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Chair based exercise programme for older people in community settings

Submission date
29/01/2018

Recruitment status
No longer recruiting

Registration date
30/01/2018

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Exercise can improve health and quality of life in older people however not all older people are able to participate in the type of exercises which have been shown to be helpful. Some older people who find usual exercise programmes too strenuous may be encouraged to exercise while remaining seated, called chair based exercises (CBE). Our research group found limited research on CBE, with little consensus about what the treatment should be, or whether it has any effects on physical or mental health. A consensus development process has been completed with a group of experts to determine a set of principles of CBE. Agreement was reached on a definition, who should be using it and potential benefits. From this we have devised a treatment approach which we now want to ensure is deliverable and acceptable. As this is a complex intervention delivered in a variety of community settings we need further information before conducting a large trial and plan to undertake a feasibility study to answer the following: can the intervention be delivered as intended, how to recruit participants and centres, what are the best measures to evaluate if CBE has been beneficial, and is the intervention acceptable to patients, staff and family members? The aim of the study is to improve the health of older people through appropriate strategies to participate in physical activity.

Who can participate?
Adults aged 65 years and older who are willing to participate in a 12 week chair based exercise program or 12 week group therapy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the chair based exercise. This is done in hour twice weekly sessions for 12 weeks that are led by a physiotherapist. Each session includes a warm up, strength training, cardio, stretches and a cool down. Those in the second group are randomly allocated to one of two groups. Those in the first group receive no interventions. Those in the second group receive the group reminiscence sessions which are delivered by Age UK staff up to twice a week for 12 weeks. In these groups, participants share memories and experiences of the past. Participants are followed up three and six months after the programmes to assess how acceptable and feasible the study is.

What are the possible benefits and risks of participating?
This is a feasibility study and we will not know the benefits of the chair based exercise programme after this study. The exercises used in the programme are routinely used in clinical practice and the programme will be led by an experienced physiotherapist. Participants will be giving up your time to attend the programme and complete the measures for the study to help plan for a future study.

Where is the study run from?
Queens Medical Centre (UK)

When is the study starting and how long is it expected to run for?
October 2014 to March 2017

Who is funding the study?
National Institute for Health Research

Who is the main contact?
Miss Katie Robinson (Public)
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Contact information

Type(s)
Public

Contact name
Miss Katie Robinson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18200

Study information

Scientific Title
Chair based exercise (CBE) programme for older people in community settings: a feasibility study

Acronym
CBE Feasibility Study

Study objectives
The chair based exercise is programme will be able to be delivered and will be acceptable to older people and host centres.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 1, 30/01/2015, ref: 15/EM/0005

Study design
Randomised; Both; Design type: Treatment, Physical, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Specialty: Ageing, Primary sub-specialty: Ageing

Interventions
Participants are randomized to one of two groups. Centres are randomised by an independent statistician and are randomly allocated to either the intervention or the control group. Within the control group, centres are further randomised to usual care or an active control of group reminiscence therapy. Randomisation of centres are completed after the baseline data was taken. Due to the staggered nature of the intervention delivery the 4 centres in each cohort are randomised separately

1. Chair based exercise intervention: A group programme (max of 10 participants), 12 weeks, up to twice a week and up to an hour for each session. Led by a physiotherapist. Each session to include a warm up, progressive strength resistance training, cardiovascular interval training, endurance training, developmental stretches, cool down, and music will be used if appropriate.

2. Control: Participants in the control centres are randomised to receive either ‘group reminiscence sessions’ or no intervention. The group reminiscence sessions are delivered in up to 3 settings by Age UK staff up to twice a week for 12 weeks and each session lasts up to an hour. This involves taking part in a social group where participants can share memories and experiences of the past.

Participants in both arms complete baseline outcomes then post intervention (3 months from randomisation) and then 6 months after randomisation.

Intervention Type
Other

Primary outcome measure
Feasibility and acceptability of the study are measured at baseline, three and six months using:
1. Number of centres willing to take part
2. Number of participants willing to take part
3. Attrition rates
4. Characteristics of centres assessed using type of funding, number of attendees, function and mobility of participants.
5. Acceptability of research assessed using drop of rates, completion of questionnaires

Secondary outcome measures
1. Most appropriate outcomes for definitive trial (well-being, strength, mobility, function, progression to standing exercise, health related quality of life) at 3 and 6 months post intervention.
2. Tolerance to the intervention is assessed using adherence, adverse events, patient experience using qualitative interviews

Overall study start date
15/10/2014

Completion date
30/03/2017

Eligibility

Key inclusion criteria
Host centres
1. Located in the former Nottingham City or Nottinghamshire County PCT areas
2. Providing services for people 65 years and over

Participants
1. Willing to participate in 12 week CBE exercise programme or 12 week group reminiscence therapy
2. Unable to take part in standing exercise programmes using any of the following criteria:
2.1. Unable to complete Timed Up and Go
2.2. Timed Up and Go 20 seconds or greater
2.3. Unable to complete 4m walk test
2.4. 4 meter walk test slower than 0.6m/second

Participant type(s)

Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 117; UK Sample Size: 117

Key exclusion criteria
Host Centres
1. Nursing registered care homes
2. Active enforcement action by the Care Quality Commission at care home or centre

Participants of Intervention Study
1. Contraindications to exercise e.g.unstable angina
2. Unable to understand and follow instructions for exercise programme

Date of first enrolment
01/02/2015

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham University Hosptials NHS Trust
Derby Road
Nottingam
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and this submission is intended to be within a year of completing the trial. Additional study documents are held by the sponsor and are available from the contact author.

Intention to publish date
30/03/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Katie Robinson.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/04/2018		Yes	No
HRA research summary			28/06/2023	No	No