quality.

A description of the main concepts derived from each paper was recorded<sup>106</sup>, shared constructs across studies and areas of discordance were noted. The themes were combined using an interpretive method of meta-data synthesis grouping themes where they had greatest explanatory power. A taxonomy was constructed that categorised findings in three domains that are discussed below.

## Results

The review identified 39 papers (34 studies)<sup>107-145</sup>, of which 29 were rated as reasonable quality or better (CASP  $\geq$  7), with a good level of agreement between reviewers (Weighted Kappa=0.66). The ten papers not meeting quality criteria were primarily rated as weak due to a lack of rigour in data analysis or a failure to comment on bias in the design<sup>110, 118, 119, 122, 125, 126, 128, 130, 135, 136</sup>.

The 34 studies spanned a broad range of psychosocial intervention types, which included exercise and other therapeutic activities (6)<sup>112-114, 119, 127, 140</sup>; music(5)<sup>131-134, 138</sup>; reminiscence (4)<sup>115, 123, 130, 137</sup>; communication strategies (3)<sup>108, 110, 143</sup>; models of dementia care (3)<sup>116, 135, 145</sup>; methods of orientation (2)<sup>111, 126</sup>; animal interventions (2)<sup>124, 125</sup>; staff training and supervision (3)<sup>120, 129, 142</sup>; and other (6)<sup>107, 117, 121, 139, 141, 144</sup>. Common themes were identified in three overarching categories: elements of a successful intervention; conditions required for a successful intervention; and challenges to a successful intervention.

### *Elements of a successful intervention*

Aspects that predicted successful interventions were categorised by whether they elicited benefit to people with dementia or to care staff.

### People with dementia

Beneficial interventions often supported people in 'connecting with others' by enhancing communication. Conversation was stimulated between residents, staff and family through various means, including animals, dolls, music and reminiscence items or 'memory boxes'<sup>109, 118, 124-126, 130, 138, 141</sup>. Studies reported particular success with volunteer-led approaches<sup>124, 125, 139</sup>, Music and dance interventions were useful in

supporting people to better express emotions<sup>109, 113, 114</sup>, with group activities improving cooperation and a sense of inclusion<sup>133, 127, 141, 145</sup>.

Successful interventions also focused on ensuring that participants felt they were making a meaningful contribution to an activity, for example through taking care of an animal<sup>109, 115, 124, 130, 137, 139, 141, 145</sup>. Structured or spontaneous reminiscence was also a valuable element<sup>114, 118, 124, 125, 134, 137, 141</sup>.

### Care staff

There was a consensus that care staff find psychosocial approaches valuable in enabling them to build better relationships with individuals and their families.<sup>115, 117, 120, 121, 130</sup>. Closeness between staff and residents was fostered by experiential learning which encouraged staff to consider the perspectives of a person with dementia<sup>116, 120, 145</sup> and opportunity to reflect on their approach to residents and the likely impact on them. Reflection reportedly led to changes in care giving behaviour<sup>120, 129, 130</sup>,<sup>120, 129</sup> particularly when supervision from senior staff was available<sup>129, 115, 129, 142</sup>.

### *Conditions required for a successful intervention*

All studies highlighted the reliance on staff to support people with dementia to access the psychosocial interventions<sup>109, 127, 128, 136</sup>. Person-centeredness, and the importance of relationship building was a major theme, both as a benefit and a determinant of being able to individualise their approach.<sup>109, 113, 114, 119, 123, 127, 134, 136, 137, 140</sup>.

The involvement of family members was also key to personalising care<sup>109, 138, 144</sup> and a source of mutual appreciation and respect<sup>123, 129, 144</sup>. A number of studies described successful approaches to stimulate collaboration between relatives and staff<sup>127, 143, 113, 116, 124</sup>.

### *Challenges to a successful intervention*

A number of challenges were identified, many of which related to the additional work, the requirement for flexibility of team rotas<sup>113, 138, 144</sup> and low staffing as a significant barrier to implementation<sup>138, 144, 122, 142, 121</sup>. However, with the exception of two

studies<sup>128, 136</sup> , the benefits conferred were thought to override the difficulties <sup>113, 122, 138, 142, 144</sup> .

Wide ranging staff responsibilities and reporting requirements, were frequently cited as a barrier to the implementation of psychosocial approaches. <sup>121, 135</sup> . Staff reported a perceived pressure to focus on responding to challenging behaviour, physical care and safety rather than supporting individual interactions <sup>108, 117, 121, 140, 136</sup> .

Finally, a number of challenges were described regarding negative attitudes towards psychosocial interventions and a general lack of knowledge about their potential benefit<sup>113, 128, 131 136, 144</sup> .

## **Discussion**

Overall, the meta-synthesis identified how important positive benefits from psychosocial interventions can be achieved. The major learning outputs that were taken forward are outlined below.

It is critical to involve staff and care home managers as active participants and to ensure they have personal investment in the intervention through collaborative, sympathetic approaches that openly accept the burden and challenges they experience

Buy-in by family members is also critical. Workshops and group events are effective in promoting this.

Flexibility is an essential aspect, ensuring the intervention is adaptable to different home structures and staffing levels, and tailored to resident abilities and interests.

Organisational support is needed to sustain learning and change in practice, particularly since training and mentoring involve considerable time investment by staff.

It is important to make a clear health economics argument to support this.

Cultural change is required to encourage staff to think about residents individually and address concerns about a new intervention alongside identifying benefits.

Person-centred care is fully accepted as the framework for intervention, with established means of tailoring interventions an individual's needs.

Training is critical, and particularly effective when it includes scenario-based, interactive elements and the opportunity for staff to reflect on their practice.

### *Limitations*

Qualitative meta-synthesis offers a systematic, relevant overview of international qualitative research whilst retaining much of the detail that individual studies provide. However, there is a risk that synthesising across qualitative studies could compromise the integrity of the individual projects, and their emphasis on context and holism<sup>100</sup>. We are mindful that this review identified a heterogeneous set of studies ranging in care setting, intervention type and methodological design. To convey the context of the study comprehensive details are published in Appendix 1 (WP2a)

We also recognise that the sample size is large for a meta-synthesis, but are satisfied that the scope of the review was sufficiently focussed and believe that the range of data assisted in identifying the properties and key concepts that can be applied across groups and settings.

### **Implications for the WHELD programme**

The recommendations outlined above were taken forward to the intervention development phase of WP2 (described below). The identification of key elements of successful interventions combined with the outputs of the review in WP1 indicated the need for incremental evaluation of individual elements of psychosocial interventions to enable an examination of the breadth of their respective benefits.

## **WHELD Therapy Development**

### **Rationale**

The work completed in WP1 and WP2 provided a comprehensive picture of the requirements and existing resources available for the creation of an optimised person-centred care intervention. The next phase of work sought to operationalise this information through a period of collaborative development work with a Therapy Development Group (TDG) and associated expert panel.

### **Aims & Objectives**

The aim was to develop an optimised person-centred care intervention for people with dementia living in care homes, which would include a training programme for care staff.

Specific objectives within this were:

To coordinate a large-scale expert consultation and TDG to gather informed opinion on the most appropriate design and content for the WHELD intervention

To operationalise the WHELD intervention by developing a manual for use in care homes

To finalise the design of the evaluation of the WHELD intervention for WP3.

### **Methods**

#### *Selection and scrutiny of interventions*

During October and November 2010, a TDG was convened, consisting of the WHELD investigators, lay representatives and care home experts including providers and inspectors.

The expert panel reviewed existing programmes with evidence of efficacy to identify elements to be included in a person-centred care programme. The Focussed

Intervention for Training and Support (FITS)<sup>31</sup>, N.E.S.T.<sup>146</sup> including Simple Pleasures<sup>92</sup> and Improving Dementia Care<sup>33</sup> interventions were scrutinised to identify which elements had proven most effective, which could also be combined into a consistent conceptual framework for person-centred care. The manuals were also reviewed against the emerging literature identified in WP1 and meta-synthesis in WP2. The language and style of the interventions was reviewed with consideration of the UK context of delivery.

#### *Expert consultation: Workshops*

A series of workshops were coordinated to gather opinions and experience from a wide audience. Workshop participants included 89 national and international experts from research backgrounds, clinicians from nursing, occupational therapy, physiotherapy, clinical psychology and psychiatry, care home managers and practitioners, and family carers. Two groups were conducted with 40 participants in each to achieve a robust consensus.

Meetings commenced with presentation of WP1 work and an overview of the evidence base. Participants were asked to consider the evidence and provide recommendations regarding the selection of interventions to include in WHELD. In a second session participants developed recommendations for refinement of the person-centred care training outlined in the FITS programme<sup>31</sup> in order to improve implementation. Suggestions were prioritised by consensus working to create a list that informed the manual development for the intervention.

#### *Intervention Creation*

The TDG collated and operationalised the outcome of the expert panels to produce the WHELD intervention. Manuals of the four selected interventions and overall protocol were produced. Members of the TDG also liaised with three key external experts (Linda Buettner, Jiska Cohen-Mansfield, Linda Teri) regarding their existing interventions and how they might be adapted for WHELD<sup>34, 40, 146</sup>. The formative materials were then edited to reflect UK practices where necessary. Where there was overlap between materials, a decision was made based on the workshop feedback about which would best meet the criteria for being effective and feasible for a UK care home setting. The full intervention was circulated to all WHELD investigators for

comment, and finally to members of the TDG. The final version was approved by the WHELD Programme Management Group.

## **Results**

### *Intervention selection*

Four key interventions to be used within the WHELD programme - person-centred care training for staff – which acted as the underpinning framework for the delivery of all interventions, social interaction, physical exercise and review of antipsychotic medication.

Four existing evidence-based interventions were highlighted for adaptation to create the WHELD intervention. These were the FITS person-centred care manual<sup>31</sup>, a non-drug protocol focusing on pleasant activities<sup>40</sup>, the N.E.S.T intervention<sup>146</sup> and the Seattle protocols<sup>38</sup>. Specific recommendations were made for refinements to individual elements based on safety and UK context specific considerations.

### *Adaptation of interventions for WHELD*

The TDG developed a manual of the four interventions and overarching delivery protocol, outlined below.

**Person-centred care training for staff:** This intervention combines elements of several effective interventions promoting person centred care. These included the FITS person-centred care training package<sup>31</sup> and opportunities for experiential learning about adapting care practice to meet the needs of someone with dementia. Using residents' life stories was a foundation to understand individuals' needs and preferences. A structured assessment of unmet needs<sup>146</sup> underpinned positive individualised care planning using SMART goals to implement activities based on a person's preferences<sup>92</sup>.

**Review of Antipsychotic Medication:** Previous studies that have achieved reductions in antipsychotic use have incorporated a formal review of antipsychotic medications according to standardized protocols<sup>31</sup>. The National Service Framework recommends

that reviews occur every three months. The TDG agreed that review would be undertaken using best practice guidelines for the prescription of antipsychotics in people with dementia<sup>30</sup>. The aim was for care staff to understand the need for regular review and develop a process led by the home which enabled this to be undertaken by the resident's GP. Workshops were also designed for GPs to support them in following the best practice guidelines.

**Social Interaction:** This intervention was based on the Positive Events Schedule, N.E.S.T intervention, Seattle protocols and Cohen-Mansfield's 'tool box' of psychosocial interventions, which were individualized to the needs of a particular individual<sup>38,146-148</sup>. A version of the 'tool box' approach had been evaluated in several small pilot studies and in a large open four week trial as part of the CALM-AD clinical trial<sup>149</sup> and used in the FITS study<sup>31</sup>. Activities promoting social interaction were adapted for a UK care setting with the aim that it should be delivered for 60 minutes a week or a 20% increase in activity if the resident already engaged in this level of activity.

**Exercise:** The Reducing Disability in Alzheimer Disease (RDAD) programme, which focuses on activities, strength, balance and flexibility training<sup>150</sup> was identified as the best evaluated programme for people with dementia, showing significant benefits for activity, mood and health in an RCT<sup>34</sup>. RDAD exercises were adapted to be simply and safely delivered by care staff with no formal physiotherapy or exercise training. Walking or pleasant activities of the residents' choice, including seated exercise or circle dance were incorporated from the exercise section of the N.E.S.T. protocols<sup>146</sup>. The aim was that it should be delivered for 60 minutes a week or a 20% increase in activity if the resident already engaged in this amount of exercise.

#### *Operationalisation of the WHELD intervention*

The TDG produced a manual for the delivery of WHELD as an incremental intervention for evaluation. The delivery was designed as a training programme coordinated by a central WHELD Therapist, who then provided support and supervision for care home staff. Care homes also nominated WHELD Dementia Champions to act as internal mentors with responsibility for implementation of interventions within the care homes. The TDG therefore produced one detailed Therapist Manual, providing detailed

information on the delivery of each intervention, and one Dementia Champion Manual, which was for care home staff. The manual aimed to maintain distinctiveness between the elements which were delivered but did not preclude homes from developing activities and interventions of their own volition.

## **Discussion**

The work completed in WP2 follows a clear pathway from theoretical basis, through conceptual framework to a tangible operational intervention. The WHELD intervention represents a synthesis of knowledge drawn from clinical trial data, existing resource and qualitative analysis, and collated for use by a broad expert consensus process.

## **Concluding Remarks for WP2**

WP2 successfully collated evidence from different sources including systematic review, qualitative review, expert consensus and existing operationalised interventions to prioritise interventions for the new WHELD intervention. The large consensus process gives additional validation to the final intervention which was taken forward to evaluation in WP3.

## **Major Outputs of WP2**

### **Publications**

Available in Appendix 1

WP2a) Lawrence V, Fossey J, Ballard C, Moniz-Cook E, Murray J. Improving quality of life for people with dementia in care homes: making psychosocial interventions work. *The British Journal of Psychiatry: The Journal of Mental Science* 2012; **201**:344-51. <http://dx.doi.org/10.1192/bjp.bp.111.101402>

### **WHELD Intervention materials**

WHELD Therapist Manual

WHELD Dementia Champions Manual

## **Work Package 3**

**Factorial pilot evaluation of non-pharmacological interventions in combination with Person-Centred Care training in care homes**

## **Abstract**

**Objective:** To establish the feasibility, effectiveness and cost-effectiveness of person-centred care training for care staff alone and in combination with antipsychotic review, social interaction and exercise.

**Methods:** A nine-month cluster-randomized factorial RCT of the WHELD intervention in 16 care homes. All received person-centred care. Eight were randomly assigned to antipsychotic review, social interaction or exercise. Primary outcome measure was antipsychotic use. Secondary outcome measures were BPSD and mortality. Costs of care were defined, and cost-effectiveness analysed using CSRI. Focus group discussions with staff discussed their expectations.

**Results:** Antipsychotic review reduced antipsychotic use by 50% (odds ratio 0.17, 95% confidence interval [CI] 0.05 to 0.6). Antipsychotic review plus social interaction significantly reduced mortality but increased BPSD compared with the group receiving neither antipsychotic review nor social interaction (score difference + 7.37, 95% CI 1.53 to 13.22). This detrimental impact was mitigated by concurrent delivery of social interaction ( -0.44, CI -4.39 to 3.52). The exercise intervention significantly improved neuropsychiatric symptoms ((-3.58, 95%CI -7.08 to -0.09) but not depression (-1.21, CI -4.35 to 1.93). Focus groups highlighted that successful training must acknowledge and respond to “whole home” issues.

**Conclusions:** Person-centred care, antipsychotic review and social interaction showed benefit to quality of life, antipsychotic use and mortality and has indications of cost-effectiveness.

## **Background and Rationale**

The work completed in the WHELD programme WP1 and WP2 builds on a growing body of literature [35](#). Our meta-analysis highlighted the benefit conferred by social interaction and pleasant activities on both BPSD and antipsychotic use<sup>46</sup>, and of physical activity through personalized exercise on mood<sup>34</sup>. This suggested that augmented person-centred care with these elements would be effective.

Up to 2008, cohort studies and audits in the US and Europe reported that 40% of people with dementia in care homes were receiving an antipsychotic<sup>151-153</sup>. In recent years the concerted effort to reduce unnecessary prescribing has led to a 15-50% reduction in prescriptions across US and Europe<sup>26-28</sup>. Whilst recent randomised antipsychotic discontinuation studies have reported benefits following withdrawal of antipsychotics<sup>18</sup>, there have been no randomised trials of rigorous antipsychotic review.

Working papers detailing work plan and analysis plan are attached at Appendix 2

### **Aims & Objectives**

WP3 reports a factorial evaluation of the WHELD intervention, to evaluate the effectiveness of person-centred care training for care staff alone and in combination with antipsychotic review, social interaction and exercise interventions.

## **Factorial randomised controlled trial of the WHELD intervention**

### **Rationale**

Our work had raised clear questions regarding the potential to build an effective, feasible real-world intervention to manage antipsychotic use and BPSD in care homes.

### **Hypotheses**

Person-centred care plus antipsychotic review will result in the reduction of antipsychotic prescribing

Person-centred care and social interaction will result in reductions in BPSD, particularly agitation and aggression,

Person-centred care and exercise will improve mood

### **Methods**

Full details of the methodology for WP3 are available in Appendix 1 WP3a (<http://www.ncbi.nlm.nih.gov/pubmed/23305152>) and WP3b (<http://dx.doi.org/10.1176/appi.ajp.2015.15010130>) and WP3g (<https://doi.org/10.1002/gps.4572>) <sup>154,155,179</sup>

A nine-month cluster-randomized factorial RCT of the WHELD intervention in 16 care homes. All received person-centred care. Eight were randomly assigned to each of antipsychotic review, social interaction or exercise so that two of the 16 homes had each possible combination of treatments. The eight care homes assigned to each type of intervention (factor) were compared to the eight care homes not assigned to that intervention (factor) to determine the impact of each intervention. A further analysis was undertaken to examine whether there were any additional benefits of receiving more than one type of intervention.

### **Inclusion Criteria**

The participants were people with dementia as defined by the Clinical Dementia Rating<sup>156</sup> (score of 1 or greater) and the Functional Assessment Staging<sup>157</sup> (stage 4 or greater).

### Interventions

#### *Person-centred care*

Person-centred care used tools developed for the Focused Intervention for Training of Staff program<sup>31</sup>. Supplementary materials were drawn from the best available training manuals<sup>35</sup>, augmented by leadership training using principles from our systematic qualitative review<sup>102</sup>

#### *Antipsychotic review*

Antipsychotic prescriptions were reviewed by primary care physicians or psychiatry specialists, based on existing guidance<sup>7, 30</sup>.

#### *Social interaction with pleasant activities*

The objective was to use the evidence-based protocols described in WP2 to provide one hour of social interaction each week through positive planned social interactions for each resident. Personalised activities were developed based on conversation with each resident, their life history information and interests to ensure that the activities and interactions were individually tailored. The aim was to enhance resident interactions with staff, family, and volunteers, delivered through individual or group sessions based on their preferences. <sup>32, 34, 40</sup>.

#### *Exercise*

Exercise was promoted through enjoyable physical activities based on published approaches<sup>38,146</sup>. Assessment of the resident's interests informed a personalized exercise plan developed by the therapist and champion, accounting for health and fitness levels.

### **Outcome Measures**

Primary Outcome Measure: Antipsychotic use, recorded according to British National Formulary classification

Secondary outcome measures:

Depression: Cornell Scale for Depression in Dementia<sup>158</sup>.

Agitation using the 29-item Cohen-Mansfield Agitation Inventory<sup>159</sup>.

BPSD, measured through the 10 domains of the Neuropsychiatric Inventory, care home version<sup>160</sup>.

Health-Related Quality of Life (health-related quality of life), as measured by DeMQoL-proxy<sup>161, 162</sup>

Mortality

Dementia severity as measured by the Clinical Dementia Rating (CDR)<sup>156</sup> and Functional Assessment Staging (FAST) instrument<sup>157</sup>.

All assessments were undertaken based on informant interviews with members of care home staff conducted by trained members of the WHELD research team.

It should be noted that there are some differences between the secondary outcomes reported in the protocol and those highlighted in the narrative of the text and reported in papers. As stated in the protocol mental health (depression, agitation, overall neuropsychiatric symptoms in WP3b, apathy in WP3d). Quality of life was also reported as a secondary outcome (WP3g) in line with the protocol. Physical morbidity was complicated and inconsistently described and we therefore adopted mortality as a secondary outcome as a proxy for severe physical morbidity. Mortality is presented in the text and in the paper WP3b. Other secondary outcomes in the protocol included falls which were also inconsistently reported and therefore we did not feel that they could be reliably included in the report. The coding complexities of recording non-antipsychotic psychotropic medication made it difficult to incorporate a meaningful analysis in the trial report – we have however made these data available to an ongoing NIHR systematic review. One of the original goals was also to examine mediating factors related to the delivery implementation. The large volume of data made this impractical, but it was routinely used to guide supervision and improve the fidelity of intervention delivery. These changes were approved by the trial steering committee.

### ***Power Calculation***

Based on PASS 11 (power analysis and sample size software), sample sizes of 96 in each group gives 82% power to detect a difference between the two proportions of - 0.20. The test statistic used is the two-sided Z test to compare two independent

proportions for a cluster randomised trial where the intra-cluster correlation is assumed to be 0.05. The significance level of the test is 0.05. After adjusting for a drop-out rate of 25%, the sample size required was 128 per arm, or about 16 participants per home. Based upon the effect size (>0.50) seen in the CADRES study, the study was designed to detect an effect size of 0.5 for the other outcomes. A total of 128 patients for each of the group comparisons gives 80% power to detect a treatment difference at a two-sided 0.05 significance level, if the true effect size is 0.5. Cluster randomisation reduces efficiency and leads to loss of power but was essential as the intervention has to be implemented throughout individual care homes. The design effect, otherwise known as the inflation factor (IF), is defined as the ratio of the total number of patients required using cluster randomisation to the number required using individual randomisation. Statistical theory leads to the following formula:  $DE = 1 + [(m - 1) \times r1]$  where  $r1 = s2b / (s2b + s2w)$  called the intraclass correlation coefficient (ICC), where  $s2b$  is the between cluster variance and  $s2w$  is the within cluster variance. ICCs for authentic resident outcome measures (rather than process outcomes) rarely exceed 0.03. An estimated average of 16 eligible participants per cluster leads to an inflation factor of 1.45. Therefore 186 participants were required to give this level of power for each outcome. Given the frailty of the population and the estimated mortality rate a total sample size of 240 was stipulated to allow for mortality and drop-out. This sample size does not give power to correct for multiple testing with respect to the three primary hypotheses.

### ***Statistical Analysis***

Analyses accounted for intervention, baseline demographic and clinical characteristics, and site as covariates and exposure variables. The analysis used multiple linear regression models for continuous outcome measures and logistic regression models for binary outcome measures. [163-165](#).

The primary outcome was an intention-to-treat analysis, with age, gender, and severity of dementia included as covariates.

Although our protocol paper does not document our planned between group analyses it was always the intent to report these analyses. The pre-specified primary outcomes for each comparison antipsychotic review, social interaction, and exercise were

antipsychotic use, agitation, and depression respectively. Of the three comparisons we were in greatest need of statistical power for the antipsychotic outcome. We therefore sought a sample size of 96 per group to show a 20% difference in this outcome with 82% power.

This approach was approved by the trial steering committee. The statistical analysis plan was agreed by the TSC, DMC, and trial statistician prior to datalock. The statistical analysis plan is available at Appendix 2.

## **Results**

### **Factorial RCT**

The main factorial study demonstrated that antipsychotic review significantly reduced antipsychotic use by 50% (odds ratio 0.17, 95% confidence interval [CI] 0.05 to 0.60). Antipsychotic review plus social interaction intervention significantly reduced mortality (odds ratio 0.26, 95% [CI] 0.13 to 0.51) compared with the group receiving neither but the antipsychotic review intervention showed significantly worse outcome in neuropsychiatric symptoms compared with the group receiving neither (score difference +7.37, 95%CI 1.53 to 13.22) This detrimental impact was mitigated by concurrent delivery of the social intervention ( -0.44, CI -4.39 to 3.52). The exercise intervention significantly improved neuropsychiatric symptoms (-3.58, 95%CI -7.08 to -0.09) but not depression ( -1.21, CI -4.35 to 1.93). None of the interventions had a significant impact specifically on agitation. The cohort characteristics and results are described in detail in Appendix 1 WP3b

(<http://dx.doi.org/10.1176/appi.ajp.2015.15010130>) and WP3e

(<https://dx.doi.org/10.1002/gps.4637>).

### Additional Economic analysis

An economic analysis was conducted using baseline data to understand the main cost drivers for people with dementia in care homes. This was an additional output not stated in the hypotheses, and is provided for information in Appendix 1 (paper in Appendix 1 WP3e/<https://doi.org/10.1002/gps.4637>)

## **Discussion**

The WHELD intervention conferred a significant 50% reduction in antipsychotic use, even in a population with a baseline antipsychotic use below 20%. Exercise conferred significant benefits to overall BPSD. In addition, the group receiving antipsychotic review in combination with social interaction had a significant reduction in mortality. Social interaction alone also conferred benefit to health-related quality of life.

The detrimental impact of antipsychotic review on BPSD and health-related quality of life was an important finding, probably explained by the changed landscape of antipsychotic prescribing<sup>25-28</sup>. The antipsychotic review intervention was based on guidance created before the substantial reductions in antipsychotic use over the last five years<sup>30</sup>. While this has achieved significant benefits, it has meant that the severity of BPSD in people who are now receiving antipsychotics is likely to be much higher compared with previously.

The mortality figures also have important implications, particularly since mortality risk has been a key driver in the campaign to reduce antipsychotic use<sup>166</sup>. Although antipsychotic review alone reduced mortality by more than 30%, this became statistically significant only in combination with social interaction.

## **Implications for the WHELD Programme**

WP3 clearly demonstrated the feasibility of the WHELD intervention to reduce antipsychotic use in people with dementia and suggested the potential for benefit in quality of life.

## **Qualitative Analysis: Implementation of psychosocial interventions in care homes**

### **Rationale**

This qualitative analysis collated the opinions of care home staff about the interventions and their view on the most effective means of implementing psychosocial interventions. The aim was to glean practical and theoretical factors that could then be integrated into the WHELD intervention and optimization in WP4.

### **Methods**

Focus group discussions were conducted with care staff prior to the factorial study. Purposive sampling was conducted to obtain the perspectives of staff in a variety of roles with a range of experience and expertise. Focus group discussions were held with eight to 12 members of the care team where possible to explore successful working practices, challenges and priorities within the care home as well as specific attitudes and beliefs surrounding psychosocial interventions and the support that would be required to deliver them. The discussions were recorded and transcribed verbatim; observations and impressions were routinely noted at the end of each group. Transcripts were subjected to thematic analysis through the constant comparison method<sup>167</sup>.

### **Results**

Participants in the focus groups included 53 care assistants (45%), 30 senior care assistants (25%), 13 activity therapists (11%), six registered nurses (6%), five deputy managers (4%), two managers (2%) and 10 other staff (8%). Three key themes emerged: “undervalued and understaffed”; “centrality of relationships” and “existing practices and desire for support”. which are described in detail in Appendix 1 WP3c<sup>168</sup>/<http://dx.doi.org/10.1002/gps.4322>- abstract, link to full AAM in Appendix 1

The work related to the implementation of a specific social activity was published as a separate report<sup>169</sup> (<https://scholarworks.wmich.edu/jssw/vol40/iss4/16>).

## Discussion

The outcomes of the thematic analysis emphasise the importance of acknowledging “whole home” issues such as environmental, care practice and attitudinal factors<sup>31</sup>. A collaborative approach that seeks the views of staff from the outset, provides positive feedback, and does not judge past or present care practices offers an effective method of engagement<sup>170</sup>. The work revealed optimism among staff that the training programme might, firstly, enhance their status among relatives, managers and care commissioners and, secondly, encourage these parties to commit greater resources to delivering psychosocial care.

The review of non-pharmacological interventions conducted in WP2 chimes with the findings of this WP, indicating the critical barrier of limited resources in care homes<sup>171</sup>. The expressed enthusiasm for one-to-one time with residents is a positive outcome that could be fostered to promote person-centred care and job satisfaction<sup>172</sup>. Research elsewhere has indicated that the more staff relate to residents as individuals the less they perceive difficult behaviour as challenging<sup>173</sup>. Training and support interventions need to acknowledge, however, that empathising with residents and becoming involved in their lives can contribute to burnout if not accompanied by appropriate support<sup>174</sup>. Participants cited the value of peer support in this respect. More generally, the importance of teamwork in improving quality of care is well-documented<sup>175</sup>, as is the role of leadership in promoting communication and relationships among staff<sup>176</sup>. Training and support programmes need to recognise the impact of these dynamics and assist managers in promoting information flow among staff, facilitating inclusive discussions about care delivery, incorporating diverse points of view and building positive relationships among all those living and working in the care home<sup>177</sup>. This should extend to family members who were frequently criticised for being unduly critical of staff. <sup>178</sup>.

## **Implications for the WHELD programme**

Qualitative work conducted with care staff clearly highlighted the need to involve the entire staff team in any new intervention in order to have complete 'buy-in', as well as ensuring that trainers fully acknowledge the cultural and resource challenges inherent in care home settings and strive to work with staff to overcome them.

## **Concluding Remarks for WP3**

WP3 was successfully delivered, demonstrating an impact on quality of life, antipsychotic use and mortality with the combination of person-centred care, social interaction and Antipsychotic review. These therefore appeared to be the key components to integrate into a single optimized intervention in WP4.

The qualitative work provides clear insights into the needs for delivery of the intervention to support future implementation. In practical terms this includes effective supervision and support for therapists, enabling 'on-the-job' learning and understanding the drivers for motivation and engagement amongst care home staff.

Based on qualitative feedback from this WP and WP4 (reported in the next section), the decision was made to develop a lower cost champion model for intervention delivery.

## **Major Outputs for WP3**

### **Publications**

Available in Appendix 1

WP3a) Whitaker R, Ballard C, Stafford J, Orrell M, Moniz-Cook E, Woods R, et al. Feasibility study of an optimised person-centred intervention to improve mental health and reduce antipsychotics amongst people with dementia in care homes: study protocol for a randomised controlled trial. *Trials* 2013; 14:13. <http://dx.doi.org/10.1186/1745-6215-14-13>

WP3b) Ballard C, Orrell M, YongZhong S, Moniz-Cook E, Stafford J, Whitaker R, et al. Impact of Antipsychotic Review and Nonpharmacological Intervention on Antipsychotic Use, Neuropsychiatric Symptoms, and Mortality in People with Dementia Living in Nursing Homes: A Factorial Cluster-Randomized Controlled Trial by the Well-Being and Health for People with Dementia (WHELD) Program. *The*

*American journal of psychiatry* 2016; 173:252-62.  
<http://dx.doi.org/10.1176/appi.ajp.2015.15010130>

WP3c) Lawrence V, Fossey J, Ballard C, Ferreira N, Murray J. Helping staff to implement psychosocial interventions in care homes: augmenting existing practices and meeting needs for support. *International journal of geriatric psychiatry* 2016; 31:284-93. <http://dx.doi.org/10.1002/gps.4322>.- abstract, link to full AAM in Appendix 1

WP3d) Rajkumar A, Ballard C, Fossey J, Corbett A, Woods R, Orrell M, et al Apathy and its response to antipsychotic review and non-pharmacological interventions in people with dementia living in nursing homes: WHELD - A factorial cluster randomised controlled trial *JAMDA* 2016; 17(8): 741-747.  
<https://doi.org/10.1016/j.jamda.2016.04.006> - abstract, link to full AAM in Appendix 1

WP3e) Romeo R, Knapp M, Salverda S, Orrell M, Fossey J, Ballard C. The costs of care homes for people with dementia in England: A modelling approach *International journal of geriatric psychiatry* 2016 <https://dx.doi.org/10.1002/gps.4637>

WP3f) Fossey J, Lawrence, V. Staff views on the involvement of animals in care home life: An exploratory study. *J Soc. and Soc. Welfare.* 2013; 4: 305-33.  
<https://scholarworks.wmich.edu/jssw/vol40/iss4/16>

WP3g) Ballard C, Orrell M, Sun Y, Moniz-Cook E, Stafford J, Whitaker R, et al Impact of antipsychotic review and non-pharmacological intervention on health-related quality of life in people with dementia living in care homes: WHELD—a factorial cluster randomised controlled trial. *International Journal of Geriatric Psychiatry.* 2017; 32: 1094-1103 <https://doi.org/10.1002/gps.4572>.- abstract, link to full AAM in Appendix 1

### **Success Indicator**

One of the care homes involved in the factorial study won Care Home of the Year at the National Care awards for the year that the home was involved in the WHELD programme.

# **Improving person-centred care for people with dementia in care homes (NIHR WHELD)**

## **Work Package 4**

### **Evidence-Based and User-Driven Optimisation of the WHELD Intervention for Use in a Real-World Setting**

## **Abstract**

**Objectives:** WP4 sought to optimise the WHELD intervention through a series of review and consultation steps.

**Methods:** (i) Review of the outcomes of WP3 with expert and governance groups, (ii) Review of study materials and their usage with WHELD therapists, and (iii) Focus group discussions with 41 care staff involved in the factorial trial in WP3 to understand their experience of involvement in research and use of the WHELD intervention. The intervention was then refined according to the outputs.

**Results:** A number of key changes were made to the intervention. The optimized intervention consisted of person-centred care and social interaction, with activities elements from the exercise package and a cascade version of the antipsychotic review intervention in which staff prompted GPs for review. The delivery model was adapted for implementation and cost-effectiveness, replacing intensive therapist time with a Champions model. The focus group discussions relating to both the overall research experience and the use of WHELD materials reported a generally positive experience for staff and beneficial aspects of the WP3 package were identified. However, there were issues identified in relation to the extra burden of data collection for research and the perceived pressure of time to deliver the intervention alongside routine care activities.

**Conclusions:** The adaptations of the intervention and protocols ensured that the WHELD programme was fit for full evaluation in WP5.

## **Background and Rationale**

The factorial trial completed in WP3 provided robust, meaningful data regarding the value of the four elements of the WHELD intervention, in addition to critical information regarding the most valuable outcome measures for a full evaluation and the importance of user involvement in intervention development.

This work was completed in the context of a considerable literature and academic consensus that supports the need and rationale for an intervention that draws together the best available interventions to create an optimised, 'real-life' approach that is both effective and feasible for implementation. WP3 provided key evidence of effectiveness, but highlighted the need to optimise the intervention further to ensure it could be feasibly rolled out. A critical factor in this was the need to involve end users in the refinement process. Existing literature consistently reports the need for a collaborative approach that seeks the views of staff from the outset, provides positive feedback, and does not judge past or present care practices offers an effective method of engagement<sup>170</sup>.

Cost-effectiveness is also a critical aspect in the prospective success of any health service intervention, particularly in the care sector where resources are limited and there is considerable competition for commissioning. This aspect was clearly highlighted in the cost function analysis performed in WP3 which indicated the need to integrate meaningful cost-effectiveness measures into large-scale trials, as well as improving needs-based care for people with dementia.

WP4 therefore collated the findings of the programme to date and consisted of a collaborative final optimisation stage to create a final WHELD intervention described in a manual for full evaluation in WP5.

### **Aims & Objectives**

The overall aim of WP4 was to optimise the overall WHELD intervention for full RCT evaluation.

This was achieved through the following objectives:

To conduct a review of the materials used in WP3 and collate learning points for supervisions conducted with WHELD therapists regarding feasibility of intervention delivery

To conduct a consultation with key groups (Programme Management Group, Therapy Development Group) to agree on the requirements for adaptation of the WHELD intervention

To conduct a series of focus group discussions with care staff, with the aim of ensuring a collaborative approach to the intervention optimisation

To adapt the intervention manuals to reflect the approved amendments

## **Methods**

### **Review of use of WHELD intervention materials**

A full review of the WHELD manuals was conducted by a sub-group of the PMG. The review focused on determining where resources could be adapted and combined as a means of streamlining the intervention. This process involved three main steps:

Reviewing feedback from therapists collected during the factorial study in WP3

Collation of notes taken during supervisions with WHELD therapists in WP3

Coordination of an end-of-study meeting with therapists involved in WP3.

### **Consultation with expert groups**

Expert consultation was conducted in two ways. First, a meeting was convened with the Programme Management Group, in which the study statistician presented the statistical outputs from the factorial trial in WP3. The group then discussed the implications for the recruitment strategy and intervention design and made recommendations for refinement. Second, consultations were conducted with selected members of the Therapy Development Group (specifically, Prof Dawn Brooker, Graham Stokes and care home managers). These discussions focused on the most effective way to streamline the intervention to make it deliverable in a real-world setting. The outputs of these consultations were collated and used to inform the intervention optimisation.

### **Focus Group Discussions with care staff**

Six focus group discussions were conducted with 41 care home staff selected from six of the care homes (two from each site) from the factorial trial in WP3. The focus group discussions aimed to explore staff's experiences of being involved in a research trial and which elements of the research and intervention they felt had been successful. The discussions also explored any unhelpful or challenging aspects and any learning points for staff members. Focus group discussions were recorded and transcribed

verbatim; observations and impressions were noted at the end of each group. Inductive thematic analysis was used to identify themes and interpret the data.

### **Intervention Optimisation**

The outputs of the consultation and Focus group discussions were collated by two investigators (CB, JF) and one therapist (LG). This sub-group adapted the existing manuals from each individual intervention element to create the optimised WHELD intervention manual.

## **Results**

### **Review of materials in Work Package 3**

Review of the patterns of usage and therapist feedback regarding the WHELD manuals and resources highlighted key points for adaptation. These were:

The need to emphasise the purpose of the materials to be used as templates for adaptation by individual homes according to their processes and structures. It was felt that homes had not fully appreciated this flexibility in the resources.

Language and terminology in activities derived from the N.E.S.T. manual required further adaptation for a UK audience

A number of N.E.S.T. manual activities had not been used due to perceived cultural differences in the UK settings. These were recommended for removal.

Staff time required to set up and deliver interventions was highlighted as an important factor in the likelihood of the usage of these activities. Time-intensive activities were de-prioritised in favour of less intensive options.

Staff skills in delivering group activities were reported to often be lacking. Improved training and support in developing and applying these skills were therefore prioritised. Peer support and supervision for WHELD therapists was highlighted.

Feedback clearly described the need for a launch event at each care home to ensure buy-in and engagement of all staff, and to promote motivation within the study. Certification of training and involvement was also considered to be a driver for continued engagement.

### **Consultation with expert groups**

The PMG discussion resulted in three main recommendations for optimisation of the WHELD intervention. These were:

To retain the Social Interaction intervention as a key element due to the significant benefit conferred in the factorial study

To include a reduced selection of activities taken from the Exercise intervention as part of the pleasant activities component of the social interaction intervention

To reduce the focus on intensive Antipsychotic Review due to the negative impact on BPSD. The group recommended that all participants be reviewed, but that this be prompted by trained care staff. The group suggested that the active GP education element of the intervention was removed to ensure the intervention was streamlined for a real-world setting.

The consultation with members of the TDG resulted in one main recommendation relating to the implementation and delivery of the intervention. The group agreed that although it provided consistency and support, the delivery model utilised in WP3, in which a therapist provided training and intensive support, was highly resource-intensive and therefore not feasible or cost-effective for a real-world setting. To provide an intervention which required less intensive support from the WHELD therapist, the Dementia Champions role was extended with more emphasis on a 'train the trainer' model with supervision from the therapist. This approach has been increasingly used in practice in recent years and is regarded as cost effective and a means of skill building within services, although published evidence is limited.

## **Focus Groups with care staff**

### *Focus group discussion demographics*

Six focus groups, involving 41 staff, were conducted across six of sixteen care homes within the UK who had participated in a 9-month randomised control trial of psychosocial interventions for people with dementia described in WP3. Participants included 24 care assistants (59 %), 6 senior care assistants (15 %), 5 activity therapists (12 %), 1 registered nurse (2 %), 2 managers (5 %) and 3 housekeeping staff (7 %). They ranged in time spent working at the home from 3 months to 20 years, the median amount of time being 12 staff who had worked in the home for 3-5 years. 41% of staff reported no formal care qualification, 20% had their highest level of National Vocational Qualification (NVQ) at level 2 and 24% at NVQ level 3.

### *Thematic outcomes related to WHELD research aims and process*

The FGD were transcribed verbatim and analysed using thematic analysis. This led to the identification of three key themes relating to the research experience: 'recognising preparedness'; 'working together' and 'learning more than expected'. These are

detailed in the publication in Appendix WP4a <http://dx.doi.org/10.1080/13607863.2018.1525603>. The learning for the research team in relation to optimising the approach and materials for work package 5 is summarised here. The majority of staff felt that the study had value and was a good means of raising the profile of dementia care practice. They reported that it had been valuable to include a range of staff due to differing perceptions of care between staff seniorities and shifts, particularly including both day and night staff. Staff also felt that it had been valuable for the WHELD Therapist to get to know the home in the early phase of the study and be able to respond to their hopes and concerns about the research. Knowing residents' needs was key to being able to implement the ideas, and could be best achieved by care staff themselves. Some of the WHELD materials were identified as being particularly helpful in facilitating staff collecting and recording information about residents. In terms of the process of delivery, FGDs highlighted the benefits of the therapist working alongside dementia champions in the care homes for a sustained period to build trust and confidence in adopting the WHELD approach.

Staff appreciated feedback and positive affirmation of their good practice and had found this motivating in several respects including the development of person-centred protocolled activities. Also in relation to developing skills in team working and educating colleagues, involving resident's families more actively in care planning and in systematically recording information. Families' knowledge was particularly highlighted as valuable in understanding a resident's distress and in helping to resolve challenging situations.

Staff reported some barriers to effective person-centred care. Situations were described in which staff opinions of best practice conflicted with family wishes and their understanding of dementia and staff believed that some families were reluctant to be closely involved with activities. Despite this, instances were also identified where family involvement had been helpful. This theme highlighted a need to provide better operationalisation for family working in the WHELD manual. A second issue in person-centred care was the involvement of volunteers. Conflicting views were held regarding the benefit of additional capacity balanced with the burden of increased administration and support from staff.

The social interaction and exercise interventions were described positively by staff, although time constraints were cited as a considerable barrier, in addition to resident reluctance to take part on occasions. Staff reported that it was therefore very helpful that the goals for recommended activity time were weekly, allowing for flexibility. These were regarded as helpful, realistic and achievable, and staff clearly articulated their understanding of the value of the approach. Several staff also reported that taking part in the activities had been personally rewarding as well as benefitting residents, with identifiable positive emotional and personal impacts.

FGDs were positive about the antipsychotic review intervention, showing an understanding of the importance of judicious antipsychotic use. Staff particularly valued the closer working with GPs and felt that where this collaboration worked well it motivated staff to be more proactive in this aspect of the residents' care.

### **Refinement of intervention protocol**

Two investigators (CB, JF) and a WHELD therapist (LG) optimised the intervention manual to reflect the recommendations from the consultations. This involved combining the individual manuals for person-centred care, social interaction and exercise into one WHELD Therapist Manual. The work also involved the creation of a new WHELD Champions Manual to support the new delivery model.

The newly adapted manuals and associated protocols were circulated and approved by all members of the PMG.

### **Finalisation of RCT protocol**

Based on the evidence in the three review activities, refinements were made for the protocol for the future RCT evaluation of the WHELD intervention and approved by the PMG. These included:

The success of recruiting care homes in WP3 confirmed the feasibility of a 'cold contact' approach to recruitment directly from Care Quality Commission registers.

Recruitment protocols were adapted to use a stepwise approach across geographical areas within each site to be more time and cost effective. A care home demographic

screening questionnaire was included earlier in the recruitment process. Home information was adapted to provide clarity on the time commitment involved for homes. The number of assessment measures were reduced by removing the CANE scale from the protocol. Detailed process monitoring with WHELD therapists in a larger RCT was not feasible. For this reason, a qualitative package was planned in WP5 to capture this information and to reduce burden on the therapists.

## **Discussion & Implications for WHELD Programme**

WP4 drew on consultations with a range of stakeholders who had been involved in WP3 to understand how best to adapt the intervention, delivery model and evaluation protocol. It was important to consider the overall experience of staff in the whole research process in recognition that these elements may have an indirect impact on staff motivation and effectiveness in engaging with the project. This approach proved helpful in triangulating information about which elements had been effective and which required revision, both from a process and content perspective. The resulting adaptations of the intervention and protocols ensured that the WHELD programme was fit for full evaluation in WP5.

### *Limitations*

This work was pragmatic and resulted in an optimised intervention for WP5. However, it would have been helpful to engage with residents and family members directly about their experiences. Unfortunately, due to the nature of the intervention delivery and extent of impairment of residents this was not deemed feasible within the scope of WP3 or WP4.

## **Concluding Remarks for WP4**

This was a largely operational WP, combining consultation with key groups with a period of refinement and optimisation of the WHELD intervention. The process followed by the investigator team resulted in a fit-for-purpose intervention portfolio and trial protocol. This fulfilled the stated objectives of the WP.

Of note, this WP particularly benefitted from user involvement and PPI throughout, ensuring that the various discussions and alterations were directly informed by stakeholder feedback and opinion.

## **Major Outputs for WP4**

### **Publications**

Available in Appendix 1: WP4

WP4a)

Fossey J, Garrod L, Lawrence V, Testad I, Stafford J, Murray J. (2018) “We should see her like part of the team”: An investigation into care home staff’s experiences of being part of an RCT of a complex psychosocial intervention, *Aging and Mental Health*.

DOI:10.1080/13607863.2018.1525603

<http://dx.doi.org/10.1080/13607863.2018.1525603>

### **Optimised WHELD intervention**

Final WHELD intervention manual

Final WHELD Champions manual

**Improving person-centred care for people with dementia in  
care homes (NIHR WHELD)**

**Work Package 5**

**Randomised controlled trial and field testing of the WHELD  
intervention in care homes**

## **Abstract**

**Objectives:** WP5 aimed to establish the effectiveness and cost-effectiveness of the optimised WHELD intervention and to determine factors influencing sustainability for use in UK care homes.

### **Methods:**

This was achieved through i) A large RCT of the optimised intervention compared to usual care; ii) An integrated cost-effectiveness analysis of the optimised intervention; iii) A qualitative analysis of WHELD materials used by WHELD therapists and supervisors to determine to factors associated with successful implementation; and iv) A qualitative analysis with care home staff to determine the sustainability of the WHELD intervention.

### **Results:**

WP5 successfully delivered a robust and rigorous clinical evaluation of the optimised WHELD intervention utilising a champion's model. The intervention conferred a statistically significant improvement in QoL (DEMQOL-Proxy Z score 2.82  $p=0.0042$ , mean difference 2.54 SEM 0.88, 95% CI 0.81, 4.28; Cohen's D effect size 0.24). there were also statistically significant benefits in agitation (CMAI Z score 2.68,  $p=0.0076$ ; mean difference 4.27, SEM 1.59; 95% CI -7.39, -1.15; Cohen's D 0.23) and overall neuropsychiatric symptoms (NPI-NH Z score 3.52,  $p<0.001$ ; mean difference 4.55, SEM 1.28; 95% CI -7.07, -2.02; Cohen's D 0.30) benefits were greatest in people with moderately severe dementia.

### **Conclusions**

These findings suggest that the WHELD intervention confers benefits to QoL, agitation and Neuropsychiatric symptoms, albeit with relatively small effect sizes, as well as cost saving in a model that can readily be implemented into nursing homes.

Future work should consider how to facilitate sustainability of the intervention in these settings.

## **Background and Rationale**

WP5 represents a culmination of extensive evaluation, consultation and optimisation work, leading to an optimised WHELD champion intervention.

### **Aims & Objectives**

WP5 aimed to establish the effectiveness and cost-effectiveness of the optimised WHELD intervention and to determine factors influencing sustainability for use in UK care homes.

This was achieved through the following main objectives:

A large RCT of the optimised intervention compared to usual care

An integrated cost-effectiveness analysis of the optimised intervention. To determine whether the intervention is cost-effective is an important factor in whether commissioners and private payers are likely to pay for the training.

A qualitative analysis of WHELD materials used by WHELD therapists and supervisors to determine to factors associated with successful implementation.

A qualitative analysis with care home staff to determine the sustainability of the WHELD intervention

## **Randomised controlled trial of the optimised WHELD intervention in UK care homes**

The first phase of WP5 was a large-scale multicentre RCT of the optimised WHELD intervention. The full paper is provided in Appendix 1:

WP5b <sup>179</sup>/<https://doi.org/10.1371/journal.pmed.1002500>

### **Aim**

The goal was to evaluate the impact of the WHELD intervention on QoL, agitation, neuropsychiatric symptoms, antipsychotic use, global deterioration, mood, unmet needs, mortality, quality of interactions, pain, and cost in comparison to treatment as usual (TAU).

### **Methods**

#### **Study design**

This study was a nine-month cluster-randomised controlled two-arm trial conducted following CONSORT guidelines in 69 UK care homes. There were three recruiting hubs based in South London, North London, and Buckinghamshire. Each cluster was randomised to receive either the WHELD intervention or TAU for nine months. All residents with dementia (defined as a score of 1 or greater on the Clinical Dementia Rating scale were eligible) Rating assessments were conducted at two time points, baseline (prior to randomization) and after 9 months .Described in Appendix 1 WP5a

<sup>180</sup>/<https://doi.org/10.1186/1745-6215-15-284>

#### **Interventions**

The WHELD intervention focused on training in PCC for care staff, promoting tailored person-centred activities and social interactions and the development of a system for triggering appropriate review of antipsychotic medications by the prescribing physician. The intervention is described in more detail in the paper Appendix 1: WP5b

<sup>179</sup>/<https://doi.org/10.1371/journal.pmed.1002500>

#### **Outcome measures**

The primary outcome was QoL, measured by the DEMQOL-Proxy <sup>181</sup>

The secondary outcome measures included agitation assessed using the Cohen-Mansfield Agitation Inventory (CMAI) <sup>159</sup>. Overall neuropsychiatric symptoms were assessed with the Neuropsychiatric Inventory–Nursing Home Version (NPI-NH) <sup>160,182</sup>. Secondary outcomes also included global severity of dementia (CDR) <sup>156</sup>, mood (Cornell Scale for Depression in Dementia [CSSD])<sup>158</sup>, antipsychotic use, unmet needs (Camberwell Assessment of Need for the Elderly [CANE]) <sup>183</sup>, quality of interactions (Quality of Interactions Scale [QUIS]) <sup>184</sup>, pain (Abbey Pain Scale) <sup>185</sup>, mortality, and cost.

Economic data for each individual in the study were collected using an adapted version of the Client Service Receipt Inventory (CSRI) <sup>186,187</sup>

All assessments were undertaken based on informant interviews with members of care home staff conducted by trained members of the WHELD research team.

### **Randomisation and blinding**

Nursing homes were allocated to receive either the WHELD intervention or TAU using secure web access (NORTH CTU at Bangor University). <sup>188</sup>

### **Sample size**

Previous studies indicated that intra-home correlation coefficients rarely exceed 0.05. Taking this into account, a sample size of 640 participants at 9 months gives 90% power to  $p < 0.05$  to detect a standardised effect size of 0.3 SDs, which is generally accepted as the lowest threshold of a clinically meaningful benefit. The recruitment of a minimum of 840 participants allowed for loss of 200 through mortality or withdrawal.

## **Data analysis**

Outcome measures were assessed at baseline and at nine months. The primary outcome measure (DEMQOL-Proxy) and the secondary outcome measures were analysed using the multilevel modelling approach to ANCOVA, with the value at nine months as the response. The baseline value was the covariate.

Mortality and antipsychotic use were compared between treatment groups using relative risk with 95% CI. QUIS used care-home-level data, and was compared between treatment groups using ANCOVA, but because of the smaller sample size did not use baseline covariates.

Cohen's d is defined as the difference between two means divided by a standard deviation for the data; i.e. the difference in the means of WHELD and TAU divided by their pooled standard deviation.

## **Cost analysis**

Costs were derived from the collection of service use data for the three-month period prior to the intervention (baseline) and the nine months of the intervention (follow-up) and consisted of three main cost categories: intervention costs, accommodation charges, and health and social care costs. Data on each nursing home resident's use of health care (obtained from the CSRI) were multiplied by appropriate unit costs to calculate health and social care costs for each participant at each time point. Mean differences in costs and 95% CIs were obtained by non-parametric bootstrapped regression (1,000 repetitions) modelling to account for non-normal distributions. A multilevel mixed model was used, controlling for baseline costs, site and age at entry into the study. The health economic analysis followed CHEERS guidelines.

## Results

### Cohort characteristics

1,006 participants were consented to the study, with 847 individuals randomised to TAU (n= 443) or WHELD (n=404). Follow-up assessments were available for 553 participants (TAU n=296, WHELD n=257), the majority of whom have moderately severe or severe dementia. Mortality accounted for the majority of participants who did not complete follow-up. Anonymised data is available in an online registry <sup>189</sup>

### Outcomes

The WHELD intervention conferred a statistically significant 2.54-point (SEM 0.88) improvement in QoL compared to TAU (95% CI 0.81, 4.28; Cohen's D 0.24, p=0.0042) as measured by the DEMQOL-Proxy over nine months. WHELD also conferred a statistically significant 4.27-point (Z score 2.68, p = 0.0076; mean difference 4.27, SEM 1.59; 95% CI -7.39, -1.15; Cohen's D 0.23) benefit on the CMAI compared to TAU with respect to agitation and conferred a statistically significant 4.55-point (Z score 3.52, p < 0.001; mean difference 4.55, SEM 1.28; 95% CI -7.07, -2.02; Cohen's D 0.30) benefit on the total NPI-NH compared to TAU. The main results are summarised in Table 1. The full results are described in WP5b

**Table 1 Effect estimates of WHELD intervention in comparison to TAU on key outcome measures (Multiple Imputation Analysis)**

Outcome Measure	Adj. Effect*	p	Mean Difference
DEMQOL-Proxy (n=553)	R=0.12	0.0042	2.54 95% CI 0.81 to 4.28
CMAI (n=553)	R = 0.11	0.0076	4.27 95% CI -7.23 to -1.15

\*Adjusted effect takes into account baseline value, age, sex, CDR, site, and clustering within care homes.

Prescriptions of antipsychotic medications were stable across the study in both treatment groups.( Change in antipsychotic use: WHELD -0.1%, SEM 0.1; TAU -0.2%, SEM 0.1 , p=0.60) There were no statistically significant differences between the WHELD and TAU groups for change in global severity of dementia, unmet needs, pain, mood or mortality. There was a statistically significant 19.7% greater increase in the proportion of positive care interactions from baseline to nine months in the WHELD group compared to the TAU group (SEM 8.94; 95% CI 2.12, 37.16, p = 0.03; Cohen’s D 0.55).

### Adverse events

A total of 549 serious adverse events were recorded during the period of the trial. The events were balanced between the 2 treatment groups, with no statistical differences.

### Cost analysis

The direct cost of delivering the intervention compared to TAU was £8,627 more per home. After adding intervention to social and healthcare costs, the costs per participant receiving the WHELD intervention were £4740 less than the cost of those receiving usual care over the 9 months of the study.

**Table 2 Unadjusted mean costs and mean cost differences at baseline and over nine months (British pounds, 2014–2015).<sup>1</sup>**

Cost category	Intervention		TAU		Intervention versus TAU*	
	Mean (£)	SD (£)	Mean (£)	SD (£)	Unadjusted mean difference (£)	95% CI
<b>WHELD intervention</b>	2,713	121	0	—	2,713	2,701 to 2,724
<b>Baseline (n = 887)</b>						

<sup>1</sup> Reproduced from Ballard et al 2018 (PLOS Medicine) 179

Accommodation charges	9,480	2,010	10,233	3,675	-753	-1,128 to -365
Hospital	387	1,759	407	2,413	-20	283 to 242
Primary care	96	126	98	148	-2	19 to 14
Community health	23	80	19	79	4	-7 to 14
Emergency	12	37	9	34	3	-1 to 7
Total health and social care costs	9,998	2,601	10,766	4,396	-768	-1,249 to -338
<b>9-month follow-up (n = 553)</b>						
Accommodation charges	28,606	10,863	33,005	12,428	-4,399	-5,725 to -2,898
Hospital	269	1,166	262	1,267	7	-183 to 188
Primary care	700	294	1,020	301	-320	-364 to -277
Community health	78	260	70	206	8	-23 to 44
Emergency	49	133	85	244	-36	-68 to -10
Total health and social care costs	29,702	8,774	34,442	11,106	-4,740	-6,129 to -3,156

In the participants with CMAI > 40 the relative treatment effect for health-related quality of life (DEMOL-proxy) increased at the 5% level (1.96; CI, 0.42 to 3.39) and the benefit on the CMAI scale improved by greater than a point compared to base-case (3.72; 95% CI, 1.28 to 6.51). However, the difference in costs was around £400 less than in the ordinary least squares model with a part of the bootstrapped confidence interval stretching to the positive part of the number line. The health economic analysis is presented in more detail in Appendix 1

WP5e. <https://www.sciencedirect.com/science/article/abs/pii/S1552526018335192> - abstract, link to full AAM in Appendix 1.

## Discussion

The WHELD intervention conferred a statistically significant improvement in QoL over nine months. There was also a statistically significant benefit regarding agitation and overall neuropsychiatric symptoms and a significant increase in the proportion of

positive care interactions between care staff and residents with dementia. Importantly, the benefits were achieved in the context of a cost saving with a model that can readily be implemented in nursing homes.

Although comparable to atypical antipsychotics the standardized effects sizes of benefit are modest in the context of a clinical intervention. The benefits do however also include improvements in quality of life, which have not been shown with pharmacological interventions or other person centred care interventions. Although there is no established threshold for a clinically meaningful benefit in quality of life or quality of care, any statistically significant benefit is important given the lack of any benefit in previous RCTs. In addition, the intervention was not just delivered to a people with clinically significant neuropsychiatric symptom, but conferred benefit amongst the broader population of people with dementia living in care homes, and could therefore be considered as a health and wellbeing intervention rather than a clinical intervention per se. Whilst the effect size would be considered marginal in terms of a clinically significant benefit, we do therefore believe that the benefits to the broader population of people with dementia in care homes make this a meaningful benefit in the quality of care. [The benefits were also smaller than hypothesized.](#)

Agitation is a frequent and distressing symptom for people with dementia <sup>14,190</sup>. The findings are favourable when compared to trials of antipsychotic medications, which show only very modest benefits over 12 weeks in the treatment of agitation in the context of significant harms <sup>13,18</sup>. Our results compare favourably to the small number of previous studies focussing on PCC, where benefits in agitation are inconsistent and none of which have reported benefits in QoL <sup>31,33</sup>. In addition, this study shows cost advantages over usual care, which has not been demonstrated with any previous drug or non-drug intervention.

Recent studies have begun to suggest that other pharmacological therapies such as citalopram<sup>191</sup> and dextromethorphan<sup>192</sup> may confer benefit for the treatment of agitation, but further studies are needed.

Elements of the WHELD intervention, such as social interaction and pleasant events, have previously been demonstrated to improve agitation in modest-sized RCTs <sup>193,194</sup>.

Incorporating them within a coherent framework such as WHELD enables straightforward and affordable implementation.

In contrast to our previous factorial RCT of the WHELD intervention, no significant reduction in antipsychotics was achieved. This is likely attributable to a combination of low baseline antipsychotic prescriptions and the more limited education programme for primary care physicians. It should also be noted that the Intra-Cluster Correlation Coefficients (ICCs) were higher than the 0.03 identified from previous studies, which may have limited statistical power. Other limitations include the challenges of measuring quality of life for people with moderately severe and severe dementia and the potential challenges of data analysis in the context of a frail group of individuals with high mortality rates.

Pain was a pre-specified secondary outcome for the WP5 WHELD RCT. As several members of our research group were particularly interested in pain in people with dementia, which we consider to be a key factor for health and well-being, we made these data available for a more detailed evaluation. An added value to the outputs from the programme, this led to a secondary paper focussed on pain experienced by people with dementia. The baseline prevalence of pain was 35.3% amongst residents with dementia. Pain severity was significantly correlated with dementia severity, neuropsychiatric symptoms, depression, agitation, and quality of life at baseline and nine months. Regular treatment with analgesics was associated with reduced pain severity. Pain was significantly associated with more antipsychotic prescriptions and with all-cause mortality during follow-up (OR 1.48; 95% CI 1.18e1.85). The full paper is shown in Appendix 1: WP5c/<https://doi.org/10.1016/j.jamda.2017.01.024> abstract, link to full AAM in Appendix 1

## **Field-testing and implementation of the WHELD intervention in UK care homes**

### **Aims & Objectives**

This evaluation gathered information on the experiences of the WHELD therapists and supervisors at the end of the intervention period, and from care home staff after a period of nine to 12 months following study completion.

### **Methods**

Focus group discussions were conducted with the 12 members of the therapy team who had delivered or supported the intervention in the WP5 RCT to explore the therapist and supervisor experiences of delivering the intervention. The detailed findings are reported in the paper in Appendix 1

WP5d <https://doi.org/10.1177%2F1471301218772178>. abstract, link to full AAM in Appendix 1

### **Results**

#### *WHELD therapist focus group discussions*

#### Feedback on therapist training and supervision

The therapists reported that they had received comprehensive training and that the content of the interventions and expectations of how they would be delivered was clear.

The participants highlighted areas that they felt required particular support. This included ensuring they had the skills needed to train Dementia Champions. They particularly supported the use of experiential exercises for successful learning. Therapists felt that development of their coaching skills during supervision were particularly valuable, as well as ensuring the promotion of a multicultural attitude and awareness of differences in language and needs amongst staff. The importance of

ongoing supervision within the homes and for the WHELD therapists themselves was also seen as an essential feature.

#### Developing relationships with care homes and staff

Therapists strongly articulated the importance of establishing a good working relationship with care homes managers and staff early in the study. This required a genuine interest in the care team as individuals to build relationships and support the Dementia Champions. All therapists acknowledged that a flexible approach was imperative. Some therapists felt that on occasion they felt they were adding pressures on staff trying to find a balance between fidelity to the intervention and other work duties.

#### Optimising success of the Champion role

There was a strong consensus advocating self-selection of Dementia Champions over nomination into the role. Multiple Champions in each home was also strongly supported as this provided peer support and built complementary skills. Buy-in from the home manager was a critical driver for success, enabling staff to dedicate time to the role. The therapists perceived that many Dementia Champions enjoyed the role and felt empowered in promoting activities and ideas with residents. For many Dementia Champions reflecting on their practice was a new and appreciated way of working.

Therapists spoke positively about the impact of WHELD on care home residents. They spoke with enthusiasm about the many individualised activities which care home staff enabled and how staff became creative in responding to people with diverse needs.

#### *Focus group discussions with care home staff*

Care homes receiving the WHELD intervention were invited to take part in focus groups 9 to 12 months after the intervention had concluded. The results are reported in detail in Appendix 1 WP5f. <https://onlinelibrary.wiley.com/doi/pdf/10.1002/gps.5066>

#### Demographics

In total 47 care home staff participated in the focus groups. Almost half of participants were carers or senior carers, three were nurses (6%), six activity co-ordinators (13%), three managers (6%), six assistant managers (13%) and six traditionally non-direct care roles, (13%). 32% of focus group participants had been WHELD Dementia Champions during WP5. The remaining participants started work in the home after the intervention had finished.

#### Value of the WHELD programme

The first theme emerging related to staff recognising the value of the research for different groups of people. They described benefits in the way they recognised the individual and interpersonal needs of residents and acknowledged that some of the methods allowed them to get to know residents better. Leading to positive responses from residents which were rewarding for staff. Staff also saw value for themselves in forming relationships within the team and enhancing their ability to provide care. During the study some homes had adapted the organisational routines and found this helpful in developing a team approach to sharing person-centred care principles with the wider staff group. Many homes felt that participating in WHELD had also changed their perspective on working with families.

#### Skills development in care staff – “Being well practiced”

The second theme related to the skills staff felt they developed. All homes felt that the person-centred philosophy was a feature that had endured following the research. A notable element in achieving this was the development of empathy and being able to identify more closely with residents. Experiential learning exercises, run by dementia champions with their colleagues, were particularly helpful. WHELD also helped develop new communication skills and better abilities to tailor their approach to individuals. This sustained change in perception that activities could be done “any time” and incorporated into physical care tasks through the use of conversations and short individual activities was particularly beneficial.

#### Sustainable practice – “Taking ownership”

The third theme that emerged was being able to adopt the “WHELD” approach as the “homes own”. Where there was a strong local leadership from managers and peers to develop creative ways of working with residents, then homes found ways to continue

with the approach and ensure that the underlying philosophy and valued practice was not lost.

#### Perspective on research involvement

The staff generally held a positive view of research and a sense of pride at having contributed to a major study.

#### **Discussion**

Discussion with care home staff represented a unique opportunity to explore their perceptions of the long-term impacts of WHELD and the factors influencing sustainability. The focus group discussions highlight that the ethos of person-centred care and associated approaches can be embedded and that a number of the WHELD materials continue to be used after study involvement has ceased.

## **Concluding Remarks from WP5**

WP5 successfully delivered a robust and rigorous clinical evaluation of the optimised WHELD intervention utilising a champion's model. Significant benefits were seen in the treatment of agitation, overall scores of neuropsychiatric symptoms and significant health-related quality of life benefits were seen in individuals with agitation compared to treatment as usual.

There are also economic benefits from a low resource multi-component intervention aimed at people with dementia living in a care home setting.

Feedback from therapists and staff involved in the trial also confirmed a positive and empowering experience.

## **Major Outputs from WP5**

### **Published papers**

Available in Appendix 1.

WP5a) Whitaker R, Fossey J, Ballard C, Orrell M, Moniz-Cook E, Woods RT, et al. Improving Well-being and Health for People with Dementia (WHELD): study protocol for a randomised controlled trial. *Trials* 2014; 15:284. <http://dx.doi.org/10.1186/1745-6215-15-284>

WP5b) Ballard C, Corbett A, Orrell M, Williams, G., Moniz-Cook E, Romeo R, et al. Impact of person-centred care training and person-centred activities on quality of life, agitation and antipsychotic use in people with dementia living in nursing homes: A cluster-randomized controlled trial of the WHELD intervention. *PLoS Med* 15(2): e1002500. <https://doi.org/10.1371/journal.pmed.1002500>

WP5c) Rajkumar A, Ballard C., Fossey J, Orrell M, Moniz-Cook E, Woods R., et al. Epidemiology of Pain in People With Dementia Living in Care Homes: Longitudinal

Course, Prevalence, and Treatment Implications. *JAMDA*; 2017 18:453.e1-453.e6.  
<https://doi.org/10.1016/j.jamda.2017.01.024>- abstract, link to full AAM in Appendix 1

WP5d) Fossey J, Garrod L, Garcia A, Testad I. A qualitative analysis of trainer/coach experiences of changing care home practice in the Well-being and Health in Dementia (WHELD) randomised control trial, *Dementia* 2018  
<https://doi.org/10.1177/1471301218772178> - abstract, link to full AAM in Appendix 1

WP5e) Romeo R, Zala, D, Knapp M, Orrell M, Fossey J, Ballard, C. Improving the quality of life of care home residents with dementia: Cost effectiveness of an optimised intervention for residents with clinically significant agitation in dementia. *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*; 2019 15(2): 282-291  
<https://www.sciencedirect.com/science/article/abs/pii/S1552526018335192> - abstract, link to full AAM in Appendix 1

WP5f) Fossey J, Garrod L, Tolbol Froiland C, Ballard C, Lawrence V, Testad I. What influences the sustainability of an effective psychosocial intervention for people with dementia living in care homes? A 9 month follow- up of the perceptions of staff in care homes involved in the WHELD Randomised Controlled Trial. *International Journal of Geriatric Psychiatry*; 2019 34:674-682.  
<https://onlinelibrary.wiley.com/doi/pdf/10.1002/gps.5066>

**Improving person-centred care for people with dementia in  
care homes (NIHR WHELD)**

**Work Package 6**

**Dissemination of the study outcomes and impacts**

## **Abstract**

### **Objectives:**

WP6 sought to effectively disseminate the findings of the programme in order to impact on practice and maximise the output of the research.

### **Methods:**

A dedicated dissemination phase involved a series of tailored activities to maximise the impact of the WHELD programme. Work included academic publication and presentations, outreach to GPs, updating of national best practice guidelines and additional events for care homes.

### **Results:**

Dissemination activities were successfully completed. Key activities included regional workshops for GPs which received excellent feedback and response, and the creation of an e-learning module for GPs with the British Medical Journal Learning portal. The national guidelines on BPSD management were updated and endorsed by NHS England. Additional events and workshops were held with care home staff, and investigators presented the findings at numerous national and international conferences. All findings were prepared for publication in peer-reviewed journals.

### **Conclusions:**

WP6 constituted an integrated, broad approach to ensuring the outputs of the WHELD programme were effectively communicated in a targeted manner. WP6 exemplifies the success of the WHELD programme and highlights the importance of the key findings from the clinical evaluations conducted throughout the study. Involvement of key healthcare professionals, particularly GPs and care home staff was purposely selected to ensure that the learning from the programme informs future practice in a meaningful way.

## **Background & Rationale**

The WHELD programme consisted of a series of high quality research elements that sought to understand the UK care home landscape, develop and optimise a complex care intervention, evaluate it in a real-world environment and fully understand its implications for care home residents and staff. Ultimately the aim of this programme was to improve care provided to people with dementia, with a focus on improving management of BPSD, increase quality of life and promote the judicious use of antipsychotic medications.

Dissemination activity is an integral aspect of a successful research programme, and an essential step in ensuring that research informs improvements to clinical and care practice. There was therefore a need to dedicate time and resource to the final adaptations of the intervention, inform peripheral resources to support ongoing implementation and move towards the roll-out of WHELD as an intervention.

### **Aims & Objectives**

WP6 aimed to maximise the impact and success of the WHELD programme through a dedicated dissemination package. This was achieved through the following specific objectives:

Academic publication of the findings collated throughout the WHELD programme

Populate a dedicated website to promote the WHELD outcomes

Delivery of workshops to GPs across the UK to disseminate the findings

Update of the national BPSD management guidance resource, in partnership with NHS England

Creation of an e-learning module for GPs in partnership with the British Medical Journal (BMJ)

Seek additional opportunities for presentations and workshops to target audiences

Disseminate findings to care home audiences through events and tailored communications

Seek opportunities for further funding to promote implementation of the WHELD intervention

## **Dissemination Activity**

### **Publications**

The outputs from each WP in the WHELD programme have been successfully published, with some additional publications in writing or in press at the time of publication of the final report. A full list of publications is available in Appendix 1.

### **WHELD Study Website**

A succinct online presence was created for the WHELD study to provide information about the study and its impacts. The site is hosted by Oxford Health NHS Foundation Trust at <http://www.oxfordhealth.nhs.uk/research/making-a-difference/improving-wellbeing-and-health-for-people-with-dementia-wheld/>

The website does not aim to provide detailed information about the study. Instead, it is tailored to an online audience, providing snapshots of impacts and YouTube video footage of care home staff describing their experience of the study. There are also plans to produce additional pieces of footage in the future as part of an ongoing resource to support training.

### **GP Learning Workshops: Optimising the use of Antipsychotic Medication and Non-Pharmacological Treatment for People with Dementia**

A major dissemination activity for WP6 was a series of GP workshops that ran across the UK in November 2015 to January 2016. The GP training resources used in the factorial study in WP3 were accredited and used as the basis for these events. The four-hour workshops were held in York, Exeter, Bicester (Oxfordshire), Manchester and London. In addition to information provision, workshops were delivered with additional time for GPs to explore how they could implement best practice in antipsychotic prescribing and support care home staff to adopt non-pharmacological approaches in response to BPSD. All the workshops were facilitated by a core group

from the WHELD team, with other members of the project team and local figureheads supporting individual workshops in each locality.

Feedback from the 118 attendees at the GP workshops was overwhelmingly positive, with all members rating their learning as 'Very Effective' or 'Effective', and stating that the event had met their learning objectives. Testimonial statements from attendees included the following:

*"I was surprised to discover that antipsychotics are not very effective and glad to discover that social interaction has evidence to support its recommendation"*

*"I obtained more information on antipsychotic medication use in people with dementia"*

*"Understood the risks around prescribing antipsychotic medication. Makes complete sense to use a person centred approach"*

*"Became aware of non-pharmacological methods of managing behavioural problems in dementia"*

*"Excellent, very interesting and relevant afternoon"*

*"Definitely think harder about risks and harm of prescribing drugs and benefits of not"*

This programme has now been accredited by the Royal College of General Practitioners for further training workshops.

### **Creation of BMJ e-learning Module for GPs**

Outreach to primary care and eliciting change in these settings is known to be challenging due to the competing priorities GPs experience in their role. In order to increase the reach of the learning for GPs, inform judicious antipsychotic use and promote the use of non-drug treatment approaches, an online resource for GPs was

also created. An E-learning module was created in partnership with the BMJ which collated the key clinical messages arising from the WHELD programme.

The e-learning module was created through the following steps:

Initial discussion between BMJ authors and investigators (AC, CB, JF) to establish format and timelines for delivery

Creation of 12 learning objectives. Objectives were designed to have a practical focus with relevance to commonly encountered situations in clinical practice

Joint working between BMJ writing team and investigators to create 12 scenarios, based on the learning objectives. Each scenario included four possible outcomes, with one correct answer, two partially correct and one incorrect answer. Each answer given was accompanied by further information to support understanding.

Final version of the module created by the BMJ and approved by the investigator team (CB, JF, AC).

The WHELD E-learning module has now been launched as part of the BMJ portfolio of online healthcare education materials, BMJ Learning. [Sign Up Form - Dementia Assessment Module](#)

### **Update of Best Practice Guidance for Management of BPSD**

A core element of the antipsychotic review component of the WHELD intervention was derived from an existing best practice guide published by Department of Health and Alzheimer's Society in 2012<sup>30</sup>. Authorship of the original version of the guide involved several of the WHELD investigators and it has become widely used in the UK and worldwide. The outcomes of the WHELD programme, in addition to newly published evidence from related studies, resulted in the existing guide becoming outdated.

A key dissemination activity was therefore to produce an updated version of the best practice guide as a means of promoting evidence-based practice in addition to

disseminating the outcomes of the WHELD programme. This process involved the following steps:

Review of existing manual by the three leading authors (CB, AC, Prof Alistair Burns)  
Involvement in a Delphi Consensus Meeting led by the International Psychogeriatrics Association in 2015 which discussed recent evidence pertaining to BPSD management and antipsychotic use

Collation of the relevant WHELD outcomes with the Delphi outcomes

Creation of detailed changes to the content and format of the best practice guide

Liaison with a professional designer to adapt the guide

Approval of the updated guide by all related authors.

The guide is endorsed by NHS England (primary endorser), Alzheimer's Society and the Royal Colleges and is available on

<http://medicine.exeter.ac.uk/apex/research/primarycarementalhealth/projects/dementia/>

### **Additional outreach activities**

The WHELD investigator team has also contributed to a number of events, presentations and publicity opportunities as part of WP6 and developed some further research. These **are detailed in Appendix 2**

### **Concluding Remarks from WP6**

WP6 constituted an integrated, broad approach to ensuring the outputs of the WHELD programme were effectively communicated in a targeted manner. WP6 exemplifies the success of the WHELD programme and highlights the importance of the key findings from the clinical evaluations conducted throughout the study.

Furthermore, the involvement of key healthcare professionals, particularly GPs and care home staff was purposely selected to ensure that the learning from the programme informs future practice in a meaningful way.

# **Improving person-centred care for people with dementia in care homes (NIHR WHELD)**

## **Overall Summary and Discussion**

## **Patient and Public Involvement in the WHELD Programme- Discussion and reflections on the programme by our PPI co- investigator**

**Contributed by Barbara Woodward-Carlton (Lay Co-Investigator)**

I was very pleased to be invited to be part of the WHELD Project funded by NIHR some six years ago. I can remember saying to Clive Ballard “Do you really think I can do this?” After this length of time I can say, sincerely, it has been gratifying to have an involvement in this research. I had worked with the lead researchers as a Research Network Volunteer, Alzheimer’s Society, on the Focussed Intervention for Training of Staff project which had demonstrated that, beyond doubt, quality of life could be greatly improved for people with dementia in care homes by implementing the evidenced based findings of that project.

The WHELD research which followed on from that project has made a huge difference to the lives of those with dementia in care homes. The WHELD Therapist and Dementia Champions Manuals are models of thoroughness based as they are on person centred care enabling successful psychosocial interventions in care homes. The training for the therapists and other members of staff enables knowledge to be translated into practice and the enhancement of skills.

To deliver *planned personalised interaction* to residents involving staff, families, and volunteers necessitates training. The resources provided are truly comprehensive and if properly used in care homes transform the lives of both those with dementia and those who care for them and so give a greatly enhanced quality of life to both groups.

I am totally convinced of the value of this research, the results are simply stunning. I hope it can be successfully implemented in care homes across the UK and even beyond. As someone who has been involved in PPI for many years now, knowing that such interventions can make a huge difference to lives of those with dementia, it is my fervent hope that these findings will be adopted throughout the care system. It has been my pleasure to have had an involvement with such a group of talented, caring

researchers who are so committed to making life better for those with dementia. It would be such a waste of money, expertise and time if such planned personalised interactions did not become compulsory in all care homes.

Additional public and patient involvement is summarized in the table below reported in line with the GRIPP2 framework<sup>195</sup>

**Table 3: WHELD Programme PPI Reporting (GRIPP2)**

Section & Topic	Item	Reported on page No.
Aim	The aim was to integrate PPI in a meaningful way in the WHELD programme, focusing on the views, experiences and perspectives of people affected by dementia and people who support them in care homes.	61
Methods	PPI in the WHELD study involved:	61
	A lay representative (Barbara Woodward-Carlton) as a full member of the Programme Management Group	122-3
	Lay representation on the Therapy Development Group, which led the design and development of the WHELD intervention	61-65
	TDG & Focus groups with care staff in WP4 to discuss experience of research and contribute to development of the optimised WHELD intervention	84,88 88
	Lay representation on specialist groups involved in the consultation phase in WP4 which optimised the WHELD intervention	84
	Partnership with Alzheimer’s Society to inform PPI and Dissemination strategies	88
		122-3

Study Results	<p>Outputs relating to PPI in the WHELD programme were:</p> <p>Co-investigator Woodward-Carlton was fully involved and embedded in the WHELD management process and contributed to management, development and intervention discussions and dissemination</p> <p>Sharing events involving care home staff to highlight study achievements held after WP3 and WP5</p> <p>A care home manager participated in ENRICH project to provide lay information for other care homes considering research involvement  <a href="https://enrich.nihr.ac.uk/files/Case%20Studies/cs-01-A_care_home_perspective.pdf">https://enrich.nihr.ac.uk/files/Case%20Studies/cs-01-A_care_home_perspective.pdf</a></p> <p>Staff reflections about the study available at  <a href="http://www.oxfordhealth.nhs.uk/research/making-a-difference/improving-wellbeing-and-health-for-people-with-dementia-wheld/">http://www.oxfordhealth.nhs.uk/research/making-a-difference/improving-wellbeing-and-health-for-people-with-dementia-wheld/</a></p>	<p>88</p> <p>122-3</p> <p>Appendix 2</p> <p>Appendix 2</p> <p>Appendix 2</p> <p>Appendix 2</p>
Discussion & Conclusions	<p>The PPI activity involved some family carers and predominantly people working in care homes, who contributed their perspectives on both the overall research process and advice on the development of the research intervention. These participants had the most relevant experience related to delivering the intervention and so their views were prioritised. Their contribution shaped the overall project development, shared between participating centres and has also been documented through ENRICH to enhance learning more widely.</p>	<p>107</p> <p>Appendix 2</p>

Reflections / critical perspective	Stakeholder views were sought for each work package and dissemination in the project and have contributed to the overall results Advice was not sought directly from people with dementia living in care homes as part of the process and could have been a valuable addition to the PPI process. Many care home residents have advanced communication difficulties and engaging them in the process would require creative and adapted strategies. Our reflections on this have led to the development of a project to improve communication with people with these needs, which is being led by the University of Exeter.	122-3 Appendix 2 92
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### **Investigator Team Discussion and Reflections on the WHELD programme**

The WHELD programme built upon a series of systematic reviews to design and optimize a person-centred care training package by augmenting person centred care with personalized pleasant activities/social interaction, exercise and antipsychotic review. This was evaluated in a factorial RCT demonstrating tangible added benefits, including improvements in quality of life and reduced mortality as well as a reduction in antipsychotic use. Further optimization of the intervention developed a training approach that used a champion model to make the programme more pragmatic – an essential component for successful implementation. The definitive RCT of the WHELD champion intervention conducted in WP5 highlighted significant benefits in quality of life and neuropsychiatric symptoms (including agitation) for people with dementia, at a lower cost than usual care. This provides an evidence-based platform to enable effective implementation in care home settings for people with dementia.

Although the programme had a number of methodological strengths, there were also limitations. The qualitative work undertaken to inform the optimization of the intervention was focussed largely on the participating staff who were responsible for delivering the intervention, but we recognise that residents with dementia who received the intervention delivered by the staff were not included in the qualitative studies and could provide a valuable perspective. In designing the study, we carefully considered the challenges of measuring quality of life in people with moderate- severe dementia and therefore relied predominantly on a proxy measure. In addition, we opted for a treatment as usual control in work package 5 due to the scale of the study (69 care homes), but this may have inflated the magnitude of observed benefits.

The intervention in WP5 was optimized not just for efficacy, to also to design an intervention that was more suitable for practical implementation in real world settings. However, as part of the adaptation of the intervention there was a less proactive approach to GP education as part of antipsychotic review and the modified WHELD intervention did not achieve an overall reduction in antipsychotic use in this RCT. The GP intervention has however been developed as a British Medical Journal educational module, and in practice it should therefore be possible to implement the WHELD intervention directly in care homes and promote the GP educational component in parallel.

A key question is whether the benefits are meaningful. The standardised effect sizes of benefit for WHELD were small in the context of a clinical intervention (Cohen's D standardized effect sizes 0.23-0.3). However, the benefits included improvements in QoL, which have not been demonstrated with other pharmacological or non-pharmacological treatments. The benefit in QoL was modest but is important given the absence of any benefit in previous studies. The findings are particularly favourable when compared with those of trials of antipsychotic medications which show only modest benefits in treating agitation over 12 weeks and with the potential of significant harms.

## **Discussion of implications for practice**

Firstly, with regard to antipsychotic use, the clinical trials in the programme provide evidence that advocates the continued judicious prescribing of antipsychotics that follows the changing landscape of their use in the UK and worldwide. Given the findings related to antipsychotic review, prescribers should balance the potential impacts of antipsychotic withdrawal and carefully balance the harm to benefit ratio associated with antipsychotics.

Secondly, the programme has clearly demonstrated the value of social interaction and individualised pleasant activities in the treatment and care of people with dementia. Clinicians and care staff should consider these approaches as part of usual care.

Finally, the qualitative work conducted in this programme has highlighted opportunities and challenges in implementation of psychosocial approaches in care homes.

## **Recommendations for future research**

The WHELD investigator team would like to make recommendations for future research in this field.

Firstly, there is a need to examine the sustainability of the WHELD intervention in care homes. The programme has demonstrated effectiveness over nine months, and this raises the question of whether this impact would be translated to longer-term effects for residents.

Future research might also examine cost effective models of delivery to achieve sustained benefit. A pilot is underway to develop an e-learning version of the WHELD intervention, and it will be important to evaluate the effectiveness of this approach for care staff and its impact on residents.

An interesting secondary outcome from the RCT in WP5 was the significant impact of the intervention on pain in people with significant pain at baseline. Pain is a major health concern in people with dementia, and is a common underlying factor in BPSD. It will therefore be interesting to consider the effectiveness of training and tailored non-drug interventions on this key clinical factor.

## **Acknowledgements**

### Contribution of Authors

Professor Clive Ballard is Professor of Age-Related Diseases at The University of Exeter. He is the Chief Investigator for this programme and a member of the TDG and PMG. Professor Martin Orrell is the Director of the Institute of Mental Health at the University of Nottingham. He co-led WP2 and was a centre lead for the RCT in WP5. He was a member of the TDG and PMG. Professor Esme Moniz-Cook is Professor of Clinical Psychology at the University of Hull. She co-led WP2 and the TDG, and was centre lead for the RCT in WP5. She was a member of the PMG. Professor Bob Woods is Director of Dementia Service Development Centre. He chaired the PMG. Dr Rhiannon Whitaker was a Senior Statistician at Bangor University and is CEO of Whitaker Research Ltd. She led the statistics and statistical design of the programme, and was a member of the PMG. Dr Anne Corbett is Senior Lecturer in Dementia Research at the University of Exeter. She led WP6. Professor Dag Aarsland is a Chair of Old Age Psychiatry at King's College London. He led work in WP1 and was a member of the TDG and PMG. Dr Joanna Murray is Senior Lecturer in Qualitative Research at King's College London. She led the qualitative research analysis in WP3 and was a member of the PMG. Dr Vanessa Lawrence is Lecturer in Qualitative Research at King's College London. She led the qualitative research work in WP2 and co-led WP3. Dr Ingelin Testad is Director of SESAM at Stavanger University and Professor of Nursing at the University of Exeter. She led recruitment to the RCTs in WP3 and WP5. Professor Martin Knapp is Professor of Social Policy at the London School of Economics. He led the health economics in WP3 and WP4 and was a member of the PMG. Dr Renee Romeo is Senior Lecturer in Health Economics at King's College London. She managed the health economics analyses for data arising from WP3 and WP5. Dr Darshan Zala is a Research Associate at King's College London. He supported health economics data analysis from WP3 and WP5. Jane Stafford was the programme manager for WHELD. Dr Zoe Hoare is a Senior Statistician at N.WORTH in the University of Bangor. She supported statistical analysis for WP5. Lucy Garrod is a Research Therapist at Oxford Health NHS Foundation Trust and was a WHELD therapist in WP3 and therapy supervisor in WP5 and contributed to the qualitative evaluation in WP5. Dr Yongzhong Sun is a statistician at N.WORTH at Bangor University. He performed statistical analysis for WP3 and WP5. Dr Eddie

McLaughlin is Director of Adult Mental Health Services at Oxford Health NHS Foundation Trust. He was the NHS Manager for the programme. Mrs Barbara Woodward-Carlton is a Research Network Volunteer at Alzheimer's Society and a former carer of a person with dementia. She provided a lay perspective throughout the programme. Dr Jane Fossey is Associate Director of Psychological Services at Oxford Health NHS Foundation Trust. She led one of the systematic reviews in WP1, led WP3 and the qualitative work in WP5 and co-led WP2 and WP4, supervised the programme manager, provided NHS management and was a member of the TDG and PMG.

### **Data Sharing Statement**

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review and appropriate agreements being in place. Data from the RCT described in WP5 is in the Dryad repository: <https://datadryad.org/resource/doi:10.5061/dryad.75373>

The authors will be happy to discuss potential collaborations regarding other data, and will make anonymised data available on that basis.

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## Appendix 1:

### Publications arising from the WHELD programme

(Publications are results papers unless expressly referred to as protocols)

Work Package	Publication	Status at time of report submission (November 2019)
WP1a	<p>Testad I, Corbett A, Aarsland D, Lexow K, Fossey J, Woods B, <i>et al.</i> The value of personalized psychosocial interventions to address behavioural and psychological symptoms in people with dementia living in care home settings: a systematic review. <i>International psychogeriatrics / IPA</i> 2014;26:1083-98.  <a href="http://dx.doi.org/10.1017/S1041610214000131">http://dx.doi.org/10.1017/S1041610214000131</a>            COPYRIGHT: © International Psychogeriatric Association 2014</p>	Published
	<p><i>Author Approved Manuscript (Green Open Access) available on University of Exeter repository at:</i>  <a href="http://hdl.handle.net/10871/39578">http://hdl.handle.net/10871/39578</a></p>	
WP1b	<p>Fossey J, Masson S, Stafford J, Lawrence V, Corbett A, Ballard C. The disconnect between evidence and practice: a systematic review of person-centred interventions and training manuals for care home staff working with people with dementia. <i>International journal of geriatric psychiatry</i> 2014;29:797-807.  <a href="http://dx.doi.org/10.1002/gps.4072">http://dx.doi.org/10.1002/gps.4072</a>            Copyright © 2016 John Wiley &amp; Sons, Ltd.</p>	Published

	<i>Author Approved Manuscript (Green Open Access) available on University of Exeter repository at: <a href="http://hdl.handle.net/10871/39556">http://hdl.handle.net/10871/39556</a></i>	
<b>WP2</b>	Lawrence V, Fossey J, Ballard C, Moniz-Cook E, Murray J. Improving quality of life for people with dementia in care homes: making psychosocial interventions work. <i>The British journal of psychiatry : the journal of mental science</i> 2012;201:344-51. <a href="http://dx.doi.org/10.1192/bjp.bp.111.101402">http://dx.doi.org/10.1192/bjp.bp.111.101402</a> COPYRIGHT: © Royal College of Psychiatrists, 2012	Published
	<i>Author Approved Manuscript (Green Open Access) available on University of Exeter repository at: <a href="http://hdl.handle.net/10871/39561">http://hdl.handle.net/10871/39561</a></i>	
<b>WP3 a Protocol</b>	Whitaker R, Ballard C, Stafford J, Orrell M, Moniz-Cook E, Woods R, <i>et al</i> Feasibility study of an optimised person-centred intervention to improve mental health and reduce antipsychotics amongst people with dementia in care homes: study protocol for a randomised controlled trial. <i>Trials</i> . 2013 Jan 10;14:13. <a href="https://doi.org/10.1186/1745-6215-14-13">https://doi.org/10.1186/1745-6215-14-13</a> © Whitaker et al.; licensee BioMed Central Ltd. 2013 <i>Open Access</i>	Published
<b>WP3 b</b>	Ballard C, Orrell M, Sun Y, Moniz-Cook E, Stafford J, Whitaker R, <i>et al</i> . Impact of Antipsychotic Review and Nonpharmacological Intervention on Antipsychotic Use, Neuropsychiatric Symptoms, and Mortality in People With Dementia Living in Nursing Homes: A Factorial Cluster-Randomized Controlled Trial by the Well-Being and Health for People With Dementia (WHELD) Program. <i>The American journal of psychiatry</i> 2016;173:252-62. <a href="http://dx.doi.org/10.1176/appi.ajp.2015.15010130">http://dx.doi.org/10.1176/appi.ajp.2015.15010130</a> Copyright © American Psychiatric Association	Published
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<b>WP3 c</b>	Lawrence V, Fossey J, Ballard C, Ferreira N, Murray J. Helping staff to implement psychosocial interventions in care homes: augmenting existing practices and meeting needs for support. <i>International journal of geriatric psychiatry</i> 2016 31: 284-93 <a href="http://dx.doi.org/10.1002/gps.4322">http://dx.doi.org/10.1002/gps.4322</a> Copyright © 2015 John Wiley & Sons, Ltd.	Published
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<b>WP3 d</b>	Rajkumar A, Ballard C, Fossey J, Corbett A, Woods R, Orrell M, <i>et al</i> Apathy and its response to antipsychotic review and non-pharmacological interventions in people with dementia living in nursing homes: WHELD - A factorial cluster randomised controlled trial <i>JAMDA</i> 2016; 17:741-747 <a href="https://doi.org/10.1016/j.jamda.2016.04.006">https://doi.org/10.1016/j.jamda.2016.04.006</a> © 2016 AMDA - The Society for Post-Acute and Long-Term Care Medicine.	Published
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<b>WP3 e</b>	Romeo R, Knapp M, Salverda S, Orrell M, Fossey J, Ballard C. The cost of care homes for people with dementia in England: a modelling approach. <i>Int J Geriatr Psychiatry</i> . 2017 Dec;32(12):1466-1475. <a href="https://doi.org/10.1002/gps.4637">https://doi.org/10.1002/gps.4637</a> Copyright © 2016 John Wiley & Sons, Ltd. <i>Open Access</i>	Published
<b>WP3 f</b>	Fossey J, Lawrence, V. Staff views on the involvement of animals in care home life: An exploratory study. <i>J Soc and Soc Welfare</i> 2013 4:305-33. <a href="https://scholarworks.wmich.edu/jssw/vol40/iss4/16">https://scholarworks.wmich.edu/jssw/vol40/iss4/16</a> <i>Freely available on line for non-commercial use courtesy of Journal of Sociology and Social Welfare</i>	Published

	<a href="https://www.bepress.com/products/digital-commons">https://www.bepress.com/products/digital-commons</a>	
<b>WP3 g</b>	Ballard C, Orrell M, Sun Y, Moniz-Cook E, Stafford J, Whitaker R, <i>et al</i> . Impact of antipsychotic review and non-pharmacological intervention on health-related quality of life in people with dementia living in care homes: WHELD-a factorial cluster randomised controlled trial. <i>Int J Geriatr Psychiatry</i> . 2017 Oct; 32 (10):1094-1103. <a href="https://doi.org/10.1002/gps.4572">https://doi.org/10.1002/gps.4572</a> Copyright © 2016 John Wiley & Sons, Ltd.	Published
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<b>WP4</b>	Fossey, J., Garrod, L., Lawrence, V., Testad, I., Stafford, J., Murray, J. “We should see her like part of the team”: An investigation into care home staff’s experiences of being part of an RCT of a complex psychosocial intervention. <i>Ageing and Mental Health</i> 2018 <a href="http://dx.doi.org/10.1080/13607863.2018.1525603">http://dx.doi.org/10.1080/13607863.2018.1525603</a> <i>Open access</i>	Published
<b>WP5 a protocol</b>	Whitaker R, Fossey J, Ballard C, Orrell M, Moniz-Cook E, Woods R, <i>et al</i> Improving Well-being and Health for People with Dementia (WHELD): study protocol for a randomised controlled trial. <i>Trials</i> . 2014; 15:284 <a href="https://doi.org/10.1186/1745-6215-15-284">https://doi.org/10.1186/1745-6215-15-284</a> © Whitaker et al.; licensee BioMed Central Ltd. 2014 <i>Open Access</i>	Published
<b>WP5 b</b>	Ballard C, Corbett A, Orrell M, Williams G., Moniz-Cook E, Romeo, R., <i>et al</i> Impact of person-centered care training and person-centered activities on quality of life, agitation and antipsychotic use in people with dementia living in nursing homes: A cluster-randomized controlled trial of the WHELD intervention <i>PLoS Med</i> 15(2): e1002500. <a href="https://doi.org/10.1371/journal.pmed.1002500">https://doi.org/10.1371/journal.pmed.1002500</a> © 2018 Ballard et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits	Published

	unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. <i>Open Access</i>	
<b>WP5 c</b>	Rajkumar A., Ballard C, Fossey J, Orrell M, Moniz-Cook E, Woods R., <i>et al</i> Epidemiology of Pain in People With Dementia Living in Care Homes: Longitudinal Course, Prevalence, and Treatment Implications <i>JAMDA</i> 2017; 18(5): 453e1-453e6 <a href="https://doi.org/10.1016/j.jamda.2017.01.024">https://doi.org/10.1016/j.jamda.2017.01.024</a> © 2017 AMDA - The Society for Post-Acute and Long-Term Care Medicine.	Published
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<b>WP5 d</b>	Fossey J, Garrod L, Guzman A, Testad I. A qualitative analysis of trainer/coach experiences of changing care home practice in the Well-being and Health in Dementia (WHELD) randomised control trial. <i>Dementia</i> 2018 Copyright © 2018, © SAGE Publications <i>Dementia</i> First Published April 26, 2018 <a href="https://doi.org/10.1177/1471301218772178">https://doi.org/10.1177/1471301218772178</a>	Published
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<b>WP5 e</b>	Romeo R, Zala, D, Knapp M, Orrell M, Fossey J, Ballard, C. Improving the quality of life of care home residents with dementia: Cost effectiveness of an optimised intervention for residents with clinically significant agitation in dementia. <i>Alzheimer's &amp; Dementia: The Journal of the Alzheimer's Association</i> ; 2019 15(2): 282-291 <a href="https://www.sciencedirect.com/science/article/abs/pii/S1552526018335192">https://www.sciencedirect.com/science/article/abs/pii/S1552526018335192</a>	
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	<a href="http://hdl.handle.net/10871/39575">http://hdl.handle.net/10871/39575</a>	
<b>WP5 f</b>	<p>Fossey J, Garrod L, Tolbol Froiland C, Ballard C, Lawrence, V, Testad, I. (2019) What influences the sustainability of an effective psychosocial intervention for people with dementia living in care homes? A 9 month follow- up of the perceptions of staff in care homes involved in the WHELD Randomised Controlled Trial <i>Int. J. Geriatric Psychiatry</i></p> <p><a href="https://onlinelibrary.wiley.com/doi/pdf/10.1002/gps.5066">https://onlinelibrary.wiley.com/doi/pdf/10.1002/gps.5066</a></p> <p><i>Open Access</i></p>	Published

## **Appendix 2:**

Working papers in respect of WP3

- a) Agreed Work Plan
- b) Analysis plan

## WHELD WP3 work plan

SAP for WP3 has currently not been executed in full. Some of this analysis will inform the analysis of WP5.

### Tasks

1. YS to gather all reports given to Rhiannon
2. YS to do demographics/descriptive analysis 
  - a. This is to include an assessment of those who did not complete FU.

With agreement from the PMG we will analyse as an independent data set (this requires as a minimum to take clustering into account in the models).

Care home 3006 will be analysed as it was allocated to PCC intervention group, but not to its originally allocated interventions, i.e. all the other three interventions in addition to PCC. The analysis will be run including and excluding this care home to notionally describe the effect.

### Drug data

#### Antipsychotics

Binary data at baseline was provided by the trial team.

Follow up data for initial analyses completed using binary data constructed by YS using drug assessment date. We now understand that this should have been the main assessment date.

A reasonable assumption to make at this point would be to assume that this binary data has been constructed correctly.

It has now been decided that the variable has been constructed correctly. Drug assessment date and main assessment date may be up to 1 month apart. This is to be considered as one time point.

YS to provide the cases where this window is exceeded to allow a description of the distribution and and assess on a case by case basis what to do for each of these

The information has now been clarified for WP5.

#### Psychotropics

Binary data will be constructed at baseline and follow up using the same criteria as for antipsychotics.

Essentially, we will use the assumption “no stop date implies still on drug” to construct the binary data on condition that the patient has used the drug(s) in the last 12 months.

A=Assessment date, DS =drug start date, DE=drug end date, (when constructing this variable ignore drug assessment date).

DS>DE>A Assign 0 not on drug

DS>A>DE Assign 1 on drug

A>DS>DE Assign 0

DS>A no DE Assign 1 on drug

A with NO DS or DE assume if drug recorded then assign 1 on drug . If this is a large proportion of cases we may need to check this with a sensitivity analysis.

## Deaths

A complete case analysis will be carried out first, which means all deaths will be excluded from the analysis initially because they have not provided any data for outcome measures at follow up stage.

In the second step, analyses will be carried out to impute deaths as “best” and “worst” scenarios, where appropriate, to see how the results for complete case analyses will change.

Do a sensitivity analysis with the Y:-

1. Assign Y all 0 no drug
2. Assign Y all 1 on drug
3. Randomly assign 0/1's in proportion with what is seen in the data set. This may be sensible to do on a MI level.

1 and 2 will give the extremes of the assumption and 3 will give a feeling of what was likely to have happened.

For continuous variables multiple imputation in the usual way will be included in all analysis. This is for both the withdrawals and the deaths.

Finally the analysis plan should be run including the clustering



## WHELD WP3 Statistical Analysis Plan

An Optimized Person Centred Intervention to Improve Mental Health and Reduce Antipsychotics amongst People with Dementia in Care Homes

Version 1 12/9/12

CO- SPONSORS: Oxford Health NHS Foundation Trust & King’s College, London

FUNDERS: NIHR Programme Grants for Applied Research

STUDY COORDINATION CENTRE: Oxford Health NHS Foundation Trust

COREC reference: 11/SC/0066

DATA MANAGEMENT CENTRE: NWORTH - Bangor’s Clinical Trials Unit

Statistical Analysis Plan Authorship		
Rhiannon Whitaker	Methodological PI/Statistician	
Yongzhong Sun	Trial Analyst	
Clive Ballard	Chief Investigator	

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## 1 STUDY DESIGN

The study design is a cluster randomised, 2x2x2 factorial design with 2 replications, pilot study in 16 care homes. It is estimated that each cluster will include a minimum of 12 participants (depending upon size of the care home, the number of people with dementia and the number consenting).

Each cluster will receive a randomly allocated intervention for a minimum of 9 months.

## 2 DATA MANAGEMENT AND ANALYSIS

It is planned that anonymous data and all appropriate documentation will be kept securely for a period of 7 years following the completion of the trial, subject to discussion with relevant Ethics Committees.

### Quantitative data management

Administrative databases will be held at the study centre. All participants and care homes will be identified by a unique study number; this number will be used to tag all research data sent outside the study centre, for example to NWORDH. Quantitative research data will be entered via a web interface to the MACRO™ research databases held at NWORDH. Primary data management will be conducted by the research team in the study centre, and the secondary cleaning and preparation of the data for analysis will be conducted by NWORDH.

### 2.2 Missing data and imputation strategies

There will be four types of missing data for a participant in the dataset:

- Baseline demographic details
- Missing items within a questionnaire
- Missing outcome measures at follow up
- Complete missing data at follow up (usually arising from participant death).

Key demographic variables will be obtained directly from care homes where possible. Where demographics are described, missing data will be noted. In order to maintain power, if a key covariate is missing, modal group substitution will be used to facilitate the analysis.

For items missing within a questionnaire:

- First the published rules for dealing with missing items for the relevant measure will be used where appropriate.
- Further missing items will be replaced with the mean score (mean value substitution MVS) of the remaining items in the questionnaire as long as the number of missing items does not exceed 10% of the total number of items in the questionnaire.
- If there are more than 10% missing items in the questionnaire the outcome measure will not be calculated at that time point.

*Complete case data* will be defined as the data for participants whose relevant outcome measures at both baseline and follow up (at 9 months) are available after implementing the “10% rule”.

*Full data set:* Once the missing item rules have been applied we will make a full assessment of the remaining missing data and any consequential systematic biases which may occur by only analysing complete case data. Then we will design and test potential imputation strategies we may employ in WP5. These imputation strategies will be simple, clear and meaningful, to provide useful interpretations. We will run a series of sensitivity analyses (using the analysis plan described below) to test the imputation strategies both for defining the bounds of the analysis (extreme case scenarios) and for the a priori design of the imputation strategy for WP5. Particular attention will be made to establishing a best practice solution for dealing with the missing endpoints due to death.

### 3 STATISTICAL ANALYSIS

Outcome measures for pilot evaluation will be assessed at baseline and 9 months and are listed in Appendix 1. Each measure will be calculated as given in the relevant reference papers for that measure where appropriate although some flexibility needs to be maintained.

#### 3.1 Descriptive analysis

The trial participant and care home flow will be reported to CONSORT standards. Descriptive statistics for three different interventions AR (antipsychotic review), SI (social intervention and pleasant activities) and Ex (exercise) in characteristics at both the individual patient and care home levels will be tabulated. Graphical techniques will be used where necessary. Any patterns of missing data will be described. The CONSORT diagram information will be assessed to identify potential differences in dropout rates and other data quality issues in order to inform the design of WP5

#### 3.2 Modeling strategy

The covariates with major baseline differences will be detected and they are potential confounders and will be adjusted for in the corresponding ANCOVAs in the following steps.

The study hypotheses will be tested with standard multiple linear regression models for continuous outcome measures and with standard logistic regression models for binary outcome measures, followed by specifying robust standard errors to assess the likely effect of the clustering on standard errors to allow for the clustering within care homes. To address the problem of possible discrepancy resulting from the above two procedures, suitable summary measures for each cluster may be calculated and these summary measures then will be analysed using standard linear regressions, to provide further assurance regarding the appropriate conclusions.

This is a pilot study therefore, for simplicity, we will analyse data only for those individuals with complete data because we only have two measurement occasions. We will then perform a series of sensitivity analyses based on some well-considered imputation strategies to assess the robustness of our main analysis results based on the complete data.

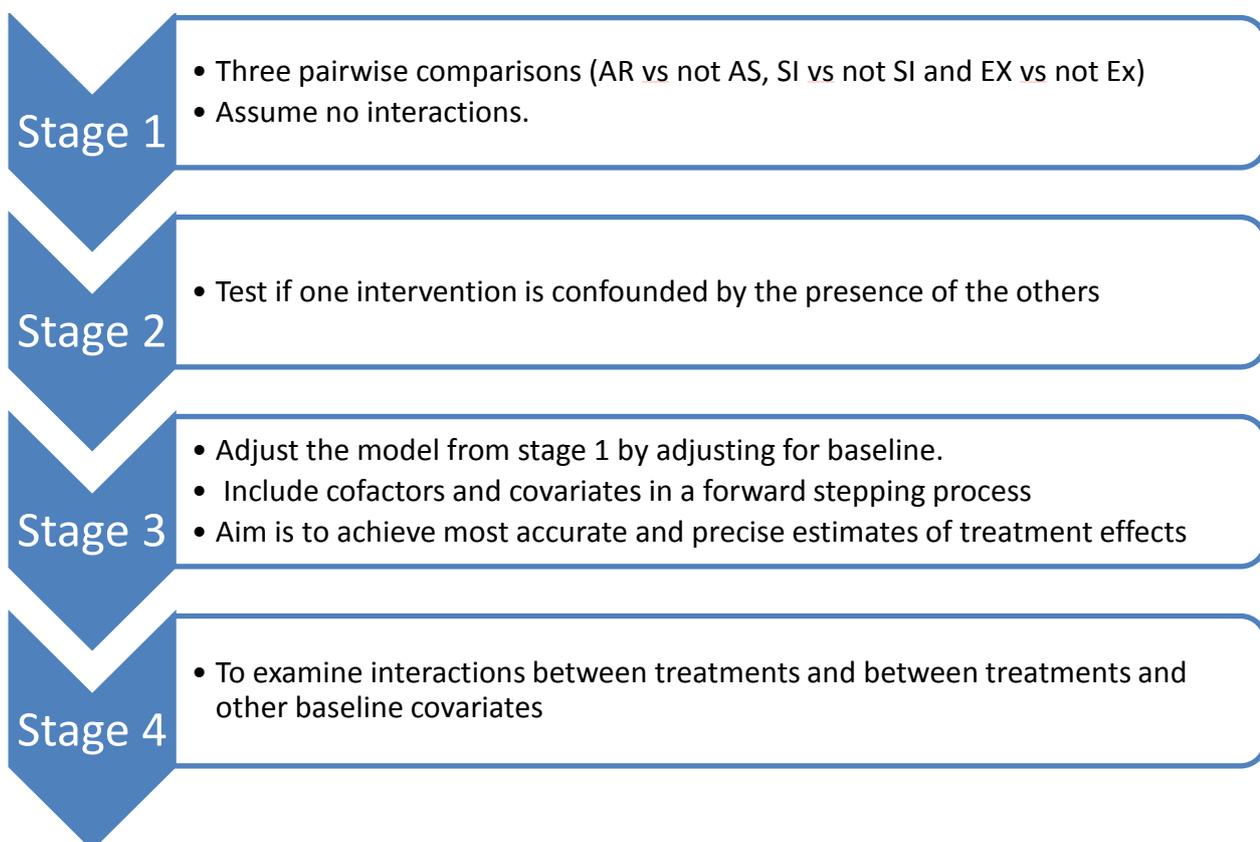
The strategy for linear and logistic regression modelling work is based on the individual post-treatment measurements at 9 months (as outcome measures) and is illustrated in figure 1.

*Stage 1.* We consider the three different interventions AR, SI and Ex separately in three regression models; this gives us the maximum power to obtain an initial idea about the crude treatment effect: how a particular intervention is effective in achieving a desired treatment result for a specific outcome measure by comparing the group of all individuals on the treatment with that not on the

treatment. In this way, the full potential of a factorial design may be utilised. In particular, this modelling assumes no interactions between treatments.

*Stage 2:* We investigate whether the treatment effect of one intervention is accounted for by the other two interventions. The presence or absence of the three interventions will be simultaneously entered into the model to see which effects remain significant. If an intervention is found to be non-significant in relation to a specific outcome, the binary exposure may be excluded from the model. This may imply that this intervention has little or no effect on the outcome when taking the other interventions into account.

**Figure 1: Modelling strategy for WP3.**



*Stage 3:* We will include baseline outcome as a covariate at this stage to provide the best precision of treatment comparisons between each of the three interventions and person centred care (PCC) at the end of treatment. Then the possible confounders detected from the descriptive analysis will be adjusted for in a forward stepwise process. The aim is to achieve the most accurate and precise estimates of the treatment effect.

*Stage 4:* Two-way interaction effects between treatments and between treatments and other baseline covariates may be examined at this stage, focusing on those that are of most interest to us. In particular, for interactions between two interventions, we will adopt a p-value of 10% as the threshold for significance to reflect the exploratory nature of this investigation and to ensure that we identify any promising effects. These interaction terms will be added into the model one by one, to ensure the maximum power to detect them. They have been left to the last step, after allowing for all

other possible linear adjustments to explain the model. The results based on this model may be used to describe the additional benefits conferred by the 3 key interventions compared with PCC.

If any interaction effects between treatments were found, we will need to discuss the implications of this very carefully with the team in order to select the best possible combination of interventions to take forward to WP5. In this case, the statistical power of the analysis to this point will be inevitably reduced.

For each intervention, we will tabulate the results based on two models: one with only main effects as developed by step 3 and the other including interaction terms as obtained from step 4. The effect estimates, standard errors and P-values from these models will be reported. The estimates for standard errors and P-values will be used to contrast with the corresponding estimates obtained by specifying robust standard errors to assess the likely clustering effect within care homes.

### 3.3 Intra-class correlations.

To inform sample size calculation at WP5, a random effect model will be used to analyse the primary outcome measure CMAI, to provide appropriate estimates for intra-class correlations due to care homes. Intra-class correlations for the other outcome measures will be calculated and tabulated in the same manner.

## TIMELINE

Baseline data complete	Complete
Consort	Complete
Data extract syntax written and tested	Complete
Baseline demographics described	Complete
Measure calculation syntax written and tested	August 15 <sup>th</sup>
DMEC meeting	September 21st
Follow up entry data complete and handed over	Est. Jan 2013
Initial results reported	+ 4 weeks
WP5 protocol development	+8 weeks
Further analysis	April-June 2013

## APPENDIX 1: EDITED EXTRACTS FROM THE PROTOCOL, OVERVIEW

### A1.1 Glossary of abbreviations

AR	Antipsychotic Review
CANE	Camberwell Assessment of Need for the Elderly
CDR	Clinical Dementia Rating Scale
CMAI	Cohen-Mansfield Agitation Inventory
COREC	Centre of Research Ethical Campaign
CONSORT	Consolidated Standards of Reporting Trials
CQC	Care Quality Commission
DEMQOL	Measure of Health related quality of life for people with dementia
DMEC/TSC	Data Monitoring and Ethics/Trial Steering Committee
Ex	Exercise
FAST	Functional Assessment Staging
FITS	
FG	Focus groups
PCC	Person Centred Care
PI	Principle Investigator
ICCs	Intra class correlations
NEST	
NICE	National Institute for Clinical Excellence
NIHR	National Institute of Health Research
NPI-NH	Neuropsychiatric Inventory – Nursing Home version
NWORTH	North Wales Organisation for Randomised Trials in Health
QoL	Quality of Life
QoL-AD	Quality of Life in Alzheimer’s Disease
RAID	Rating Anxiety in Dementia
RCT	Randomised Controlled Trial
SDs	Standard Deviations
SI	Social Interaction
TMG	Trial Management Group

WHELD	An optimized intervention “welding together” the most effective elements of the best currently available intervention programmes and a standardised manual and training programme
WP	Work Package

## **A1.2 Trial administration**

### **A1.2.1 Trial Management Group (TMG)**

Chief Investigator (Clinical): Prof Clive Ballard

Co-investigators:

Ms Jane Fossey	
Prof Martin Orrell	Prof Dag Aarsland
Prof Esme Moniz-Cook	Ms Joanna Murray
Prof Robert Woods	Prof Martin Knapp
Mr Eddie McLaughlin	Dr Susanne Sorensen
Mrs Rhiannon Whitaker	Mrs Barbara Woodward-Carlton

Trial Manager/Coordinator: Dr Jane Stafford

Trial Statistician and NWORDH Clinical Trials Unit (CTU) Investigator (Methodological): Rhiannon Whitaker

### **A1.2.2 Data Management Centre**

NWORDH - Bangor's CTU

Address: Bangor University, College of Health & Behavioural Sciences, Institute of Medical & Social Care Research, Y Wern, Normal Site, Holyhead Road, Bangor, Gwynedd LL57 2PZ

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Website: <http://www.bangor.ac.uk/imscar/nworth>

## **A1.3 Abstract**

700,000 people in the UK have dementia, 250,000 of whom live in care homes. These individuals have complex mental health problems, disabilities and social needs, compounded by widespread prescription of harmful sedative drugs. Dementia is a national priority with a vast impact on Health and Social Care Services. The optimized programme (WHELD) will combine the most effective elements of existing approaches to develop a comprehensive but practical intervention. This will be achieved by training care staff to provide care that is focused on an understanding of the individual and their needs; and by using additional components such as exercise, activities and social interaction to improve mental health, reduce the use of sedative drugs and also improve quality of life (QoL).

Work Package 3 (WP3) is the pilot study and qualitative evaluation to help develop the larger randomised controlled clinical trial (Work Package 5, WP5) which will establish the value of WHELD.

The overarching goal of the programme is to provide an effective, simple and practical intervention, which improves mental health of, and reduces sedative drug use in, people with dementia in care homes; which can be rolled out nationally to all UK care homes as an NHS intervention.

## **A1.4 Keywords**

Dementia

Care Homes

Quality of life

Antipsychotic medication

Behavioural symptoms

Cost effectiveness

Implementation

Person centred care

Exercise

Social interaction

## A1.5 Study Summary

**TITLE** Work Package 3 WHELD programme

**DESIGN** Pilot factorial trial and qualitative and process evaluation utilising focus groups.

**AIMS** To help develop the intervention for testing in Work Package 5.

**OUTCOME** Quantitative:

**MEASURES**

Agitation, other behavioural and neuropsychiatric symptoms

Antipsychotic and other psychotropic drugs use

Mood and depression, quality of life, dementia severity

Unmet needs

Falls

Quality of interactions between staff and residents using the observational tool

Amount of staff time needed and cost of each intervention

Qualitative:

Use of case examples to understand the skills development and development of person centred attitudes amongst care home staff

The process of implementation within the environment in which the interventions take place. Staff beliefs, attitudes and behaviour in their work with people with dementia are key components of this context. Staff perspectives on the implementation of the interventions.

**POPULATION** Residents of 16 care homes

**ELIGIBILITY** Care homes identified from those rated 'adequate' or better in the CQC register, in the Oxfordshire, Buckinghamshire and London localities.

8 homes selected from a convenience sample and another 8 randomly selected.

Exclusion criteria:

Less than 60% of the residents have dementia.

Receiving special support from local authority

All individuals residing in participating care homes who scores '1' or greater on the CDR and score '4' or greater on the FAST.

Exclusion criteria:

Data will not be collected from individuals for whom consent has not been obtained

**DURATION** Up to 20 months

## APPENDIX 2: EDITED EXTRACTS FROM THE PROTOCOL:WP3

### A2.1 Study Objectives

Quantitative Evaluation will be undertaken using a factorial design. Evaluations will be undertaken to understand the breadth of additional benefits conferred by 3 key interventions compared with Person Centred Care alone.

- (A) Person Centred Care (PCC)
- (B) Antipsychotic Review (discontinuation and safety) (AS)
- (C) Social intervention and Pleasant Activities (SI)
- (D) Exercise (EX)

#### A2.1.1 Hypotheses

We hypothesise that each intervention will significantly improve several key outcomes, but none of the interventions will improve all outcomes on their own. This pilot study is not powered to answer these questions definitively. The role of these hypotheses is to guide the analysis and to generate firm hypotheses for testing in the main trial (WP5).

Specifically we hypothesise that, compared to Person Centred Care alone:

- (1) The combination of Person Centred Care and Antipsychotic Review will result in the reduction of antipsychotic prescribing
- (2) The combination of Person Centred Care and Social intervention and Pleasant Activities will result in additional improvements in agitation/aggression, especially in individuals already experiencing these symptoms at the baseline evaluation
- (3) The combination of Person Centred Care and Exercise will improve overall mood and will reduce the number of falls

#### A2.1.2 Secondary objectives and qualitative evaluation

A key secondary objective will be to determine the specific impact of each therapy on a range of outcomes including mental health, psychotropic drug use, physical health and quality of life; as well as the impact on potentially important mediating factors such as activities, social interaction, staff attitudes and the quality of the interaction of care staff with people with dementia to inform subsequent work.

The purpose of the qualitative research is to increase our understanding of the process of implementation within the care environment. Staff beliefs, attitudes and behaviour in their work with people with dementia are key components. Recognition and acknowledgement of staff perspectives is also essential to negotiating the implementation of the interventions.

## A 2.2 Study design

### A2.2.1 Overall design

The study design is a cluster randomised, 2x2x2 factorial design with 2 replications, pilot study in 16 care homes. It is estimated that each cluster will include a minimum of 12 participants (depending upon size of the care home, the number of people with dementia and the number consenting).

Each cluster will receive a randomly allocated intervention for a minimum of 9 months.

Evaluations will be undertaken to understand the breadth of benefits conferred by 3 key interventions to be assessed when used **in addition** to the Person Centred Care training package, whose efficacy has already been established.

(A) Person Centred Care (PCC): PCC training will be delivered using the operationalized FITS manual [2], with demonstrated efficacy in a robust randomised controlled trial (RCT) [3] and incorporating relevant updated materials since original publication. This will be further augmented by additional elements of leadership training on the basis of input from an expert therapy development group.

(B) Antipsychotic Review: This will involve specific review of antipsychotic drugs by participants' own General Practitioners or specialists, based upon the principles outlined in the NICE dementia guidelines [1] and facilitated by an antipsychotic care pathway developed by the Alzheimer's Society in partnership with the Department of Health. General Practitioners will be offered an initial seminar outlining the best practice guidelines and they will be prompted when 12 week antipsychotic reviews are due (as advised by the NICE/SCIE guidelines). Care home staff will also be offered a seminar about the safe prescribing, monitoring and review of antipsychotics. In addition, for all participants continuing to receive antipsychotics after the initial review or where antipsychotics are started or re-started, a detailed medical antipsychotic care plan will be advised, using the principles outlined in the antipsychotic care pathway. This will include planned dates for further antipsychotic review.

(C) Social Interaction and Pleasant Activities: An intervention manual will be developed based upon 3 evidence based approaches and specific communication skills training to enhance staff–resident interactions. The approaches will include: (1) The Positive Events Schedule, developed and demonstrated to be effective in the treatment of agitation and depression in people with dementia in non-care home settings [44]; (2) The Social Interaction intervention demonstrated to be effective for the treatment of agitation in people with dementia in care homes by Cohen-Mansfield and colleagues [6]; (3) The NEST programme developed by Beuttner and colleagues [7]. Minor adaptations will be undertaken, in collaboration with the authors who developed the manuals, to ensure that they are suitable and practical for administration in a UK care home setting.

(D) Exercise: The main focus will be to promote exercise through encouraging enjoyable positive activities that involve exercise. Teri and colleagues have developed an effective approach, based upon their Positive Event Schedule approach, but focussing specifically on exercise based activities [5]. The NEST manual [7] and the ROM Dance programme [8], which has been shown to be effective in an RCT for older people in care settings with Arthritis [9], will be used as specific resources to offer people enjoyable individual and group exercise activities to augment activities identified specifically as hobbies or enjoyable activities by individual participants.

Treatment	Care home															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
B	-	-	-	-	+	+	+	+	-	-	-	-	+	+	+	+
C	-	-	+	+	-	-	+	+	-	-	+	+	-	-	+	+
D	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

In the above design, care homes 1 and 9 will receive PCC only, while care home 4 will receive Social Interaction and Exercise in addition to PCC and care home 13 will just receive Antipsychotic Review in addition to PCC.

Each intervention will be delivered by 2 trained therapists, who will receive an intensive 10 day training package, each of whom will coordinate the delivery of the intervention into 8 care homes. Part of the intervention will be to train 2 lead care staff members (WHELD champions) in each care home to implement the intervention.

#### **A 2.2.2 Number of participants and power of the study**

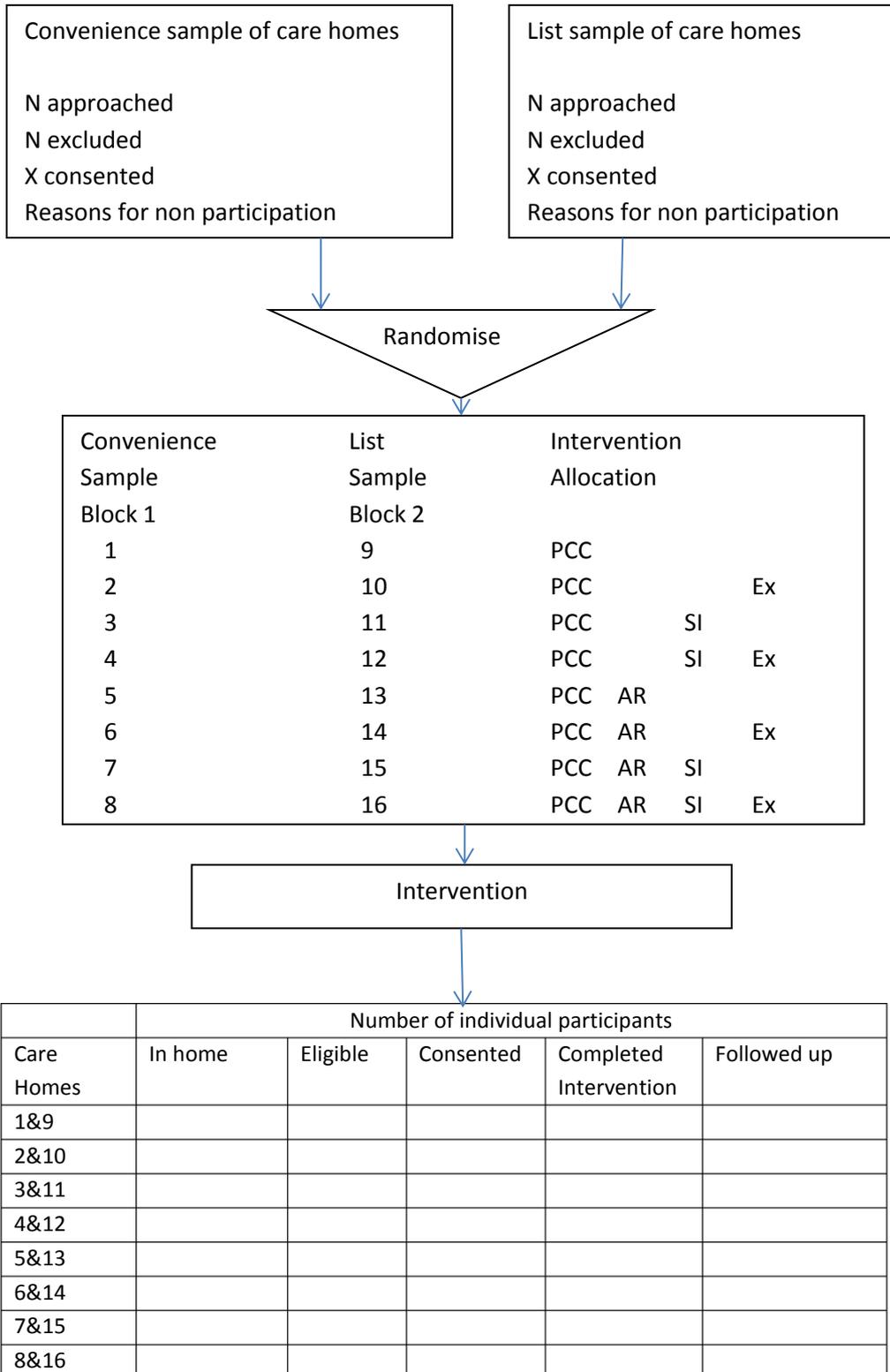
16 suitable care homes will be identified, recruited, randomised and the intervention delivered to all participating residents. The minimum target participant recruitment is 12 individuals with dementia per care home, therefore the target minimum sample size is 192, with a suggested upper recruitment limits of approximately 256 (i.e. 16 individuals with dementia per care home).

Baseline and follow up data will be collected on all consented residents who meet the inclusion criteria at each participating care home. This is a pilot study, whose main purpose is to collect data to enable the design and sample size calculation for the follow on RCT. As such the size of effect for the outcome measures, their standard deviations (SDs) and intra class correlations (ICCs) are unknown.

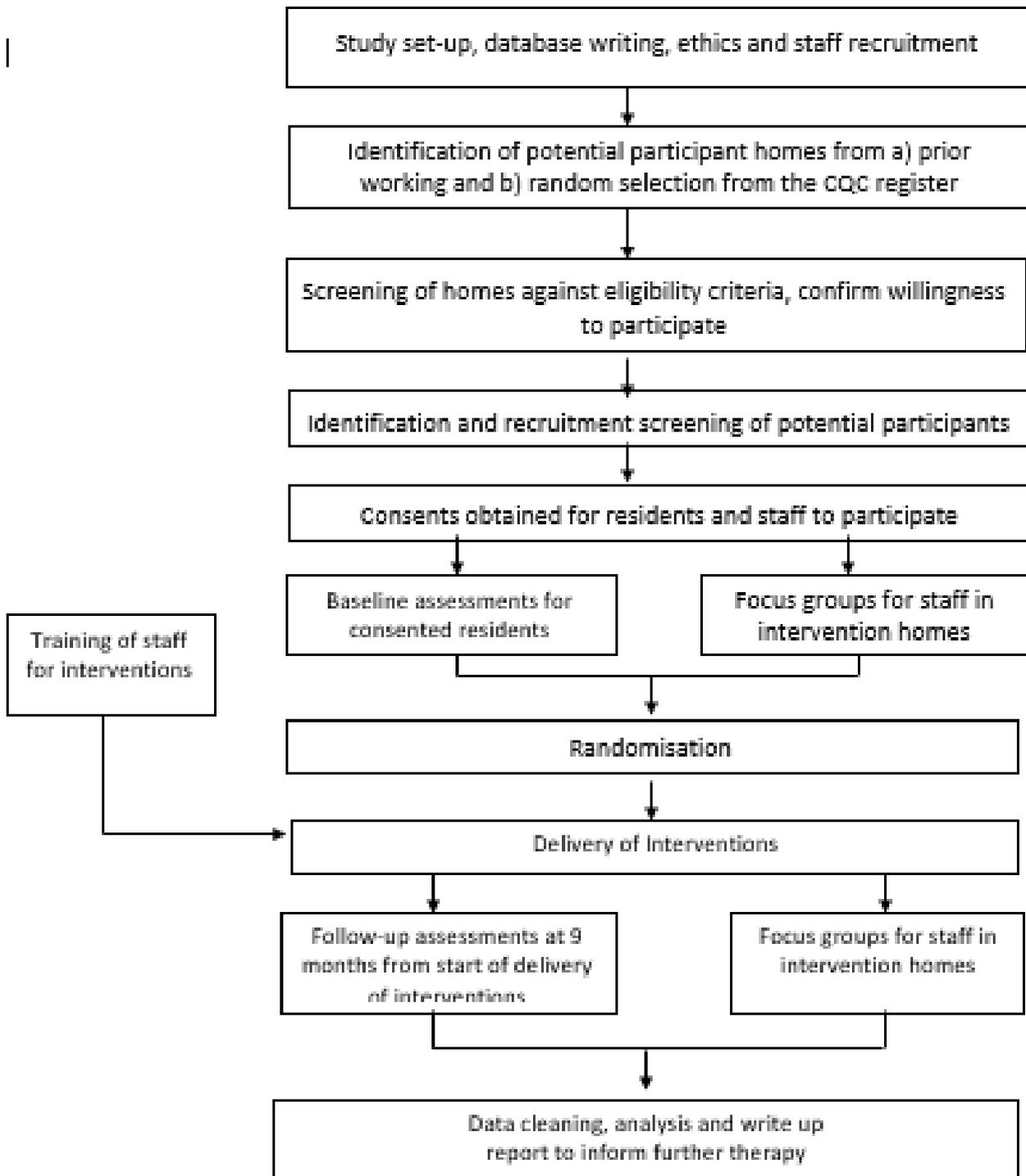
#### **A2.2.3 Randomisation**

A restricted randomisation method will allocate the 8 interventions to the 8 care homes in the two samples. The randomisation will be completed as a complete list randomisation meaning that all care homes will have been recruited before the randomisation is performed. The restriction ensures an equal distribution of the number of interventions to each geographic location. The system has been coded and validated in R (statistical package).

**A2.2.4 Design and Consort diagram**



A.2.2.5 Flow Chart (full milestones shown in WHELD Programme Gantt chart)



## **A2.3 Participant Entry**

### **A 2.3.1 Home selection: inclusion, exclusion and withdrawal criteria**

8 care homes will represent a convenience sample (block 1) of local care homes, already known to the research team, which meet the inclusion and exclusion criteria and have previously expressed a willingness to participate in research. The other 8 care homes will be identified from all care homes in the research area rated as 'adequate' or better on the CQC register (block 2). The list of eligible care homes will be randomised and the homes approached in the order of appearance on the randomised list. If a care home declines to participate the next care home on the list will be approached.

Inclusion:

- Care homes scoring 'adequate' or better on CQC register

Exclusion:

- Care home in which 60% or less of the residents have dementia
- Care homes receiving special support from local authority

Withdrawal Criteria:

- Care homes are free to withdraw from the study at any time.

### **A2.3.2 Participant selection: inclusion, exclusion and withdrawal criteria**

All residents who would be potentially eligible for evaluation will be identified by the care home staff.

Inclusion for evaluation:

- All individuals residing in participating care homes who meet diagnostic criteria for dementia, score '1' or greater on the CDR [11] and score '4' or greater on the FAST [10].

Exclusion from evaluation:

- Any resident for whom consent is not obtained

Withdrawal Criteria:

- Individual participants would be able to withdraw from the study evaluation at any time.

### **A 2.3.3 Staff selection: inclusion, exclusion and withdrawal criteria**

All staff working in participating care homes would be potentially eligible to participate in the focus groups as part of the qualitative evaluation. Consent for their participation will be sought separately. They will be excluded if consent is not obtained and are able to withdraw from the study at any time.



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## APPENDIX 4: OUTCOME MEASURES

(CMAI and antipsychotic use are two primary outcome measures)

Outcome measure	Subscale	Abbreviation	Scoring	Thresholds	References
Cohen-Mansfield Agitation Inventory (CMAI)		CMAI	Sum of all 29 items (scored 1/2/3/4/5/6/7)	There are no reported thresholds	Cohen-Mansfield 1989 [12], 1991 [20]
	Physical aggressive (items 1-11)	CMAI_pa	Sum of all 11 items (scored 1/2/3/4/5/6/7)		
	Physical non-aggressive (items 12-21)	CMAI_pna	Sum of all 10 items (scored 1/2/3/4/5/6/7)		
	Verbal aggressive (items 22-24)	CMAI_va	Sum of all 3 items (scored 1/2/3/4/5/6/7)		
	Verbal non-aggressive (items 25-29)	CMAI_vna	Sum of all 5 items (scored 1/2/3/4/5/6/7)		
Antipsychotic use			Antipsychotic doses were converted into chlorpromazine equivalents and then added together		Woods 2003 [21]
	Proportion of residents receiving drugs		A binary variable: 1 for on antipsychotic treatment and 0 for not on the treatment		
Use of other psychotropic drugs			Psychotropic doses were converted into chlorpromazine equivalents and then added together		Woods 2003 [21]

	Proportion of residents receiving drugs		A binary variable: 1 for on psychotropic treatment and 0 for not on the treatment		
Neuropsychiatric Inventory – nursing home version (NPI-NH)		NPI-NH	<p>Neuropsychiatric Inventory has 12 domains in total. For each behavioural domain, frequency is rated 1 to 4 and severity is rated 1 to 3. The score for each domain is: domain score = frequency × severity. A total NPI-NH score can be calculated by adding all of the first ten domain scores together. All twelve domain total scores can be summed in special circumstances where the neurovegetative symptoms are of particular importance.</p> <p>Occasional Disruptiveness is rated 1 – 5. The disruptiveness score is not included in the total NPI-NH score but should be calculated separately by summing the disruptiveness scores of the behavioural domains.</p>		Woods 2000 [13]; Cummings 2009 [22], 1997 [23]
Cornell Depression Scale		CSDD	There are 19 items in total. Each item is rated for severity on a scale of 0-2 (0=absent, 1=mild or intermittent, 2=severe). The item scores are added.	<p>&gt;10, probable major depression</p> <p>&gt;18, definite major depression</p> <p>&lt;6, absence of significant depressive symptoms</p>	Alexopoulos 1988 [14], 2002 [24]
Rating Anxiety in Dementia (RAID)		RAID	Total score is the sum of items 1 to 18, each scored 0/1/2/3	≥11 suggests significant clinical anxiety	Shankar 1999 [15]

Camberwell Assessment of Need in the Elderly (CANE)		CANE	It is to be noted that scoring is a secondary aspect of the CANE as its primary purpose is to identify and assess individual unmet needs. (not used for this purpose in this research). The total CANE score is based on the rating of section 1 of each of the 24 problem areas (scored 0/1/2)		Reynolds 2000 [16]
	Count total number of met needs		The variables may take values between 0 and 24		
	Count total number of unmet needs		The variable may take values between 0 and 24		
	Count total number of needs identified		The variable may take values between 0 and 24		
Assessment of QoL for people with dementia (DEMQOL)		DemQoL	Sum of 28 items (scored 1/2/3/4). Positive items are scored reversely. Higher scores mean a better quality of life.		Smith 2007 [17]
	Overall quality of life		A four-point scale based on the patient's overall rating on his/her quality of life (the 29th item in the questionnaire)		
Assessment of QoL for people with dementia (DEMQOL proxy)			Sum of 31 items (scored 1/2/3/4). Positive items are scored reversely. Higher scores mean a better quality of life.		Smith 2007 [17]
	Overall quality of life	DemQoL-proxy	A four-point scale based on the care giver's overall rating on patient's quality of life (the 32nd item in the questionnaire)		

QoL in Alzheimer's Disease (QoL-AD)		QoL-AD	Sum of 13 items (scored 1/2/3/4). Higher scores mean a better quality of life.	Patient and caregiver reports can be evaluated separately and/or combined into a single score	Logsdon 1999 [18]
QoL in Alzheimer's Disease (QoL-AD proxy)		QoL-AD-proxy	Sum of 13 items (scored 1/2/3/4). Higher scores mean a better quality of life.		Logsdon 1999 [18]
Quality of Interaction Schedule (QUIS, observational tool)		QUIS	<p>It can be used as both a qualitative and quantitative tool to provide a measure of the quality of interaction between staff, patients and visitors. (used as a quantitative tool for WHELD).</p> <p>Simple percentages of the quality of interactions are perfectly acceptable for straightforward evidence of the quality of verbal and non verbal communication e.g. 20% of observation were positively social (n=20), 70% were basic care interactions (n=70), 5% were neutral interaction (n=5) and 5% were negative interaction (n=5). The scoring rule may depend on how the data were collected.</p>		Dean 1993 [19]
Incident reporting form	Number of fractures within last 12 months		A binary variable: 1 for residents with one or more fractures and 0 for none		
	Proportion of residents with one or more falls		A binary variable: 1 for residents with one or more falls and 0 for none		