ISRCTN57066881 https://doi.org/10.1186/ISRCTN57066881

'The Home-based Older People's Exercise (HOPE) Programme: An Exercise Programme to Improve the Functional Status of Older People

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/05/2010	**Overall study status** Completed	
Last Edited 22/04/2014	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7886

Study information

Scientific Title
Improving the functional status of community dwelling, frail older people: the impact of a targeted exercise programme

Acronym
HOPE

Study objectives
Our exploratory randomised controlled trial is to investigate whether the HOPE Programme, a 12 week exercise programme designed for frail older people living at home, can improve functional status, daily living activities and quality of life. Participants will be stratified by baseline Timed Up and Go test and will undergo concealed random allocation to the HOPE Programme or usual care. The HOPE Programme, developed and refined by multiperspective qualitative methods involving our user group and experienced healthcare professionals, will be delivered by community based therapists to older people under the care of a case manager (e.g. Community Matron) or older people who are housebound, defined as being unable to leave the house without the assistance of another person, in Bradford, UK.

Primary outcome will be the Timed Up and Go test. Secondary outcomes will include Barthel Index of Activities of Daily Living, quality of life measures and self-reported falls. We will also record participant comorbidity and operationalised measures of frailty.

As of 23/02/2011 this record has been updated, in response to a protocol amendment which was approved on 01/10/2010 by the Bradford REC. All changes can be found under the relevant section with the protocol update date of 01/10/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bradford Research Ethics Committee approved on the 23rd June 2009 (ref: 09/H1302/55). Amendment approved on 01/10/2010.

Study design
Single centre randomised interventional treatment and prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Age and ageing

Interventions
Our exploratory randomised controlled trial is to investigate whether the HOPE Programme, a 12 week manualised exercise programme designed for frail older people living at home, can improve functional status, daily living activities and quality of life. Participants will be older people under the care of a case manager (e.g. Community Matron) or older people who are housebound, defined as being unable to leave the house without the assistance of another person, in Bradford, UK. Participants will be stratified by baseline Timed Up and Go Test (TUGT) and will undergo concealed random allocation to the intervention or control group. The intervention group will receive a copy of the HOPE Programme Exercise Manual and will also receive regular home visits from community-based therapists who will both teach the HOPE Programme to participants and provide support with compliance. Support will also be provided by regular telephone contact from therapists. Participants who are randomised to the control group will receive usual care from the case manager and GP.

Primary outcome will be the TUGT. Secondary outcomes will include Barthel Index of Activities of Daily Living, quality of life measures and self-reported falls. All outcomes will be measured at baseline and at 12 weeks post randomisation. We will also record participant comorbidity and operationalised measures of frailty.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Timed Up and Go test at 12 weeks post-randomisation

Secondary outcome measures
1. Barthel Index of Activities of Daily Living, measured at baseline and at 12 weeks post-randomisation
2. EQ5D measure of health, measured at baseline and at 12 weeks post-randomisation
3. Edmonton Frail Scale, measured at baseline and at 12 weeks post-randomisation
4.Geriatric Depression Score, measured at baseline and at 12 weeks post-randomisation

Overall study start date
01/04/2010

Completion date
30/09/2011

Eligibility

Key inclusion criteria
Current protocol (amendment approved 01/10/2010):
1. All patients who are under the care of a case manager (CM) in Bradford, UK. There are currently 21 CMs in Bradford, each with a caseload of approximately 50 patients
2. Older people who are housebound, defined as being unable to leave the house without the assistance of another person
3. Male and female, no age limits

Initial information at time of registration:
1. All patients who are under the care of a case manager (CM) in Bradford, UK. There are currently 21 CMs in Bradford, each with a caseload of approximately 50 patients.
2. Male and female, no age limits

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Planned sample size: 100

Key exclusion criteria
Current protocol (amendment approved 01/10/2010):
1. Severe dementia
2. Poorly controlled angina
3. Current participation in an alternative exercise programme (e.g. falls prevention programme, pulmonary rehabilitation)
4. Unable to stand from a chair and walk without the assistance of another person
5. Registered blind
6. Receiving palliative care

Initial information at time of registration:
1. Severe dementia
2. Poorly controlled angina
3. Current participation in an alternative exercise programme (e.g. falls prevention programme, pulmonary rehabilitation)
4. Unable to stand from a chair and walk without the assistance of another person
5. Registered blind

Date of first enrolment
01/04/2010

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Health Research
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Institute for Health Research (UK)

Sponsor details
Duckworth Lane
Bradford
United Kingdom
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Sponsor type
Research organisation

Website
http://www.bradfordresearch.nhs.uk/

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust (UK)

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/06/2011		Yes	No
Results article	results	01/09/2014		Yes	No