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Enabling health and maintaining independence for older people at home: the 'HomeHealth' trial

Submission date
06/04/2020

Recruitment status
No longer recruiting

Registration date
22/04/2020

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
As we get older, we may develop a number of health conditions that affect how we feel and our ability to manage without help. For some of us it can mean we start to become frail, with less energy, appetite and muscle strength and find it harder to do household tasks such as shopping or cooking. Few health services exist to help prevent things getting worse. Researchers have designed a new service ‘HomeHealth’ with older people, health/social care workers, voluntary sector, policy-makers and experts. 'HomeHealth' aims to enable older people to maintain their independence and activities they enjoy. Over six visits a support worker helps people find ways to reduce the impact of feeling tired, low in energy, low/anxious, poor appetite, memory concerns or low muscle strength. The service has been tested with 51 older people, and it was liked, showed potential to help people stay independent and feel better, was of modest cost and merited a larger study (trial). The researchers now aim to test if HomeHealth helps older people who are becoming frail stay independent for longer and provides value for money if offered as part of standard NHS care.

Who can participate?
People aged 65 or over, registered with General Practices in London (Camden), Yorkshire (Bradford District & Craven) and North & East Hertfordshire, who are finding everyday tasks more difficult, for example getting out and about on their own, shopping, preparing meals or managing budgets

What does the study involve?
Participants will be allocated randomly to one of two groups. One group will receive HomeHealth plus any existing support, the other group will continue to get existing support only. The researchers will follow up participants for a year, to see if they are able to look after themselves without further help, measure their health and wellbeing and what services they use. They will then compare the two groups to see if HomeHealth helps people stay independent and well, and if the benefits outweigh its costs.

What are the possible benefits and risks of participating?
If the HomeHealth service is effective, participants may maintain their independence longer or receive other health benefits. At the end of the study, all participants will be given information

about health promotion services available locally and nationally. All participants will receive a £10 voucher for completing each assessment with a researcher: at the start of the study, after 6 months and after 1 year (max £30). A small number of participants will be asked to take part in an interview about their experiences, and will receive a £20 voucher for this. There are few risks to taking part in this study. It may be that participants increase their chances of having a fall if they begin new exercises at home or going out to new activities as part of the service. The support worker will however be trained to ensure activities are as safe as possible. Participants may also be upset if they do not meet the goals they set themselves or talk about sensitive issues. They may be disappointed if they are allocated to the control group.

Where is the study run from?
The study is run by researchers based at University College London, with research teams also based at the University of Hertfordshire and University of Leeds/Bradford Teaching Hospitals NHS Foundation Trust. Participants will be recruited from general practices in Camden (London), East & North Hertfordshire and Bradford District and Craven. The HomeHealth service will be delivered in participants' homes, by trained HomeHealth support workers based in local organisations such as Age UK or their local GP practice. Researchers from University of Nottingham, Glasgow Caledonian University, Kingston and St Georges University of London and Kings College London are also involved in the study.

When is the study starting and how long is it expected to run for?
November 2019 to March 2023

Who is funding the study?
National Institute for Health Research Health Technology Assessment (UK)

Who is the main contact?
1. Prof. Kate Walters
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2. Dr Rachael Frost
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Dr Rachael Frost

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
275026

Protocol serial number
CPMS 44687, NIHR128334, 128987, IRAS 275026

Study information

Scientific Title
Clinical and cost-effectiveness of an in-home personalised health promotion intervention enabling independence in older people with mild frailty ('HomeHealth'): a randomised controlled trial

Acronym
HomeHealth RCT

Study objectives
The HomeHealth service is more effective than usual care in maintaining independence in older people with mild frailty at 12 months.

Secondary: The HomeHealth service is more cost-effective than usual care in older people with mild frailty at 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/07/2020, Social Care REC (Health Research Authority, Skipton House, Ground Floor, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8127, 02071048035; socialcare.rec@hra.nhs.uk), ref: 20/IEC08/0013

Study design
Randomized; Both; Design type: Treatment, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical, Qualitative

Primary study design
Interventional

Study type(s)
Other, Efficacy

Health condition(s) or problem(s) studied
Older people with mild frailty

Interventions
Current interventions as of 06/08/2020:

Participants will be recruited through their GP practice, but the HomeHealth service will be delivered at their home. Service delivery will be face-to-face where possible (with appropriate personal protective equipment), but depending on current guidance in relation to the pandemic may be delivered remotely using video or telephone. There will be three main sites (Camden, Yorkshire, Hertfordshire), covering areas with high ethnic diversity, rural populations and varying levels of deprivation.

PARTICIPANTS
The researchers will recruit 386 participants. They will recruit older people aged 65+ with mild frailty who live in the community. They will exclude people living in care homes, who are receiving palliative care, who lack capacity to consent or who are already being case managed.

PROCEDURES
Participants will be recruited through invitations mailed out by their general practice (GP) surgery. GP surgeries will be asked to conduct list searches to identify peopled aged 65+ living in the community who are classed as mildly or moderately frail according to the Electronic Frailty Index (which is known to be oversensitive in identifying frailty level). Those who are severely frail or robust will be excluded. Practice clinicians will be asked to review the list and use existing knowledge to exclude those who are classed as very fit - managing well (categories 1-3) and those who are moderately frail or worse (category 6 or more) according to the Rockwood Clinical Frailty Scale, and those who lack capacity to consent. Practices will send postal invitations including a study leaflet, a HomeHealth service leaflet, an invitation letter and reply slip. Leaflets include a list of frailty symptoms to encourage self-identification. Those who are interested in participating will be asked to return the reply slip to the research assistant (RA) at

each site. Health and social care professionals and voluntary sector services can also refer older people to the study, and older people can self-identify through leaflets left in community areas. Study information will also be sent to local groups and voluntary sector organisations to disseminate to their members.

Each potentially interested participant will be telephoned by a RA to screen for inclusion. If positive a Participant Information Sheet will be sent to the person and a baseline assessment arranged (at least 48 hours after receipt of the information sheet). The person will be visited at home by a RA if possible to confirm eligibility if unclear, seek consent to participate and (if consenting) undertake a baseline assessment, including questionnaires and if possible, physical measures such as gait speed, height, weight and grip strength. If a home visit is not possible, remote assessments (by phone or video) will be carried out.

After the baseline assessment the participant will be randomised to receive either the HomeHealth service or treatment as usual. Both groups will receive healthy ageing booklets at the 12 month assessment. Those receiving treatment as usual will continue as normal; those receiving the HomeHealth service will receive up to six appointments over six months at their home (either face to face or remotely) with a HomeHealth support worker. The HomeHealth intervention is a manualised, tailored behaviour change intervention covering topics including mobility, socialising, mood and nutrition. Where participants consent, these appointments will be audio-recorded to assess whether the service was delivered as intended (fidelity). Types of goals set and appointments attended will be recorded.

Participants will undertake 6 and 12 month outcome assessments with a RA blinded to intervention status in order to reduce researcher bias. Participants cannot be blinded due to the nature of the intervention.

A sample of those receiving the HomeHealth service will also be invited to take part in semi-structured interviews for the process evaluation. Interviews will take place in participants' homes (with a separate RA not blind to whether participants are receiving the service) and will explore experiences of taking part in the service and engagement with the service. Consent will be sought separately for this. HomeHealth support workers and other relevant stakeholders will also be asked to participate in interviews about the service.

Participants will be asked if they consent for data to be collected from their medical notes at 24 months regarding service, mortality and moves to residential care.

PATIENT AND PUBLIC INVOLVEMENT
Three PPI representatives contributed to the proposal and will provide input throughout, one of who was a co-applicant on the grant application. The materials were reviewed by PPI representatives in the earlier study and updates of the consent form and information sheet have been reviewed by a PPI representative. Three more PPI representatives will be recruited to the Trial Steering Group to oversee the study. The HomeHealth service was co-designed with older people and other stakeholders. PPI members have provided guidance on how to optimise remote delivery of the HomeHealth service.

PROJECT TIMELINES
Month -6 to 0: Develop materials, obtain NHS ethics and HRA approval, recruit staff, set up procedures and database
Month 0-6: initial management meetings, database and trial setup, site initiation, provider training
Month 6-18: recruit participants, baseline assessments

Months 6-24: intervention delivery, process data collection, fidelity data collection
Months 12-30: outcome assessments, process evaluation interviews
Months 18-33: process evaluation analysis
Month 30-36: statistical and health economic analysis
Months 3-36: knowledge exchange activities

Previous interventions:

DESIGN
The study will be a randomised controlled trial, in order to test whether the HomeHealth service is more effective than treatment as usual in maintaining independence in older people with mild frailty. Individual participants will be randomly allocated to receive the HomeHealth service or treatment as usual through Priment Clinical Trials Unit using Sealed Envelope. Treatment as usual will be used as there is currently no standard NHS service targeted at this population. Treatment as usual consists of routine care when problems arise (e.g. GP appointments), with no specific preventative frailty support. It is currently unclear if the HomeHealth service is more effective than treatment as usual, and there are few previous studies focussing on mildly frail older people. The researchers will service use data to test whether the HomeHealth service is more cost-effective than treatment as usual. They will also carry out a process evaluation to explore how well the service is implemented and what might influence this.

SETTING
Participants will be recruited through their GP practice, but the HomeHealth service will be delivered at their home. There will be three main sites (Camden, Yorkshire, Hertfordshire), covering areas with high ethnic diversity, rural populations and varying levels of deprivation.

PARTICIPANTS
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Months 18-33: process evaluation analysis
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Months 3-36: knowledge exchange activities

Intervention Type
Behavioural

Primary outcome(s)

Independence in basic activities of daily living will be measured by the modified Barthel Index at baseline, 6 and 12 months

Key secondary outcome(s))

Current secondary outcome measures as of 06/08/2020:

1. Instrumental activities of daily living measured by the Nottingham Extended Activities of Daily Living at baseline, 6 and 12 months
2. Fried Frailty Phenotype classified by appropriate UK cutoffs for gait speed, grip strength, exhaustion, physical activity and weight loss at baseline, 6 and 12 months
3. Self-reported gait speed measured using Op het Vald's (2018) self-reported frailty measure. This will be measured at baseline, 6 and 12 months. If possible face-to-face physical gait speed assessment (m/s, average of two trials of time taken for the participant to walk a distance of up to 5 m, depending on space available, at their usual speed) will be carried out in a subset of participants to provide validation data
4. Self-reported grip strength measured using Op het Vald's (2018) self-reported frailty measure. Grip strength will be measured at baseline, 6 and 12 months. If possible, physical grip strength will be assessed using a dynamometer (kg, highest score out of three trials following established protocols) in a subsample of trial participants to confirm the validity of the self-report measure
5. Physical activity assessed by the International Physical Activity Questionnaire – Elderly at baseline, 6 and 12 months
6. Exhaustion (as a component of the Fried Frailty Phenotype) assessed by two questions from 7-item Centre for Epidemiological Studies Depression Scale at baseline, 6 and, 12 months
7. Weight loss assessed using the weight loss question from the Mini-Nutritional Assessment Short Form and if possible, weight in kg as measured by weighing scales at baseline, 6 and 12 months
8. Quality of life and Quality-adjusted Life Years measured by Euro-Qol-5D-5L at baseline, 6 and 12 months
9. Capability and Capability-adjusted Life Years measured by the ICEpop CAPability measure for Older people at baseline, 6 and 12 months
10. Wellbeing measured by the Warwick-Edinburgh Mental Wellbeing Scale at baseline, 6 and 12 months
11. Psychological distress measured by the 12-item General Health Questionnaire at baseline, 6 and 12 months
12. Loneliness measured by the University of California, Los Angeles 3-item loneliness scale at baseline, 6 and 12 months
13. Cognition measured by the telephone Montreal Cognitive Assessment (MoCA) or full MoCA at baseline, 6 and 12 months
14. Falls assessed by self-report according to the ProFANE consensus criteria at baseline, 6 and 12 months
15. Mortality assessed by report from a carer or healthcare professional and/or healthcare records at 6 and 12 months
16. Carer burden measured using questions from the Carer Quality of Life measure that forms part of the iMTA Valuation of Informal Care at baseline, 6 and 12 months

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Previous secondary outcome measures:

1. Instrumental activities of daily living measured by the Nottingham Extended Activities of Daily Living at baseline, 6 and 12 months
2. Fried Frailty Phenotype classified by appropriate UK cutoffs for gait speed, grip strength, exhaustion, physical activity and weight loss at baseline, 6 and 12 months
3. Gait speed measured in m/s as the time taken (assessed by a stopwatch) for the participant to walk a distance of up to 5m (depending on space available) at their usual speed. The average of two trials will be used. This will be measured at baseline, 6 and 12 months
4. Grip strength measured in kg using a dynamometer and following established protocols. The highest of three trials will be used. Grip strength will be measured at baseline, 6 and 12 months
5. Physical activity assessed by the International Physical Activity Questionnaire – Elderly at baseline, 6 and 12 months
6. Exhaustion (as a component of the Fried Frailty Phenotype) assessed by two questions from 7-item Centre for Epidemiological Studies Depression Scale at baseline, 6 and, 12 months
7. Weight loss assessed using the weight loss question from the Mini-Nutritional Assessment Short Form and weight in kg as measured by weighing scales at baseline, 6 and 12 months
8. Quality of life and Quality-adjusted Life Years measured by Euro-Qol-5D-5L at baseline, 6 and 12 months
9. Capability and Capability-adjusted Life Years measured by the ICEpop CAPability measure for Older people at baseline, 6 and 12 months
10. Wellbeing measured by the Warwick-Edinburgh Mental Wellbeing Scale at baseline, 6 and 12 months
11. Psychological distress measured by the 12-item General Health Questionnaire at baseline, 6 and 12 months
12. Loneliness measured by the University of California, Los Angeles 3-item loneliness scale at baseline, 6 and 12 months
13. Cognition measured by the Montreal Cognitive Assessment at baseline, 6 and 12 months
14. Falls assessed by self-report according to the ProFANE consensus criteria at baseline, 6 and 12 months
15. Mortality assessed by report from a carer or healthcare professional and/or healthcare records at 6 and 12 months
16. Carer burden measured using questions from the Carer Quality of Life measure that forms part of the iMTA Valuation of Informal Care at baseline, 6 and 12 months

Completion date
04/07/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/08/2020:

1. Older people aged 65+ years
2. Registered with a general practice in the participating site area
3. Scoring as ‘mildly frail’ on the Clinical Frailty Scale
4. Community-dwelling (including extra care housing)
5. Life expectancy of > 6 months
6. Capacity to consent to participate
7. People with dementia will not be excluded from the study, providing they fit the above criteria

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Previous inclusion criteria:

1. Older people aged 65+
2. Registered with a participating general practice
3. Scoring as ‘mildly frail’ on the Clinical Frailty Scale
4. Community-dwelling (including extra care housing)
5. Life expectancy of >6 months
6. Capacity to consent to participate
7. People with dementia will not be excluded from the study, providing they fit the above criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Total final enrolment
388

Key exclusion criteria
1. Care home residents
2. Those with moderate to severe frailty (6-9 on Rockwood Clinical Frailty Scale [CFS]) or not frail (1-4 CFS)
3. Receiving palliative care
4. Already case managed
5. Lack capacity to consent

Date of first enrolment
01/10/2020

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
Department of Primary Care and Population Health
UCL Royal Free Campus
Rowland Hill
London
United Kingdom
NW3 2PF

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
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United Kingdom
BD9 6RJ

Study participating centre
University of Hertfordshire
Centre for Research in Public Health and Community Care
Hatfield
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AL10 9AB

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR128334

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Access to the quantitative datasets generated and/or analysed during the current study will be included in the subsequent results publication, where they can be sufficiently de-identified for data-sharing and conform to ethics and data governance requirements. The primary qualitative data will not be shared as it is not possible to de-identify this data sufficiently and retain the integrity of the data.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/11/2023	24/11/2023	Yes	No
Results article		20/01/2025	28/02/2025	Yes	No
Protocol article		04/06/2022	07/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study	30/01/2025	03/02/2025	Yes	No
Protocol (other)	Version 4.0	22/04/2021	19/10/2021	No	No
Protocol file	version 7.0	07/11/2022	07/08/2023	No	No
Statistical Analysis Plan	version 4.0	24/07/2023	24/07/2023	No	No
Statistical Analysis Plan	version 5.0	18/09/2023	24/10/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes