Improving mental health and reducing antipsychotic use in people with dementia in care homes: the WHELD research programme including two RCTs

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Scientific summary

The WHELD research programme

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Scientific summary

Background

Neuropsychiatric symptoms, often referred to by consensus as behavioural and psychological symptoms of dementia, represent a major challenge to the treatment and care of people with dementia. Neuropsychiatric symptoms affect 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. The first is the development of safe and effective psychosocial interventions for behavioural and psychological symptoms of dementia as a safe and effective alternative to antipsychotic medication. Since the beginning of this millennium, there has been a growing focus on a personalised approach to delivering these interventions. The second element is high-quality training and skills development for staff to enable them to provide the best possible care, in addition to effective support for clinicians who are working with people in care home settings. These requirements are highlighted in government directives worldwide. Person-centred care is recognised as a gold standard in providing care to people with dementia, yet there are no standardised programmes to support implementation in care homes.

Objectives

The objective of this 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 optimised intervention based on the most effective currently available therapies that can provide a broad range of benefits and can be routinely implemented as part of NHS care. We also wanted to determine whether or not the intervention improves quality of life.

This was achieved by addressing the following research questions through six work packages:

- Work package 1 – what is the evidence supporting the use of psychosocial interventions for behavioural and psychological symptoms of dementia, and the use of staff training programmes in person-centred care in improving behavioural and psychological symptoms of dementia and antipsychotic drug use?
- Work package 2 – what factors influence implementation of psychosocial interventions in care home settings?
- Work package 3 – 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?
- Work package 4 – what adaptations are required to optimise the effectiveness and implementation of the Well-being and Health for people with Dementia (WHELD) programme?
- Work package 5 – what is the effectiveness and cost-effectiveness of the optimised WHELD programme?
- Work package 6 – how can the WHELD programme be effectively disseminated to maximise impact on care practice and future research?

Methods

Work package 1

In work package 1, the two systematic reviews utilised broad searches of electronic databases including MEDLINE, PsycINFO, EMBASE, Web of Science™ (Clarivate Analytics, Philadelphia, PA, USA), Clinical

Trials, British Nursing Index and the Cochrane Library to identify relevant publications that relate to psychosocial interventions, and a broader search of online search engines to identify existing person-centred care training manuals. Following protocolised review procedures, quality criteria were applied to the published studies. A review the efficacy of the training manuals was also considered.

Work package 2

A metasynthesis approach was used to conduct a review of the studies examining the implementation of psychosocial interventions in care homes. Eligible studies were coded and data were extracted for thematic analysis. Themes were combined using an interpretive method of metadata synthesis; themes were grouped where they had greatest explanatory power. Work package 2 also involved a series of intervention development steps with a therapy development group to create and protocolise an initial WHELD programme package.

Work package 3

A cluster factorial randomised controlled trial of the WHELD programme was conducted in people with dementia in 16 care homes. All care homes received person-centred care training and weekly visits from a research therapist. Eight care homes were randomly assigned to receive antipsychotic review, social interaction or exercise for 9 months, with most care homes assigned to more than one intervention. The primary outcome measure was antipsychotic drug use. Secondary outcome measures were agitation, depression, overall behavioural and psychological symptoms of dementia, quality of life and mortality. Work package 3 also involved focus group discussions with care home staff from all of the participating care homes, in which expectations of the study and its implementation were discussed, and a cost–function analysis conducted with the baseline data from the factorial study. The analysis utilised data from demographics, medical history, clinical assessment of behavioural and psychological symptoms of dementia and assessment of unmet needs to define the costs of care and the associated variables for people with dementia in care homes.

Work package 4

This work package consisted of a series of review and consultation steps that led to the optimisation of the WHELD programme. This included (1) review of the outcomes of work package 3 with expert and governance groups, (2) review of the study materials and their usage with the WHELD programme therapists and (3) focus group discussions with 41 care home staff who were involved in the factorial trial in work package 3 to understand their experience of involvement in research and the use of the WHELD programme. The intervention was then refined according to the outputs.

Work package 5

A cluster randomised controlled trial with an embedded cost-effectiveness study was conducted in people with dementia in 69 care homes, comparing the WHELD programme with treatment as usual. The primary outcome measure was quality of life (Dementia Quality of Life Scale – Proxy). Secondary outcome measures included agitation (as measured by the Cohen-Mansfield Agitation Inventory), behaviour (as measured by the Neuropsychiatric Inventory – Nursing Home version), antipsychotic drug use and pain (as measured by the Abbey Pain Scale). Staffing inputs and service use data (Client Service Receipt Inventory) 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. In addition, a focus group was conducted 9–12 months after the end of work package 5 with care staff from nine care homes that had received the intervention, to understand factors related to the sustainability of the intervention beyond the research implementation period.

Work package 6

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 general practitioners 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

Work package 1

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 (effect size 0.46) and training in person-centred care, with less consistent benefit for personalised music, exercise and validation therapy. A lack of large-scale randomised controlled trials 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 randomised controlled trial evidence. Of these four studies, the studies reported benefit to agitation, depression, overall behavioural and psychological symptoms of dementia and antipsychotic use. These were the Focused Intervention for Training and Support; the Needs, Environment, Stimulation and Techniques intervention; Dementia Care Mapping; and Improving Dementia Care manuals.

Work package 2

The metasynthesis on psychosocial implementation revealed key issues in promoting the 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 care home staff; and the need for cultural change. These findings were combined with work package 1 to inform intervention development. The WHELD programme had four key elements: (1) person-centred care training based on adapted versions of published manuals, (2) antipsychotic review by general practitioners based on national best practice guidelines, (3) social interaction and (4) exercise. The last two elements were adapted from published interventions.

Work package 3

In the factorial trial, antipsychotic review significantly reduced antipsychotic drug use by 50% (odds ratio 0.17, 95% confidence interval 0.05 to 0.60). Antipsychotic review plus social interaction significantly reduced mortality (odds ratio 0.36, 95% confidence interval 0.23 to 0.57) but showed significantly worse outcomes in behavioural and psychological symptoms of dementia than the group receiving neither antipsychotic review nor social interaction (mean difference 7.37 symptoms, 95% confidence interval 1.53 to 13.22 symptoms). This detrimental impact was mitigated by concurrent delivery of social interaction (mean difference −0.44 points, 95% confidence interval −4.39 to 3.52 points). The exercise intervention significantly improved neuropsychiatric symptoms (mean difference −3.58 symptoms, 95% confidence interval −7.08 to −0.09 symptoms), but not depression (mean difference −1.21 points, confidence interval −4.35 to 1.93 points). The focus group discussion 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 care home staff expectations and the perceived value of the proposed interventions, the value of sustained relationships and recognition of good practice.

Work package 4

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

Work package 5

In total, 847 people were randomised to the WHELD programme or treatment as usual, of whom 553 completed the 9-month randomised controlled trial. The intervention conferred a statistically significant improvement in quality of life (Dementia Quality of Life Scale – Proxy *z*-score of 2.82, mean difference 2.54, standard error of measurement 0.88, 95% confidence interval 0.81 to 4.28, Cohen's *d* effect size of 0.24; $p = 0.0042$). There were also statistically significant benefits in agitation (Cohen-Mansfield Agitation Inventory *z*-score of 2.68, mean difference −4.27, standard error of measurement 1.59, 95% confidence interval −7.39 to −1.15, Cohen's *d* effect size of 0.23; $p = 0.0076$) and overall neuropsychiatric symptoms (Neuropsychiatric Inventory – Nursing Home version *z*-score of 3.52, mean difference −4.55, standard error of measurement 1.28, 95% confidence interval −7.07 to −2.02, Cohen's *d* effect size of 0.30; $p < 0.001$). There was a statistically significant benefit in positive care interactions measured by the Quality of Interactions Scale (19.7% improvement, standard error of measurement 8.94%, 95% confidence interval 2.12% to 37.16%, Cohen's *d* effect size of 0.55; $p = 0.03$). In an additional exploratory analysis, overall benefits were greatest in people with moderately severe dementia. The WHELD programme significantly reduced health and social care costs compared with treatment as usual (cost difference −£4740, 95% confidence interval −£6129 to −£3156). Focus group discussions with 12 of the WHELD programme therapists identified a number of perceptions of the knowledge and skills required for delivering the intervention. A flexible approach to working with care 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, although helpful, required considerable input to support staff in developing confidence in cascading information to their colleagues. Focus group discussions with 47 staff from nine participating care homes took place 9–12 months following the end of the trial and the results were analysed using thematic analysis. A number of sustained benefits and practices and contributing organisational factors in the care homes were identified.

Work package 6

Dissemination activities were successfully completed in work package 6. Key activities included regional workshops for general practitioners, which received excellent feedback and response, and the creation of an e-learning module for general practitioners with the *British Medical Journal* 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 optimised 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 randomised controlled trial conducted in work package 5 provides an evidence-based platform to enable effective implementation in care home settings for people with dementia.

The results of work package 3 suggest the need for some caution when reviewing antipsychotic medications in people with dementia, and show the importance of providing an evidence-based non-pharmacological intervention in parallel with antipsychotic discontinuation to maximise the 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 behavioural and psychological symptoms of dementia, but also led to a significant improvement in quality of life and a significant 30% reduction in mortality.

The intervention in work package 5 was optimised 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 small effect sizes. 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, therefore, is difficult to compare it 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 general practitioner education as part of antipsychotic review and the modified WHELD programme did not achieve an overall reduction in antipsychotic use in this randomised controlled trial. The general practitioner intervention has, however, been developed as a *British Medical Journal* educational module; therefore, in practice, it should be possible to implement the WHELD programme directly in care homes and promote the general practitioner educational component in parallel.

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

First, with regard to antipsychotic drug 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 drug withdrawal and carefully balance the harm-to-benefit ratio associated with antipsychotic medications.

Second, 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.

Trial registration

This trial is registered as ISRCTN40313497 and ISRCTN62237498.

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