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The PACE Study: physical activity facilitation for older adults

Submission date 25/10/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2013	**Overall study status** Completed	
Last Edited 03/09/2019	**Condition category** Not Applicable	

Plain English Summary
Background and study aims
As people live longer, their risk of disability increases. Disability can affect quality of life and increase health and social care costs. It is therefore important to prevent or delay disability in the elderly by identifying an effective intervention to improve the lives of older people. There is evidence that physical activity may reduce the risk of age-related disability. Increasing physical activity levels in older adults is therefore important, but to date no physical activity intervention has been shown to substantially change physical activity behaviour in this age group. A new behavioural intervention known as Physical Activity Facilitation (PAF) has been developed for use with older adults. The aim of the programme is to keep older people active and independent as they age by encouraging individuals to incorporate physical activity into their everyday lives. This study aims to assess the feasibility of using the PAF intervention as a means of increasing physical activity and physical performance in older adults.

Who can participate?
Non-disabled inactive community-dwelling men and women aged 65 and older.

What does the study involve?
Participants will be randomly allocated into either the intervention group or the control group. Intervention group participants will receive up to three face-to-face visits and up to nine telephone support phone calls with a trained physical activity facilitator. Sessions will be delivered flexibly over a six-month period. Control group participants will receive written materials promoting a healthy lifestyle. Every participant will be invited back to a follow-up clinic after six months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Primary care practices across Bristol and the surrounding areas (UK)

When is the study starting and how long is it expected to run for?
January to July 2015

Who is funding the study?
National Institute for Health Research (NIHR) and Avon Primary Care Research Collaborative (APCRC) (UK)

Who is the main contact?
Dr Gemma Morgan
gemma.morgan@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gemma Morgan

ORCID ID
http://orcid.org/0000-0003-2472-9309

Contact details
School of Social & Community Medicine
Canynge Hall
39 Whatley Road
Clifton
Bristol
United Kingdom
BS8 2PS
-
gemma.morgan@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15367

Study information

Scientific Title
Physical activity facilitation to improve functional ability and independent living in older people at risk of disability: a feasibility study and exploratory pilot randomised controlled trial

Acronym
PACE

Study hypothesis
As people live longer, their risk of disability increases. Disability can affect quality of life and increase health and social care costs. Preventing or delaying disability in the elderly is therefore an important public health objective, and identifying an effective intervention could improve the lives of many older people.

There is evidence that physical activity may reduce the risk of age-related disability. Increasing levels in older adults is therefore important, however to date no physical activity intervention has been shown to substantially change physical activity behaviour in this population. A new theory-driven behavioural intervention, using physical activity facilitation, has been effective in producing a significant and sustained increase in physical activity in adults with depression. This programme aims to encourage people to incorporate physical activity into their everyday life. The programme is based on a psychological theory of behaviour called self determination theory (SDT). SDT proposes that real and sustained changes in behaviour only occur once an individual feels competent in the behaviour, autonomous in their decisions about that behaviour, and related or connected to others.

A similar physical activity programme, known as Physical Activity Facilitation (PAF), has been developed for use with older adults. The aim of the programme is to keep older people active and independent as they age. The programme lasts for six months and involves up to three face-to-face visits and up to nine telephone support phone calls between an individual and a physical activity facilitator. The present study aims to assess the feasibility of using this SDT-based intervention, customized for an older population, as a means of increasing physical activity and physical performance. Feasibility will be explored using a pilot randomized controlled trial design and will incorporate a mixed-methods process evaluation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/YH/0319

Study design
Inteventional single-centre randomised controlled exploratory pilot trial; Design type: Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

Condition

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Intervention: Physical Activity Facilitation (PAF) involves:
1. Assessing current attitudes to physical activity and perceived barriers.
2. Utilising motivational interviewing techniques to engage the patient's own motivation to integrate physical activity into their lifestyle, rather than providing simple advice.
3. Negotiating and offering choice of physical activity modes and of rate of progression.
4. Using appropriate behavioural strategies to support changes in physical activity and to enhance self-efficacy.

Intervention arm participants will receive up to three face-to-face visits and up to nine telephone support phone calls with a trained physical activity facilitator (PAF). Sessions will be delivered flexibly throughout a six month period.

Control arm participants will receive age-appropriate written materials promoting a healthy lifestyle. These will be posted to participants during months one and four.

Every participant will be invited back to outcome measures at a follow-up clinic six months after they were randomised or six months after they received the first PAF session, whichever is the later.

Intervention Type
Behavioural

Primary outcome measure
Short Physical Performance Battery (SPPB); Timepoint(s): At baseline: month 0, at follow-up: month 6

Secondary outcome measures
1. Accelerometer data on physical activity; Timepoint(s): At baseline: month 0, at follow-up: month 6
2. Autonomy support; Timepoint(s): At baseline: month 0, at follow-up: month 6
3. Basic psychological needs; Timepoint(s): At baseline: month 0, at follow-up: month 6
4. Cognitive function (Montreal Cognitive Assessment); Timepoint(s): At baseline: month 0, at follow-up: month 6
5. Grip strength; Timepoint(s): At baseline: month 0, at follow-up: month 6
6. Health service utilisation from routine medical records; Timepoint(s): At baseline: month 0, at follow-up: month 6
7. Lawton scale of instrumental activities; Timepoint(s): At baseline: month 0, at follow-up: month 6
8. Mood (Geriatric Depression Scale); Timepoint(s): At baseline: month 0, at follow-up: month 6
9. Motivation for physical activity; Timepoint(s): At baseline: month 0, at follow-up: month 6
10. Physical activity outcome expectations scale; Timepoint(s): At baseline: month 0, at follow-up: month 6 10. Physical activity questionnaire (PASE); Timepoint(s): At baseline: month 0, at follow-up: month 6
11. Psychological Need Satisfaction in Exercise; Timepoint(s): At baseline: month 0, at follow-up: month 6
12. Quality of life (EQ-5D); Timepoint(s): At baseline: month 0, at follow-up: month 6
13. Social support; Timepoint(s): At baseline: month 0, at follow-up: month 6

Overall study start date
01/01/2014

Overall study end date
01/07/2015

Eligibility

Participant inclusion criteria
1. Male and female aged 65 years or older
2. Community-dwelling, including those in warden-controlled accommodation
3. Inactive: undertaking less than 150 minutes of moderate-to-vigorous physical activity per week
4. Non-disabled at baseline: able to complete a 4m walk at a speed of 0.8m/s or greater, without sitting, leaning, using walking aids or another person. This practical assessment is highly predictive (>90%) of successfully completing the well-established 400m walk test within 15 minutes
5. At risk of subsequent disability: scoring less than 10 out of 12 on the Short Physical Performance Battery (SPPB)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 60

Total final enrolment
51

Participant exclusion criteria
1. Unable to participate in the intervention or unable to complete the outcome assessments due to speech, language, or sensory problems
2. Resident in a nursing home
3. Plans to move outside of the study area within six months of the screening clinic visit or plans to be away for more than eight consecutive weeks during this period
4. Currently participating in exercise-on-prescription or a physical rehabilitation programme or study
5. A documented or patient-reported medical condition including but not limited to:
5.1. Severe uncontrolled arthritis, e.g. awaiting joint replacement, that would interfere with the ability to participate in the intervention arm
5.2. Lung disease requiring regular use of corticosteroids or of supplemental oxygen
5.3. Cardiovascular disease, including unstable angina, clinically significant valvular disease, uncontrolled and symptomatic cardiac arrhythmias, uncontrolled and symptomatic heart failure, suspected or known dissecting aneurysm
5.4. Past history of cardiac arrest or presence of an implantable cardiac defibrillator

5.5. Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
5.6. Moderate or severe cognitive impairment or dementia
5.7. Severe uncontrolled psychiatric illness
5.8. Multiple falls, i.e. two or more falls in the previous three months.
6. Investigator concern about an individual's safety or ability to adhere to the intervention if enrolled in the trial

Participants will not be medically screened for the above conditions, however they will be asked about the presence or absence of each condition on enrollment. It is important that no patient is inappropriately encouraged to participate in the trial and therefore the eligibility of each participant will be judged clinically by the investigator on a case-by-case basis.

Recruitment start date
01/04/2014

Recruitment end date
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Social & Community Medicine
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Clinical Academic Training

Results and Publications

Publication and dissemination plan
A paper describing the findings is currently under consideration by a journal; the aim is to publish this in early 2019. A second paper describing the process evaluation will follow later in 2019.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to constraints around participant identification and consent. Reasonable requests for anonymised/aggregate data will be considered by the corresponding author.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/03/2015		Yes	No
Results article	results	08/03/2019		Yes	No
HRA research summary			28/06/2023	No	No