Multicentre cluster randomised trial comparing a community group exercise programme and home-based exercise with usual care for people aged 65 years and over in primary care

Steve Iliffe,[1]* Denise Kendrick,[2] Richard Morris,[1] Tahir Masud,[3] Heather Gage,[4] Dawn Skelton,[5] Susie Dinan,[1] Ann Bowling,[6] Mark Griffin,[1] Deborah Haworth,[1] Glen Swanwick,[2] Hannah Carpenter,[2] Arun Kumar,[2] Zoe Stevens,[1] Sheena Gawler,[1] Cate Barlow,[1] Juliette Cook[2] and Carolyn Belcher[2]

[1]Research Department of Primary Care and Population Health, University College London, London, UK
[2]Division of Primary Care, University of Nottingham, Nottingham, UK
[3]Clinical Gerontology Research Unit, Nottingham University Hospitals NHS Trust, Nottingham, UK
[4]Department of Economics, University of Surrey, Guildford, UK
[5]School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK
[6]Health Sciences, University of Southampton, Southampton, UK

*Corresponding author

Declared competing interests of authors: Dawn Skelton and Susie Dinan are directors for Later Life Training, who deliver FaME and OEP training to health and leisure professionals across the UK. The other authors declare that they have no competing interests.

Published August 2014
DOI: 10.3310/hta18490

Scientific summary

The ProAct65+ study

Health Technology Assessment 2014; Vol. 18: No. 49
DOI: 10.3310/hta18490

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Objective

The primary objective of the ProAct65+ trial was to determine the effect of two evidence-based exercise programmes designed for older people, compared with usual care, on the achievement of recommended physical activity (PA) targets 12 months after cessation of the intervention. A pragmatic, three-arm parallel design, cluster-controlled trial was employed, with allocation at the level of general practice. Participants were from UK-based general practices in London, Nottingham and Derby which agreed to participate in the trial and their patients aged ≥65 years, who gave informed consent to participate.

Eligibility

Practices were eligible to participate if they committed themselves for the duration of the trial and if community venues suitable for exercise classes were available in their catchment area. General practices were recruited with assistance from the Primary Care Research Networks (PCRNs) in London (Greater London PCRN) and Nottingham/Derby (East Midlands and South Yorkshire PCRN). Practices produced lists of patients aged ≥65 years, and screened patients using the exclusion criteria. Sampling varied by practice size, with all patients aged ≥65 years being invited where there were fewer than 600 patients in this age group. Larger practices were provided with a random number list to identify up to 600 patients to invite. Patients were sent trial invitation letters from their usual general practitioner (GP).

Patients aged ≥65 years who were independently mobile (with or without a walking aid) and physically able to take part in a group exercise class were eligible to join the study. Patients were excluded if they had experienced three or more falls in the previous year, had unstable clinical conditions, would be unable to follow instructions about exercise safely or were receiving palliative care. In addition, those who were already exercising at, or above, the target level were identified during the telephone call to arrange an assessment visit, and excluded. Exclusion criteria were further reviewed by the research team at the participant's recruitment visit and GPs confirmed eligibility for all participants.

Design

The trial had three arms:

1. the home-based Otago Exercise Programme (OEP)
2. a community-based group exercise programme [Falls Management Exercise (FaME)]
3. usual care.

Home-based exercise programme (Otago Exercise Programme)

This comprised 30 minutes 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 for up to 30 minutes at a moderate pace to be undertaken at least two times per week for 24 weeks. Participants received an instruction booklet and ankle cuff weights (starting at 1 kg) to provide resistance for strengthening exercises. The programme was tailored for, and introduced to, participants by trained research staff in a group session or at participants' homes if they could not attend the session. Where available, trained peer mentors (PMs) visited participants at home to start the exercise programme and carried out a further four home visits (as the participants required) and up to 12 telephone contacts.

Community-based group exercise programme (Falls Management Exercise)

The FaME programme comprised a 1-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 per week (based on the OEP, with an instruction booklet) for 24 weeks. Participants were advised to walk at least twice per week for up to 30 minutes at a moderate pace. The programme included leg muscle strengthening and balance retraining exercises that progressed in difficulty, progressive trunk and arm muscle strengthening, bone loading, endurance (including walking) and flexibility training, functional floor skills and adapted tai chi. Resistance bands and mats were used throughout the programme. Group exercises included retraining of the ability to get up from, and down to, the floor (using a backward chaining approach), floor exercises to improve balance, trunk and lower body strength and flexibility, and coping strategies to reduce the risk of complications resulting from a long lie and its complications.

Usual care

Participants in the usual-care arm were not offered either the OEP or FaME programmes, but were free to participate in any other non-trial-related exercise.

Outcomes

The primary outcome was the proportion of participants reaching or exceeding the national recommended target of $\geq$150 minutes of moderate to vigorous physical activity (MVPA) per week at 12 months after the cessation of the intervention. This was measured using the Community Healthy Activities Model Program For Seniors (CHAMPS) scale. This was supplemented by two other PA measures, the Physical Activity Scale for the Elderly (PASE) and a telephone questionnaire, Phone-FITT.

Secondary outcomes included:

1. direct health benefits (i.e. functional and psychological status, the rate of falls, the number and nature of falls, and fear of falling)
2. self-efficacy for exercise and participants' judgement of the value or importance of PA
3. health-related quality of life and quality-adjusted life-years (QALYs)
4. the NHS and private (participant) costs of each exercise programme, and possible cost offsets, identified from a comparison of health and social service utilisation of participants in all groups during the study period.

Allocation, blinding and withdrawal

Each practice was allocated to a treatment arm once all participants within that practice were recruited. General practices, their participants, and researchers having contact with practices and participants were blind to treatment arm until all participants within a practice were recruited. It was not possible to blind participants to treatment arm because of the nature of the interventions. Participants could withdraw from the trial at their own request. Data collected to the date of withdrawal were used in the analysis unless the withdrawing participant requested otherwise.

Analysis

Comparisons between treatment arms were made using random-effects models to allow for clustering between practices. Linear regression models were used for continuous outcome variables, logistic models for binary outcome variables and negative binomial models for data on rate of falls. The primary outcome was the proportions reaching the recommended PA target of at least 150 minutes of activity of moderate to vigorous intensity each week. The CHAMPS score measuring minutes of PA followed a log-normal distribution and contained many zeros, and was therefore transformed to $\log_e$ (CHAMPS score+1). The proportions whose weekly MVPA exceeded 150 minutes, and those who reported zero MVPA,

were tabulated for all time points. All analyses were adjusted for variables used in minimisation (study site, deprivation and practice list size), and for baseline values of the outcome measures. Differential effects of the intervention by age (> or <75 years) and sex were assessed for the primary outcome measures by adding terms for the interaction.

Analysis of each outcome measure was primarily conducted on complete cases. For the primary outcome, analysis was repeated with multiple imputation of missing data firstly for those who had 12 months' post-intervention data from the telephone-administered Phone-FITT PA questionnaire, using the Phone-FITT score, and then for all participants, using all variables in the substantive model and Phone-FITT (at baseline and 12 months). This was done with, and without, stratification by practice.

The full analysis set comprised all randomised participants for whom one post-baseline assessment of the primary outcome measure was available. People who did not attend classes were included in an intention-to-treat analysis.

Economic analysis

The costs of the exercise interventions were calculated from NHS and participant perspectives using study protocols and records, and participant diaries, respectively. The extent to which costs of the interventions were offset by savings elsewhere in the health-care system was explored through analysis of primary care service utilisation, and hospital treatment for injurious falls during the 6-month intervention period and for the 12 months post intervention. QALY gains from exercise were investigated using European Quality of Life-5 Dimensions utility indices obtained by transforming Short Form questionnaire-12 items scores. Cost-effectiveness was calculated using the primary PA outcome (proportion achieving at least 150 minutes of moderate or vigorous intensity PA per week) at 12 months post intervention.

Safety

The medical records were checked by GPs for all recruited participants for suitability prior to commencement of the interventions. Safe exercise guidelines were followed, pre-exercise assessments were conducted, and exercise intensity and difficulty were increased with caution to minimise injury risk. Adverse events (AEs) and serious AEs were assessed for seriousness, expectedness and causality, and recorded and monitored until resolution, stabilisation, or until shown that the study intervention was not the cause.

Ethics and consent

Written informed consent was obtained from all participants to participate in the trial, and to allow researchers to review medical records for the purposes of measuring service use and AEs. Ethical approval was granted to the trial from Nottingham Research Ethics Committee 2 (application number 08/H0408/72). National Health Service Research & Development approval was granted by NHS Nottingham City, Nottinghamshire County, Derby City, Derbyshire County and Westminster, Brent, Harrow, Hounslow and Barnet & Enfield Primary Care Trusts.

Results

Forty-three practices were recruited to the trial. The target of recruiting 12 PSIs per site was achieved and FaME arm classes were fully staffed. Thirty-eight PMs were recruited, trained and deployed in the trial: 31 in London and seven in the Nottingham/Derby practices. In total, 20,507 patients were invited to participate. Expressions of interest were received from 2752 (13%) patients and 1256 (6% of those approached) consented. Three hundred and eighty-seven participants were allocated to the FaME arm, 411 to the OEP arm and 458 to the usual-care arm. One participant withdrew after consenting but before baseline assessment could be completed, and one withdrew during the intervention period, requesting deletion of all data. Trial participants performed below normative levels on most scales, suggesting that they were a population which would benefit from increased PA.

Recruitment and retention

Of the 1256 randomised study participants, 830 (66.1%) remained in the trial at the primary end point, 12 months after the end of the intervention period. The recruitment of older people who would benefit from increasing their PA (as shown by their performance on a range of functional and psychological measures) to trials is possible in general practice. Retention of trial participants in the study remained problematic, despite the efforts made to increase it.

Primary outcome

The proportions reporting at least 150 minutes of MVPA per week rose from 40% to 49% in the FaME arm, from 41% to 43% in the OEP arm, and from 37.5% to 38.0% in the usual-care arm. Participants in the FaME arm, compared with the usual-care arm, reported more MVPA at 12 months after the intervention, adding around 15 minutes of MVPA per day. There was no statistically significant increase in MVPA in the OEP arm compared with the usual-care arm. The interventions were safe. There were no statistically significant differences in possible or probable adverse reactions between arms, during or after the intervention period.

Secondary outcomes

In the 12 months after the close of the intervention phase there was a statistically significant reduction in falls in the FaME arm compared with the usual-care arm [incidence rate ratio 0.74, 95% confidence interval (CI) 0.55 to 0.99; $p=0.042$]. Although there were fewer falls in the OEP arm, there was no statistically significant difference between the OEP and usual-care arms.

Scores on the PASE showed a small, but statistically significant, benefit for FaME compared with usual care (difference in means 11.2, 95% CI 0.2 to 20.2; $p=0.046$), but no statistically significant benefit for OEP (difference in means 7.5, 95% CI –3.8 to 18.8; $p=0.20$). Significant improvements were seen in balance confidence for both intervention arms at 12 months post intervention. The mean difference for FaME compared with usual care was –0.529 (95% CI –0.998 to –0.061; $p=0.027$), while the mean difference for OEP compared with usual care was –0.545 (95% CI –1.033 to –0.057; $p=0.029$). Participants in the FaME and OEP arms were significantly less likely to dismiss exercise as not beneficial and, in the FaME arm, were more likely to be positive about exercise, 12 months after the end of the interventions. There were no other statistically significant differences between intervention arms and the usual-care arm in self-efficacy, mental and physical well-being, quality of life, balance confidence, social networks, falls risk or functional abilities.

Economic analysis

The FaME programme is more expensive than OEP delivered with PMs (£269 vs. £88 per participant in London; £218 vs. £117 in Nottingham). There were no differences in primary care service use between groups, or in costs of hospital treatment for injurious falls over the 6-month intervention period or the subsequent 12 months. The study failed to find a significant difference between the groups in terms of QALYs. As the FaME programme, when compared with usual-care, results in 14% more participants achieving the target of 150 minutes of MVPA at 12 months post intervention, the cost per extra person exercising was £1920 in London and £1560 in Nottingham (mean £1740).

Conclusions

The FaME programme significantly increased MVPA and a significantly higher proportion of community-dwelling older adults reached the recommended target for 150 minutes of MVPA per week compared with usual care up to 12 months after the end of the intervention. No significant effect was found for the OEP on MVPA compared with usual care. The FaME programme significantly reduced the number of falls in the 12 months following the end of the intervention compared with usual care, but no significant effect was found for the OEP on the number of falls.

The FaME intervention increased PA levels, and reduced falls, but further studies are needed to measure attenuation of these effects over time and to test the impact of reinforcement of the intervention. Ways of recruiting the less-active population need further exploration. Community-based exercise programmes proposing to use PMs should explore the feasibility of this prior to embarking on the programme, and strategies to optimise PM motivation and involvement need further investigation.

Trial registration

This trial is registered as ISRCTN43453770.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 06/36/04. The contractual start date was in June 2008. The draft report began editorial review in October 2013 and was accepted for publication in February 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).