

# An intervention to improve outcomes of falls in dementia: the DIFRID mixed-methods feasibility study

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## Scientific summary

### **The DIFRID mixed-methods feasibility study**

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## Scientific summary

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### Background

Recent estimates suggest that there are 850,000 people living with dementia in the UK, which is predicted to increase to over 1 million by 2025 and to over 2 million by 2051 if current trends remain stable. Although the numbers of people with dementia in care settings have increased, most individuals with dementia still live in the community. The annual prevalence of falls in people with dementia ranges from 47% to 90%, depending on dementia subtype, with people with dementia living in their own home having almost 10 times more incident falls than cognitively intact older people. When injuries are sustained, people with dementia are less likely than other older people to recover well. Falls and fall-related injuries are a significant cause of morbidity and mortality in people with dementia.

There is presently little evidence to guide the management of falls and fall-related injuries in people with dementia, and available evidence tends to be focused on those who sustain more serious injuries, such as fractures. Multifactorial services can prevent further falls in cognitively intact older people, but their effectiveness for people with dementia has not been demonstrated. There are potentially substantial benefits to be gained if the outcome of these falls and injuries in people with dementia could be improved.

### Objectives

The overall aim of this study was to assess whether or not it is possible to design a complex intervention to improve the outcomes of fall-related injuries of people with dementia living in their own homes. During the study, the objective was expanded to include people with dementia with falls necessitating health-care attention and not just those with fall-related injuries.

The objectives were to:

- investigate existing evidence regarding the clinical effectiveness and cost-effectiveness of interventions aimed at improving the outcome of fall-related injuries in people with dementia
- understand current care pathways experienced and the services used, and to identify the additional care needs of people with dementia and their carers
- develop a new intervention for this patient group drawing on these findings
- conduct a single-arm feasibility study to deliver the proposed intervention to 10 people with dementia–informal carer dyads in each of the three sites
- assess the feasibility of outcome measurement of clinical effectiveness and cost-effectiveness outcomes
- assess the factors influencing the acceptability and implementation of the intervention and determine whether or not to progress to a full-scale randomised controlled trial.

## Methods

### *Work package 1: current research knowledge*

Reviews drew on Cochrane and Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) methodologies. The following databases were searched from inception to November 2015: MEDLINE, Cochrane Central Register of Controlled Trials, Health Management Information Consortium, EMBASE, Cumulative Index to Nursing and Allied Health Literature, Web of Science, Allied and Complementary Medicine Database and Physiotherapy Evidence Database.

For the systematic review, titles and abstracts were screened by two reviewers for relevance, and then full texts were examined in detail to determine eligibility. Discrepancies were resolved by a third reviewer. Citation information, setting (in terms of location and type of institution), population, details of the intervention and outcomes were extracted using a data extraction form. Methodological information was extracted to allow assessment of risk of bias. A planned meta-analysis proved impractical owing to study heterogeneity. We carried out a narrative synthesis, categorising studies by intervention and describing the outcomes of interest.

For the economic evaluation review, database searches were conducted in August 2016 in the following databases: MEDLINE, EMBASE and NHS Economic Evaluation Database. Data were extracted by one reviewer using a prespecified data extraction form. The quality of the included studies was assessed against a commonly used checklist for reporting economic analyses.

### *Work package 2: understanding current practice and describing current usual care*

A prospective observational study of fall-related injuries in people with dementia was conducted over 6 months, alongside a qualitative study, in three UK sites (Newcastle, North Tees and Norwich), each including three settings (primary care consultations, paramedic attendances and emergency department attendances).

Thirteen people with dementia with fall-related injuries and their carers kept a diary of service use for 3 months to describe the type and quantity of care accessed and care pathways followed by such individuals.

Qualitative interviews and focus groups were conducted with people with dementia, their carers and health and social care professionals to explore their perceptions of the care needs of people with dementia following a fall, whether or not these needs were met, what might have been improved and what outcomes were important to them. Observation of selected services was carried out, particularly those services that were difficult to capture through diaries. An integrated, thematic analysis of qualitative data sets was carried out.

### *Work package 3: developing the new intervention*

For the realist review, initial title and abstract screening was conducted by two reviewers. Data suggesting a context, mechanism or outcome were extracted by two reviewers independently (one clinician and one non-clinician) and presented for discussion at a team meeting at which disagreements between reviewers were resolved. Methodological information was also extracted. The qualitative team analysed and summarised the data relating to each context–mechanism–outcome configuration. Additional iterative searches were conducted in which gaps were identified and the same procedures were repeated.

A consensus panel was convened to review the results of work packages 1 and 2. Delphi consensus methods were used to prioritise specific elements to be combined in a complex health-care intervention.

The fit and acceptability of the proposed intervention were explored through qualitative interviews and focus groups with a range of stakeholders, including participants from work package 2.

**Work package 4: testing the feasibility and acceptability of the new intervention**

This was a feasibility study with 11 people with dementia–informal carer dyads in each of the three intervention sites.

An embedded qualitative study used normalisation process theory to assess factors influencing the acceptability and implementation of the intervention.

**Results****Work package 1**

The effectiveness of interventions to improve outcomes for people with dementia who fall was highly heterogeneous in terms of the interventions compared, the outcomes considered and the patient populations considered. Most of the interventions considered only hip fracture. The gap in the evidence base suggested that there was scope for a new intervention for fall-related injuries in dementia. Both cost-effectiveness analyses and cost–utility analyses are currently being incorporated into the protocols of two studies evaluating a falls prevention intervention in people with cognitive impairment. The inclusion of economic evaluations to determine the efficiency of alternative courses of action was recommended to inform policy-makers in the UK.

**Work package 2**

Integrative thematic analysis suggested that improving outcomes for people with dementia with fall-related injuries requires recognition and facilitation of rehabilitation potential. This, in turn, requires services and staff to work in ways that compensate for cognitive impairment. We identified three factors that influence the extent to which current services achieve these aims:

1. supportive service organisation
2. staff attitudes, knowledge and skills
3. supporting carers and their role in interventions.

**Work package 3**

The findings of the realist review built on the work of work packages 1 and 2, suggesting a number of important components of interventions for fall-related injuries in people with dementia, as well as potential mechanisms underpinning successful interventions for this patient group. These were grouped into three broad themes: (1) ensuring that the circumstances of rehabilitation are optimised for people with dementia, (2) compensating for the reduced ability of people with dementia to self-manage and (3) equipping the workforce with the necessary skills and information to care for this patient group. Drawing on the data relating to each of these themes, we suggested a number of components for inclusion in the final intervention, which were considered by the consensus panel.

The consensus process allowed us to integrate practical, empirical data from experts and practitioners with evidence from previous studies to create a robust, theoretically informed design for a new intervention. This was a complex multidisciplinary therapy intervention. Physiotherapists, occupational therapists and support workers delivered up to 22 sessions of tailored activities in the patient's home or local area over a period of 12 weeks. Outcome measures were agreed by the panel for work package 4: (1) assessment of the feasibility of study procedures, (2) the acceptability, feasibility and fidelity of intervention components and (3) the suitability and acceptability of outcome measures for people with dementia and their carers (number of falls, quality of life, fear of falling, activities of daily living, goal-setting, health utilisation and carer burden). During work package 3, it was agreed that the intervention in work package 4 should be delivered to people with dementia with a fall necessitating health-care attention and not only those sustaining a fall-related injury.

### **Work package 4**

Recruitment to the feasibility study was lower than expected; nevertheless, we met the progression criterion of recruiting  $\geq 40\%$  of eligible people with dementia. The intervention was delivered to 11 people with dementia. The study suggested that the intervention is both feasible and acceptable to stakeholders. Adherence to the initial assessment was relatively good. However, there were some difficulties in identifying meaningful goals with or for people with dementia. This suggests that further training and review of goals by a specialist member of the research team is needed. Further consideration is needed regarding the recruitment of geriatricians to support multidisciplinary team meetings, clarification of the purpose of the meetings and documentation of such meetings. There was also a need to improve the support provided to carers during the intervention.

The completion of outcome measures was mostly successful. A need for further training for therapists on the use of the Goal Attainment Scale was identified.

### **Conclusions**

The study has highlighted the feasibility of delivering a creative, tailored, individual approach to intervention for people with dementia following a fall. Although the intervention required greater investment of time than usual practice, many staff valued the opportunity to work more closely with people with dementia and their carers. We conclude that further research is now needed to refine this intervention through a pilot randomised controlled trial.

### **Trial registration**

This trial is registered as ISRCTN41760734 and PROSPERO CRD42016029565.

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## This report

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