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The development and feasibility of a new service to promote health and well-being in older people who are starting to become frailer: The HomeHealth study

Submission date
02/12/2015

Recruitment status
No longer recruiting

Registration date
02/12/2015

Overall study status
Completed

Last Edited
07/02/2018

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Meeting the needs of the growing number of older people with complex health and social problems remains a challenge to the NHS and social care. As people continue to live longer, it is important to find better ways to support their health and well-being so that they can stay active and independent for as long as possible. It is estimated that around 44% of older people have symptoms of mild frailty. Common difficulties that can be experienced include getting tired more easily, feeling weaker, a loss of appetite, low mood or finding it harder to go outdoors regularly. Having early support with these sorts of difficulties can help to maintain independence for longer. Health promotion is a way of helping people to have more control over their health so that they can improve it. Health promotion programmes aimed at older people have been introduced in the NHS in recent years, as they have the potential to make a real difference. In this study, a home-base health and well-being promotion programme has been designed in order to help promote healthy aging. The aim of this study is to find out whether this programme is feasible an acceptable way of delivering health and well-being promotion to older people in the community.

Who can participate?
Adults over 65, living at home with symptoms such as feeling like everything is more of a struggle, loss of energy or muscle strength.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a personally tailored health and well-being promotion programme, delivered using a combination of home visits by a HomeHealth worker and telephone calls over a period of 6 months. Those in the second group continue to receive treatment as usual throughout the study. At the start of the study and after 3 and 6 months, participants in both groups will be asked to complete a number of questionnaires designed to assess their general health and mental well-being. At the end of the 6 month study, the possibility of conducting a larger trial is examined by reviewing

the number of participants who have taken part in the study and how many participants completed the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
November 2014 to March 2016

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

Who is the main contact?
1. Ms Kalpa Kharicha (public)
k.kharicha@ucl.ac.uk
2. Dr Kate Walters (scientific)

Contact information

Type(s)
Public

Contact name
Ms Kalpa Kharicha

Contact details
Department of Primary Care and Population Sciences
Hampstead Campus, Rowland Hill Street
London
United Kingdom
NW3 2PF
+44 20 7830 2392
k.kharicha@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Kate Walters

ORCID ID
https://orcid.org/0000-0003-2173-2430

Contact details
Dept. Primary Care & Population Health
University College London (UCL)
Royal Free Campus
Rowland Hill Street

London
United Kingdom
NW3 2PF

Additional identifiers

Protocol serial number
17444

Study information

Scientific Title
Home based health promotion for vulnerable older people

Study objectives
To develop and test feasibility/acceptability of a new home-based intervention to promote health and well-being of older people with early frailty.

For detailed study objectives and study protocol please see: http://www.nets.nihr.ac.uk/projects/hta/1219210

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Islington, 03/10/2014, ref: 14/LO/1698

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care, Ageing; Subtopic: Ageing, Ageing; Disease: All Diseases, All Ageing

Interventions
General Practices will identify eligible patients and invite them to take part. Participants will be randomised to receive the intervention or treatment as usual. Intervention visits will be recorded and assessed for content/fidelity.

The intervention, called "HomeHealth", was developed in the first phase of the study, using a co-design process. It is an assets-based intervention, with the emphasis on maintaining capability to perform tasks that are important to the individual and participating in activities that the individual takes pleasure in. It is underpinned by behaviour change theory and employs

techniques including goal-setting and breaking down tasks into manageable steps. Behaviour change aspects of the intervention will be based on the COM-B model, which is a behaviour system involving three essential conditions: Capability, Opportunity, and Motivation.

The content of the HomeHealth service will be tailored to the needs of the individual, and will include an assessment of four core areas known to impact on frailty: mobility (balance and muscle strength), diet and nutrition, social networks and mood. Other potential areas that may be included in the service (according to individual need) are: memory concerns, medication use, sensory impairment, pain, incontinence, needs of the individual as a carer, and social/practical factors (e.g. maintaining their home or managing finances).

The HomeHealth worker will offer an initial up to 6 appointments, with the option of a further 6 if required, over a maximum period of 6 months. The initial assessment visit will be face-to-face and subsequent appointments can be face-to-face or by telephone or skype as appropriate.

Those randomised to the control arm will receive treatment as usual. Both groups will receive a booklet of local services and healthy ageing advice at 6 months follow-up. The consort diagram below outlines the follow-up for both arms. The duration of follow-up is 6 months (i.e. immediately post the 6 months intervention period only) as this is a feasibility randomised controlled trial.

Intervention Type
Other

Primary outcome(s)
Feasibility is determined by successful recruitment and retention into the study, measured at the end of the trial period

Key secondary outcome(s))
1. Quality of life outcomes are measured using the EQ-5D questionnaire at baseline and 6 months
2. Activity levels are measured using the International Physical Activity Questionnaire – Extended (IPAQ-E) at baseline and 6 months
3. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline and 6 months
4. Capability adjusted life years are measured using ICECAP-O at baseline and 6 months
5. Mental well-being is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 6 months
6. Psychological morbidity is measured using the 12-item General Health Questionnaire (GHQ-12) at baseline and 6 months
7. Grip strength is measured using a dynamometer at baseline and 6 months
8. Anthropomorphic factors (weight, height and BMI) are measured at baseline and 6 months
9. Mobility is measured using gait speed at baseline and 6 months
10. Smoking is measured using participant interviews at baseline and 6 months
11. Cognitive functioning is measured using the Montreal Cognitive Assessment (MoCA) at baseline and 6 months
12. Patient demographics are self-reported at baseline
13. Social and community services uptake is measured using an adapted Client Service Resource Inventory at baseline, 3 and 6 months
14. Functioning is measured using the Modified Barthel index at baseline and 6 months
15. Frailty is measured using the electronic frailty index (from medical records, where possible)

at baseline and after 6 months follow-up
16. Prescribed medication is determined from medical records at baseline and after 6 months follow-up

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Aged 65 or over
2. Registered with one of participating General Practices
3. Score as 'pre-frail' (0.2 - 0.35 on the Frailty Index of cumulative deficits 9)
4. Community-dwelling (including people living in extra care housing)
5. Life expectancy greater than 6 months
6. Capacity to consent to participate in this research (including those with dementia or communication difficulties who retain capacity to consent)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Those living in care homes
2. On GP palliative care register
3. Those who lack capacity to consent (e.g. advanced dementia); those already case managed (e.g. by community matrons, some reablement schemes)

Date of first enrolment
15/12/2014

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
Department of Primary Care and Population Sciences
Hampstead Campus
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No