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The REACT (retirement in action) study

Submission date 13/06/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2016	**Overall study status** Completed	
Last Edited 11/07/2024	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Physical inactivity is one of the strongest predictors of physical disability in older adults. Older people who remain fit and active are more likely to be more mobile and independent, as well as improved cognitive (thinking, learning and memory) function, mental well-being and overall quality of life. Recent research has shown that the most active older people need fewer prescriptions and are less likely to be admitted to hospital in an emergency. There is also strong evidence that higher levels of physical activity can help protect against cardiovascular disease (disease of the heart and blood vessels), diabetes and some cancers as well as reducing the risk of depression, dementia and Alzheimer's disease. The REACT study is based on LIFE, a US programme which successfully proved that physical activity prevents loss of mobility in older adults. The aim of this study is to find out whether the REACT programme can help reduce mobility-related problems in older adults.

Who can participate?
People aged over 65 years old who are starting to find everyday activities such as walking, climbing stairs and getting up from a chair difficult.

What does the study involve?
Parents are randomly allocated to one of two groups. Those in the first group take part in the REACT programme. This involves taking part in group sessions for 12 months which involve cardio, strength training, co-ordination and flexibility exercises based in leisure centres/health clubs. Sessions will be twice weekly in the Adoption phase (weeks 1-12) and weekly in the Maintenance phase (week 13-52). The sessions are designed to be enjoyable as well as involving social activities after the exercise sessions. Those in the second group are given booklets containing information about social events in the local community and health education material with a focus on healthy eating. After six months, these participants are invited to a 60-minute group session where they receive information about a variety of healthy ageing topics. After 12 months, participants are invited to a further 60-minute session where they receive further information about social activities in the area, as well as a 45-minute session after 24 months to be provided with more information about health and well-being. Participants in both groups complete a number of questionnaires and physical tests at the start of the study and again after six, 12 and 24 months.

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

Where is the study run from?
University of Bath (UK)

When is the study starting and how long is it expected to run for?
September 2015 to May 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
169691

ClinicalTrials.gov number

Secondary identifying numbers
20578, IRAS 169691

Study information

Scientific Title

A randomised controlled trial and economic evaluation of a community--based physical activity intervention to prevent mobility--related disability for retired older people: the REACT (REtirement in ACTion) trial

Acronym
REACT

Study objectives
Primary hypothesis:
Compared with the control group, participants allocated to receive the REACT programme will have significantly reduced mobility-related limitations, as indicated by SPPB score, at 24 months of follow-up.

Secondary hypothesis:
Compared with the control group, participants allocated to the REACT programme will significantly increase their levels of moderate intensity physical activity, health-related quality of life, cognitive function, physical functional ability, mental well-being and have reduced fatigue at 24 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Surrey Research Ethics Committee, 21/12/2015, ref: 15/LO/2082

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Imaging, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

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

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants will receive a standardised 12-month programme designed for delivery in leisure/community centres and fitness/health clubs where low-cost late morning capacity is available (which coincides with the periods where older adults are most likely to be out and about) and where suitable space for social activities is available. REACT will be delivered by qualified exercise professionals with experience in delivery of exercise classes in the community. Sessions will be organised as group activities with up to 15 participants per group, but there will be individually tailored elements for both aerobic exercise (where intensity will be tailored to existing aerobic capacity /fitness) and strength work (where exercises will be tailored to existing muscle strength). Activities will include cardiovascular, strength, balance and flexibility exercises and daily lifestyle-based activity in the form of neighbourhood walking and active travel. Breaks in sedentary time will also be promoted. Social activities such as post-exercise coffee meetings and community-based activities will be organised to encourage a 'social club' atmosphere.
REACT will be delivered in two progressive phases (Adoption and Maintenance) and established behaviour change techniques will be used to enhance motivation, to make realistic plans for sustainable activity, to pre-empt and overcome barriers, to engage social support and to use self-monitoring and self-regulatory techniques to support the maintenance of behaviour change. REACT will be delivered by qualified exercise professionals with experience in delivery of exercise classes in the community. The REACT co-applicants will provide training in intervention delivery methods, including detailed session plans to ensure consistency and fidelity in programme delivery.
The intervention includes a long-term target of 150 minutes of moderate intensity activity per week, which is approached progressively and takes place in part beyond the structured sessions. Participants will be encouraged to seek opportunities for physical activity throughout the day, through active hobbies such as gardening, and use of stairs, leisurely walks with friends and active travel. Supplementary instructions, 'home-friendly' exercises and written materials will be supplied to encourage generalisation of exercise performance to the home environment. Principles of progression and adaptation will be applied in order to build exercise training demand at a rate that is appropriate for current levels of function and activity. Participants will be trained to use ratings of perceived exertion and self-assessment of breathing as a method of regulating physical activity to moderate intensity levels. The initial focus is to orient participants to the concept of strength training, to build confidence in performing and completing the exercises, and to introduce the concept of training progression. The supervised setting will allow instructors to tailor the programme to individual needs and abilities early on, so as to prevent early dropout and through in-session interactions and discussion to facilitate the building of self-efficacy and support, which have been found to be key to long-term physical activity maintenance.

Control group: Participants will be given a booklet with social events and activities in their local community and a booklet with health education material focusing on healthy eating. After the completion of the six month assessment, control participants will be invited to one 60-minute group session where they will receive information on a variety of healthy ageing topics including prevention and health care. After 12-month data collection, controls will be invited to a further 60-minute group session and information about local social activity opportunities will be provided. After the 24-month data collection, controls will be invited to a final 45 minute group session. They will be provided with more information about health and well-being focussing on active living and importance of functional ability, and taster session vouchers for activities in their local community.

Participants in both groups are followed up after 6, 12 and 24 months.

Intervention Type
Behavioural

Primary outcome measure
Functional performance is measured using the Short Physical Performance Battery (SPPB) score at baseline, 6, 12 and 24 months.

Secondary outcome measures
1. Minutes of moderate intensity physical activity as measured by wrist-worn accelerometers at baseline, 6, 12 and 24 months
2. Sedentary time and breaks in sedentary time per day assessed by wrist-worn accelerometers at baseline, 6, 12 and 24 months
3. Self-reported physical activity (PASE questionnaire) at baseline, 6, 12 and 24 months
4. Hand grip strength of the dominant hand using a digital dynamometer at baseline, 6, 12 and 24 months
5. Ageing Well Profile Social scale (6 items) at baseline, 6, 12 and 24 months
6. Activities of daily living (ADL) (EQ-5D, SF-36, MAT-sf) at baseline, 6, 12 and 24 months
7. The UK Biobank Healthy Minds Questionnaire (memory, attention and executive function) at baseline, 6, 12 and 24 months
8. The incremental cost-effectiveness of the REACT intervention (EQ-5D, SF-36) at baseline, 6, 12 and 24 months
9. Pain (Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, 6, 12 and 24 months
10. Sleep Condition Indicator at baseline, 6, 12 and 24 months
11. Medical history at baseline, 6, 12 and 24 months
11. Falls Inventory at baseline, 6, 12 and 24 months
12. Health and Social Service Usage at baseline, 6, 12 and 24 months
13. Process Evaluation at 24 months
14. fMRI imaging sub-study at baseline, 6, 12 and 24 months
15. Rate of brain atrophy and decline in cognitive function (fMRI scan) at baseline, 6, 12 and 24 months

Overall study start date
01/09/2015

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Retired men and women aged 65 or older
2. Plan to reside in the target area (Bath/Bristol, Devon, Birmingham) for at least 24 months
3. Score 48 (inclusive) on the Short Physical Performance Battery (SPPB)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 768; UK Sample Size: 768

Total final enrolment
777

Key exclusion criteria
1. A documented or patient reported medical condition that would preclude participation, including:
1.1. Arthritis so severe it would prevent participation in physical activity
1.2. Parkinson's disease
1.3. Dementia
1.4. Lung disease requiring use of corticosteroids or supplemental oxygen
1.5. Severe kidney disease that requires dialysis
1.6. Severe heart disease that would prevent participation in physical activity (for example chest pain when walking one or two hundred yards or up a flight of stairs)
1.7. An implanted cardiac defibrillator, a cardiac arrest which required resuscitation
1.8. Severe uncontrolled psychiatric illness
1.9. Currently receiving radiation therapy or chemotherapy treatment for cancer
1.10. Awaiting knee or hip surgery
1.11. Major heart surgery (including valve replacement or bypass surgery) or spinal surgery in the last six months
1.12. Any other clinical condition that their GP or clinician considers would make them unsuitable for participation in a physical activity rehabilitation programme to prevent decline of lower limb functioning
2. Self-reported inability to walk across a room or the need for a walker or the help of another person
3. Existing major mobility limitation.
4. Being unable to complete the 4m walk component of SPPB
5. Current involvement in other regular (at least weekly) exercise programmes that aim to build lower limb capacity or fitness (e.g. walking programmes)
6. Living in residential or nursing care
7. Another member of the household participating in REACT

Date of first enrolment
01/03/2015

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bath
Claverton Down
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bath

Sponsor details
Vice-Chancellor's Office
Claverton Down
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BA2 7AY

Sponsor type
University/education

Website
www.bath.ac.uk

ROR
https://ror.org/002h8g185

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
Not provided at time of registration

Intention to publish date
22/06/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	17/04/2018		Yes	No
Results article		21/03/2022	22/03/2022	Yes	No
Results article	Cost-effectiveness	21/03/2022	22/03/2022	Yes	No
Results article	Qualitative results	26/04/2023	27/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Validation of the pfSTEP digital biomarker	27/05/2023	11/07/2024	Yes	No
Participant information sheet	Participant Consent Form version 4	23/03/2017	11/07/2024	No	Yes
Results article	MRI sub study results	13/07/2021	11/07/2024	Yes	No
Results article	delivery fidelity of the intervention part of the process eveluation	03/06/2022	11/07/2024	Yes	No
Results article	long-term functionality	28/07/2023	11/07/2024	Yes	No