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Promoting physical activity in people aged 65+

Submission date
11/08/2008

Recruitment status
No longer recruiting

Registration date
12/08/2008

Overall study status
Completed

Last Edited
18/07/2016

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Exercise referral schemes have been running for years, where patients seeing their GP are typically 'prescribed' a short exercise programme in a leisure centre as treatment or to prevent health problems. It is well established that exercising can not only improve physical ability, but can reduce the risk of heart disease and emotional problems, such as depression, although we tend to exercise less as we get older. For many older people home exercise or group exercise in non-intimidating environments (e.g. community halls) will be more appealing. In this study we compare two exercise training programmes designed for older people. People attending them have improved their physical ability and confidence and continued to exercise afterwards. One is a group exercise class, supplemented by home exercise and monitored by the instructor; the other involves home exercise and is supported by a similarly aged person who will encourage and monitor them throughout the programme. Both need to be tested for their effectiveness and cost effectiveness with patients in primary care in the UK.

Who can participate?
Patients aged 65 and over at participating GP practices

What does the study involve?
Participating GP practices are randomly allocated to provide to their patients either a home-based exercise programme, a community-based exercise programme, or treatment as usual. We measure improvements in the patients' level of physical activity, well being and physical ability, and determine their perceptions about the exercise, factors relating to adherence and continuation of exercise, and the cost effectiveness of implementing both programmes.

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?
June 2008 to May 2013

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00726531

Protocol serial number
HTA 06/36/04

Study information

Scientific Title
Multi-centre cluster randomised trial comparing a community group exercise programme with home based exercise with usual care for people aged 65 and over in primary care

Acronym
ProAct65+

Study objectives
1. To determine the effect on continuation of exercise of two evidence based exercise programmes designed for older people, compared with usual care i.e. with no special interventions to promote physical activity
2. To determine the health benefits of the programmes to patients starting at various levels of physical activity, particularly the effects on physical and psychological status, health status and quality adjusted life years (QALYs)

3. To estimate the costs of the exercise interventions and to assess the cost-effectiveness of community group exercise, and home-supported exercise compared with usual care.
4. To determine the acceptability of the programmes, adherence rates, enabling factors and barriers to future implementation
5. To determine participants' perceptions of the value of exercise, and the predictors of continued exercise

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/063604
Protocol in: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0019/51373/PRO-06-36-04.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Local Research Ethics Committee 2, 23/06/2008, ref: 08/H0408/72

Study design
Cluster-randomised controlled multi-centre trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Falls risk in people aged 65 years and over

Interventions
Current interventions as of 21/04/2009:
This is a cluster randomised controlled trial using minimisation for allocation at the level of general practice in two centres (London and Nottingham/Derby). Practice staff will also be advised that they will not be informed of the practice's study group allocation until after they have given consent to take part in the study, and all eligible patients from the practice have been recruited.

Arm 1: Home-based exercise programme (OEP) (n = 400)
This exercise programme consists of a 30 minute programme of leg muscle strengthening and balance retraining exercises progressing in difficulty to be performed at home at least three times per week, plus participants will be advised to walk at least twice per week for up to 30 minutes at a moderate pace, for 24 weeks. Trained peer mentors will contact and visit the patients at their home to start the exercise programme with them and will follow-up with up to three more home visits / exercise sessions as the participants require.

Arm 2: Community-based exercise programme (FaME) (n = 400)
FaME consists of one hour long PSI delivered group exercise class in a local community centre for a maximum of 15 participants, and two 30 minute home exercise sessions (based on the OEP) per week, for 24 weeks. Participants will also be advised to walk at least twice per week for up to 30 minutes at a moderate pace.

Arm 3: 'Treatment as usual' group (n = 400)

Total duration of interventions: 24 weeks
Total duration of follow-up: 24 months from the end of the intervention

Previous interventions:
This is a cluster randomised controlled trial using minimisation for allocation at the level of general practice in two centres (London and Nottingham/Derby).

Home-based exercise programme (OEP):
This exercise programme consists of a 30 minute programme of leg muscle strengthening and balance retraining exercises progressing in difficulty to be performed at home at least three times per week, and a walking plan to be undertaken at least two times per week for 24 weeks. Trained peer mentors will contact and visit the patients at their home to start the exercise programme with them and will follow-up with up to three more home visits/exercise sessions as the participants require.

Community-based exercise programme (FaME):
FaME includes and extends the OEP. It will comprise one hour long, postural stability instructor (PSI) delivered group exercise class in a local community centre for a maximum of 15 participants, and two 30 minute home exercise sessions (based on the extended OEP) per week for 24 weeks. Participants will also be advised to walk at least twice per week for up to 30 minutes at a moderate pace.

There will also be a 'treatment as usual' group.

Total duration of interventions: 24 weeks
Total duration of follow-up: 24 months from the end of the intervention

Intervention Type
Behavioural

Primary outcome(s)
1. Proportions reaching the recommended physical activity (PA) target of at least 30 minutes of activity of moderate intensity on at least 5 days each week, measured using the Community Healthy Activities Model Program for Seniors (CHAMPS), Physical ACtivity in Elderly people (PACE) and Phone_FITT questionnaires. The proportion reaching the recommended target will be compared between treatment groups using random effects logistic regression to estimate odds ratios and 95% confidence intervals (CI).

All primary and secondary outcome measures will be conducted at 6, 12, 18 and 24 months after intervention is completed.

Please note that the following primary outcome measure has been removed as of 21/04/2009:
2. Euroqol EQ-5D scores transformed into quality adjusted life years (QALYS)

Key secondary outcome(s))
Current secondary outcome measures as of 21/04/2009:
1. The direct health benefits i.e. functional and psychological status; the rate of falls and the number and nature of falls, and fear of falling.
2. Stage of change, self efficacy for exercise and physical self-perception (self-esteem relative to the physical domain), which includes measurement of perceived importance (the degree to which participants value their physical condition, body image and physical strength) to inform

predictors of exercise adherence and continuation, and participants judgement of the value or importance of physical activity.
3. Quality adjusted life years (QALYS), using SF-12® Health Survey scores transformed into EQ-5D utility weights.
4. The direct costs of delivering both exercise programmes, and the cost offsets identified from a comparison of the health and social service utilisation of participants in all groups during the study period.

All primary and secondary outcome measures will be conducted at 6, 12, 18 and 24 months after intervention is completed.

Previous secondary outcome measures:
1. The direct costs of delivering both exercise programmes, and the health and social service utilisation of participants during the study period
2. The direct health benefits i.e. functional and psychological status; the rate of falls and the number and nature of falls, and fear of falling
3. Stage of change, self efficacy for exercise and physical self-perception (self-esteem relative to the physical domain), which includes measurement of perceived importance (the degree to which participants value their physical condition, body image and physical strength) to inform predictors of exercise adherence and continuation, and participants' judgement of the value or importance of physical activity

All primary and secondary outcome measures will be conducted at 6, 12, 18 and 24 months after intervention is completed.

Completion date
31/05/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/04/2009:
1. Those aged 65+ who can walk around independently indoors and outdoors (with or without a walking aid)
2. Physically able to take part in a group exercise class
3. Those who are not already receiving any long term physiotherapy
4. Those who do not fulfil the exclusion criteria

Previous inclusion criteria:
Eligible patients (both males and females) will be those aged 65+ who can walk around at home (i.e. not chair or bed bound) and would be physically able to take part in a group exercise class.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Current exclusion criteria as of 21/04/2009:
1. Three or more falls in the previous year ("frequent fallers")
2. Resting BP >180/100 mmHg; tachycardia >100 bpm; those considered by their GP to have uncontrolled hypertension; significant drop in BP during exercise recorded in the medical records or found at initial assessment
3. Psychiatric conditions which would prevent participation in an exercise class, for example, psychotic illness
4. Uncontrolled medical problems, which the GP considers would exclude patients from undertaking the exercise programme; for example, acute systemic illness such as pneumonia, poorly controlled angina, acute rheumatoid arthritis, unstable or acute heart failure
5. Conditions requiring a specialist exercise programme, for example, uncontrolled epilepsy, significant neurological disease or impairment; unable to maintain seated upright position or unable to move about independently indoors
6. Not living independently (e.g., residential or nursing care)
7. Significant cognitive impairment (unable to follow simple instructions)
8. Already receiving long term physiotherapy

Previous exclusion criteria:
1. Three or more falls in the previous year i.e. frequent fallers (only excluded if their GP does not consent to them taking part in the exercise programme)
2. Resting blood pressure (BP) >180/100 mmHg; tachycardia >100 bpm; those considered by their GP to have uncontrolled hypertension; significant drop in BP during exercise recorded in the medical records or found at initial assessment
3. Psychiatric conditions or physical abilities which would prevent participation in an exercise class, for example psychotic illness, acute systemic illness (e.g. pneumonia); uncontrolled visual or vestibular disturbances which the GP considers would exclude patients from undertaking the exercise programme; poorly controlled angina; acute rheumatoid arthritis, unstable or acute heart failure; or conditions requiring a specialist exercise programme e.g. uncontrolled epilepsy, significant neurological disease or impairment; unable to maintain seated upright position or unable to move about independently indoors
4. Not living independently (e.g. residential care)
5. Significant cognitive impairment (unable to follow simple instructions)
6. Already receiving long term physiotherapy

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
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NW3 2PF

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012		Yes	No
Results article	results	01/07/2013		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	results	28/05/2015		Yes	No
Results article	results	01/11/2015		Yes	No
Results article	results	02/12/2015		Yes	No
Results article	results	01/11/2016		Yes	No
Protocol article	protocol	18/01/2010		Yes	No