# Home-based health promotion for older people with mild frailty: the HomeHealth intervention development and feasibility RCT

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## Scientific summary

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# Scientific summary

## Background

Frailty is common in older adults and is associated with an increased risk of adverse outcomes, including hospitalisation, functional decline, poor quality of life, increasing dependency and avoidable death. It has a major impact on health and social care costs, which will increase over the coming decades as the population ages. However, frailty is a transitional process and there exists an intermediate state of pre-, early or mild frailty, in which people are neither robust nor frail but experience some symptoms of frailty (e.g. feeling slowed up or weaker). They are also not yet dependent on others for activities of daily living. Estimates suggest that up to around 40% of older adults may be mildly or pre-frail and that over time they may transition to worsening frailty, stay the same or improve.

Therefore, mild frailty represents an important opportunity to promote health and prevent frailty and future decline. Most mild or pre-frail individuals do not present with overt symptoms and are easier targeted at home. Health promotion interventions in frail and high-risk populations have had mixed success, while reviews suggest that health promotion benefits may be greater in older adults who are younger and at lower risk of mortality. However, evidence as to the most effective ways to promote health in this population and how they may be delivered in a feasible and cost-effective way at scale is lacking. We aimed to develop a new home-based service for promoting health, functioning and well-being in mild frailty, and assess its feasibility, acceptability and costs in a feasibility randomised controlled trial (RCT).

## Objectives

Our objectives were to:

1. systematically review and synthesise existing evidence for home-based health promotion interventions for older people with mild frailty
2. explore how health and social care policies address health promotion with older people with mild frailty
3. explore key components for a new home-based health promotion intervention in interviews/focus groups with older people, carers, home care workers and community health professionals
4. coproduce a new health promotion intervention for older people with mild frailty with older people, carers, health/care professionals and other experts
5. test acceptability and feasibility of (1) delivery in the NHS and (2) recruitment, retention, outcomes and study procedures for a full RCT
6. determine the intervention costs, test the feasibility of collecting health economic data to calculate costs and effects and determine the feasibility of calculating cost-effectiveness for a full RCT from health and societal perspectives
7. conduct a mixed-methods process evaluation exploring the context, potential mechanisms and pathways to impact of the intervention.

# Intervention development

## *Evidence reviews*

### Methods

We conducted a series of evidence reviews to inform intervention development:

1. a systematic review of 14 databases/registries (1990–2016) for RCTs, observational and qualitative studies of home-/community-based interventions for older people with mild or pre-frailty
2. a systematic review of 15 databases/registries (1980–2014) for RCTs of home-based, multidomain health promotion interventions for older people with frailty/at risk of frailty, to identify behaviour change techniques (BCTs) employed within interventions and explore their potential contribution to intervention effects
3. a state-of-the-art review of systematic reviews from three databases (from inception to 2015) of single-domain interventions to promote health in fields of exercise and mobility, falls prevention, nutrition and diet, social engagement, mental health and memory in frailer or 'at-risk' older adults
4. a policy-scoping review and documentary analysis of state laws, national and local policy on frailty prevention, using iterative web searches of key documents, and a purposive sample of local government and health commissioning websites.

### Results

#### *Mild frailty*

We identified seven eligible RCTs from 1273 records. Few interventions were targeted specifically at mildly frail older adults, but some evidence suggested that exercise could benefit physical performance. No qualitative studies in this population were found and four observational studies of modifiable risk factors showed that body mass index, cognition and vitamin D may influence frailty trajectories.

#### *Behaviour change mechanisms*

We identified 19 eligible RCTs from 1213 records. There was no overlap with trials identified in the mild frailty systematic review. Frailty prevention interventions lacked explicit behaviour change content and uniformly effective mechanisms of intervention could not be identified. There was some evidence to suggest that education, enablement, changing the environment and giving instructions on how to perform a behaviour could be beneficial.

#### *State-of-the-art review*

Evidence from 69 eligible systematic reviews indicated that physical activity/falls prevention, nutritional interventions, encouraging socialising and access to psychological therapies could be effective components within a new service, but little evidence existed to support memory improvement. The strongest evidence was for physical activity/falls prevention.

#### *Policy*

We reviewed 78 local and 79 national current policies in England (2014–17). We found a lack of focus on people on a pathway to frailty. Instead, policies were targeted towards those who were frailest or towards promoting health in mid-life.

# Qualitative studies

## *Methods*

We conducted a thematic analysis of data from two sources: data collected in a previous study on health promotion for older people (30 interviews with people aged ≥ 65 years) and further new interviews and focus groups with 53 people (older people with mild frailty, carers, home care workers and health/social care professionals).

### *Results*

The interviews highlighted preferences for a focus on maintaining rather than changing current levels of health/independence and the importance of remaining socially connected. There was consensus that a new intervention should be individually tailored, address a broad range of domains (particularly mobility and socialising), be focused on independence and provide information and practical/psychological support. Stakeholders felt that this would be best delivered over a sustained period by a single trained non-specialist worker to provide continuity, with good communication skills.

## The 'HomeHealth' service intervention

We collated and synthesised this evidence with our theoretical framework to develop the basis for a prototype new home-based health promotion intervention, the HomeHealth service. The service had an asset-based approach, incorporating theories of successful ageing and behaviour change. This was refined through one-to-one meetings with commissioners, managers and practitioners in urban and semi-rural areas and three further service development panels with frailer older adults, health/social care and voluntary sector professionals, commissioners, policy-makers and academic experts and public representatives.

The resultant HomeHealth service was a manualised home-based intervention delivered by non-specialist support workers who were trained in communication skills, low mood, physical activity and exercises, nutrition and BCTs. It was intended to be delivered over 6 months in approximately six appointments of 30–60 minutes. The service was targeted at addressing four key domains: mobility, nutrition, socialising and psychological well-being, but could address other domains raised by individuals. Clients would develop personalised goals around maintaining assets and strategies to achieve these in conjunction with the support workers. Their role was to provide information, emotional and practical support, teach skills (such as exercises and problem-solving) and provide feedback on progress and maintaining goals longer term in further appointments.

## Feasibility randomised controlled trial

### *Methods*

We assessed the feasibility and acceptability of the new HomeHealth service for delivery in the NHS and for a full-scale RCT. Community-dwelling older adults aged $\geq 65$ years with mild frailty were recruited from four general practices across urban and semi-rural areas. We excluded people residing in care homes, receiving palliative care or on the dementia register. Participants were randomised in a 1 : 1 ratio to receive the HomeHealth intervention or treatment as usual (TAU).

Our success criteria for the feasibility RCT were:

1. minimum recruitment of 70% of our target of 50 people within 6 months
2. retention of 80% at 6 months
3. positive evaluation of feasibility and acceptability to older people and the NHS
4. no negative effects of the intervention on candidate primary outcomes.

We collected data through participant home visits at baseline and 6 months on a range of clinical outcomes, including functioning, frailty characteristics (e.g. grip strength, gait speed, weight), psychological well-being and distress, cognition and health behaviours (physical activity, alcohol and smoking). For the health economic analysis, self-reported quality of life, capability and additional service use (also collected at 3 months) data were collected and we extracted NHS service use data from medical notes at 6 months. Adverse event data were collected throughout. Baseline and 6-month follow-up data were collected face to face by the same researcher.

### Results

The feasibility trial was successful. We recruited 51 people within 5 months and 94% completed the 3- and 6-month outcome assessments with very few missing data, fulfilling our recruitment and retention success criteria. Participants at baseline were largely independent in basic functioning/self-care, but had complex needs. On average, participants had three or four long-term conditions, low gait speed and grip strength, low mental well-being, high levels of psychological distress, and an average cognition score in the mild cognitive impairment range. At 6 months, those receiving the HomeHealth service ($n = 26/51$) had significantly better functioning (Modified Barthel Index, adjusted effect +1.68; $p = 0.004$), better grip strength (adjusted effect +6.48 kg; $p = 0.02$) and psychological distress (12-item General Health Questionnaire, adjusted effect –3.92; $p = 0.01$) scores than the TAU arm. There were no differences in other outcomes. A total of 42 out of 51 (82%) people completed questionnaires on trial procedures and respondents found them acceptable. No negative effects were documented for our candidate primary outcomes and no serious adverse events related to the intervention were reported. The main limitation was difficulty in maintaining blinding of outcome assessments, because of the accidental unblinding by participants.

Assuming the service would be delivered by a NHS band 6 employee with a case-load of 50 people per year, the total average cost of the intervention per patient was £307. Capability-adjusted life-years (CALYs) were significantly higher in the HomeHealth group [adjusted CALYs +0.017, 95% confidence interval (CI) 0.001 to 0.031] than the TAU arm, but there were no differences in quality-adjusted life-years. Both total NHS services costs and cost of help from carers were lower in the HomeHealth group, but costs incurred were highly variable between participants as a result of high secondary care costs for a small number of participants (e.g. pacemaker fitting); therefore, limited conclusions can be drawn. Participants found it difficult to quantify the time spent by unpaid carers providing support, but otherwise there were minimal health economic missing data. We did not calculate intervention cost-effectiveness because of the small sample size and high variability in costs. The low number of missing data indicated that this would be feasible in a large-scale trial.

## Process evaluation

### Methods

We conducted a mixed-methods process evaluation. We recorded the number and duration of appointments and goals set, audio-recorded appointments and assessed intervention fidelity using checklists, collected intervention provider experiences through semistructured interviews, and explored participants' experiences of receiving the HomeHealth service through self-report questionnaires and semistructured interviews.

### Results

Intervention recipients received an average of 322 minutes of appointment time per person overall, across a median of five appointments (range 1–8 appointments), with some brief interim contacts. Nearly all participants (25/26, 96%) identified an outcome goal to achieve from the service and 62% identified additional further goals during the service. Goals most commonly focused on mobility and physical activity (73% of people), although a range was identified, including the home environment, psychological well-being and socialising. Fidelity to the intervention (including use of BCTs) was 72.1% overall per random audio-recorded appointment assessed. This is likely to underestimate fidelity, as some checklist items not completed may have been addressed in other appointments (all items were not necessarily applicable for all appointments). A total of 42 out of 51 (82%) participants completed questionnaires and 19 participants completed interviews (HomeHealth recipients, $n = 16$; and service providers, $n = 3$) for the process evaluation. These indicated that the HomeHealth service was generally well received by participants and had high engagement. Participants reported making a range of changes resulting from the intervention and valued the motivational, counselling/reflective listening and social, practical and emotional support roles of the support worker.

A number of factors affecting engagement were identified, including their physical health burden, cognitive impairment and difficulties of using BCTs in this context. Future modifications were highlighted, including alternative approaches to a goal-setting behaviour change model for those who do not like this or when it is unsuitable (e.g. for those with cognitive impairment and no carer support), further guidance on carer involvement and possible augmentation to training for the support workers.

## Conclusions and future work

Despite a widespread acknowledgement of the importance of frailty prevention, little evidence is currently available to inform intervention design and delivery, though exercise appears to be a potentially effective component. Large-scale multidomain interventions targeted at older people with mild frailty are currently lacking. There is an urgent need for further interventions in this area, particularly those that further address nutrition, cognitive decline, mental well-being and social engagement.

From older people's perspectives, new services for frailty prevention should be personalised and encompass multiple domains, particularly socialising and mobility, and be delivered by trained non-specialist workers. The language used to frame a service was important; rather than people becoming 'healthier', frailty prevention services should consider reframing health promotion in terms of maintaining independence and current health status for as long as possible.

Although only limited conclusions can be drawn from our small-scale feasibility study, it suggests that services such as these would be well-received and can be delivered at a modest cost. There appears to be some promise for improving clinical outcomes, including functioning/independence, and this now needs to be tested in a larger RCT. Our feasibility RCT suggests that this is feasible. The promising clinical and cost findings in our feasibility trial indicate that a large-scale RCT of the HomeHealth service, with minor modifications in the light of the process evaluation, is warranted.

## Study registration

This study is registered as PROSPERO CRD42014010370 and this trial is registered as ISRCTN11986672.

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