

Older people's exercise intervention in residential and nursing accommodation

Submission date 23/05/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/02/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Up to 40% of residential and nursing home residents are depressed. Both exercise and increased social interaction may have a positive effect on depression, and a group exercise programme that combines a social element and improved exercise tolerance is a promising non-drug approach to managing depression. We believe that for such a programme to be beneficial and sustainable residential home staff will also have to provide increased opportunities for residents to participate in safe physical activity in their daily lives. This study will examine whether a 'whole home' intervention, consisting of training for residential and nursing home staff and an ongoing, twice weekly, group exercise programme delivered by experienced physiotherapists, reduces the overall number of residents who are depressed after one year. We will also determine whether the programme reduces depression after six and 12 months amongst those residents identified as depressed at the start of the study.

Who can participate?

Permanent residents aged 65 or over in 77 residential or nursing homes in north east London and central England.

What does the study involve?

All able residents of all participating homes are invited to participate in a brief assessment lasting 15-20 minutes, measuring cognitive function, mobility, pain and quality of life. Participating homes are randomly allocated to either the exercise intervention or a comparison group. In the comparison group homes we implement a 'depression awareness programme' whereby we deliver brief-in house training to staff on recognising and managing depression, backed up by posters and leaflets and regular contact with study team members. In the exercise intervention group homes we implement a strategy to 'normalise' exercise into their daily routines. In addition to the depression awareness programme outlined above we provide a physical activation programme and a group-based exercise programme. The aim of the physical activation programme is to improve knowledge and awareness of the benefits of physical activity. We work with the managers at the homes and provide a review of mobility safety ensuring that appropriate walking aids and footwear are available to all residents. We work with the homes to review policies and strategies in place to promote physical activity and we identify a physical activity 'champion' within the home who will serve as the main point of contact with

the therapist and undertake a regular review of the organisation's progress. The group-based exercise programme is run by specially trained physiotherapists who run bi-weekly exercise classes in the homes. All residents are encouraged to attend these classes. Classes are appropriate to the levels of mobility of the residents. Before each class a brief risk assessment is carried out on each resident to assess their ability to participate. Classes last between 40 minutes to one hour.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Barts and The London NHS Trust (UK)

When is the study starting and how long is it expected to run for?

February 2008 to July 2011

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Martin Underwood

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 06/02/01

Study information

Scientific Title

Older People's Exercise intervention in Residential and nursing Accommodation

Acronym

OPERA

Study objectives

This study will explore depression levels amongst residents of residential and nursing homes and the impact of a whole-home intervention on the rates of depression over a 12-month period.

Hypothesis: What is the effectiveness and cost-effectiveness of a whole home physical activity intervention to reduce depression in older people in residential and nursing homes?

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/060201>

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/51270/PRO-06-02-01.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Joint University College London/University College London Hospital Committees on the Ethics of Human Research, 30/04/2007, ref: 07/Q0505/56

Study design

Cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Depression

Interventions

All able residents of all participating homes will be invited to participate in a brief baseline assessment lasting 15-20 minutes, measuring cognitive function, mobility, pain and quality of life. We will also seek consent/assent to complete a record check allowing us to collect data on medication, injurious falls and routine data.

After all baseline assessments have been done, we will randomise the homes and run the interventions for 12 months.

Control intervention homes:

We will implement a 'depression awareness programme' in control homes whereby we will deliver brief-in house training to staff on recognising and managing depression. This will be backed up by posters and leaflets and regular contact with study team members.

Active intervention homes:

We will implement a whole-home strategy in order to 'normalise' exercise into the daily routines of the homes. In addition the depression awareness programme outlined above we will provide a double-pronged intervention - a physical activation programme and a group-based exercise programme.

The physical activation programme will aim to:

1. Improve knowledge and awareness of the benefits of physical activity to residents, staff and relatives of residents.
2. We will work with managers at homes and provide an individualised review of mobility safety ensuring that appropriate walking aids and footwear are available to all individuals.
3. We will work with the homes to review policies and strategies in place to promote physical activity
4. We will identify a physical activity champion within the home who will serve as the main point of contact with the therapist and undertake regular review of the organisations progress.

The group-based exercise programme will be run by specially trained physiotherapists who will run bi-weekly exercise classes in the homes. All residents will be encouraged to attend these classes. Classes will be appropriate to the levels of mobility of residents. Before each class a brief risk assessment will be carried out on each individual to assess their ability to participate. Classes will last between 40 minutes to one hour.

Intervention Type

Behavioural

Primary outcome measure

Impact of the exercise intervention on depression levels measured through the use of the Geriatric Depression Scale (GDS) -15 at baseline and 12 months for all participants. For those who score highly on the GDS-15, we will also interview them at the 6-month stage in addition to the 2 timepoints for all residents.

Secondary outcome measures

1. Quality of life measured by EuroQoL 5 dimensions (EQ5D) at baseline and 12 months for all participants, and in addition at 6 months for those who score highly on the GDS-15.
2. Mobility measured by the Short Physical Performance Battery (SPPB) at baseline and 12 months for all participants, and in addition at 6 months for those who score highly on the GDS-15.

3. Injurious falls measured through home and hospital records. This will be collected at baseline, 3, 6, 9 and 12 months.
4. Cognitive function measured by the Mini Mental State Examination (MMSE) at baseline and 12 months for all participants, and in addition at 6 months for those who score highly on the GDS-15.
5. Pain, measured through participants' self reported level of pain on a five point scale at baseline and 12 months for all participants, and in addition at 6 months for those who score highly on the GDS-15.
6. Medication use, measured through their home records. This will be collected at baseline, 3, 6, 9 and 12 months.
7. Hospital Admissions. We will extract data on cause and duration of any hospital admissions during the study period from participants hospital records.

Overall study start date

01/02/2008

Completion date

31/07/2011

Eligibility

Key inclusion criteria

Assessment:

1. Permanent resident in residential or nursing home
2. Aged 65 or over
3. Consent/assent to assessment
4. Able to participate in baseline assessment

Record check:

5. Consent/assent

Exercise classes:

6. Able to transfer (with assistance from one person) from a wheelchair to a chair

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Approximately 1000 (residents of 80 residential and nursing homes)

Key exclusion criteria

Terminal or other serious illness

Date of first enrolment

01/02/2008

Date of final enrolment

31/07/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Barts and The London NHS Trust

London

United Kingdom

E1 2AT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

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Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

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	02/02/2011		Yes	No
Results article	results	02/02/2011		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	06/07/2013		Yes	No
Results article	results	27/04/2017		Yes	No