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The effectiveness and cost-effectiveness of a peer-volunteering active ageing programme in preventing mobility decline in older adults

Submission date	**Recruitment status**	[X] Prospectively registered
02/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2025	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Physical inactivity is one of the strongest predictors of physical disability in older adults. An older person who remains fit and active is more likely to retain physical and cognitive function, prevent disease and disability, and enjoy independence, mental well-being and a higher quality of life. A key to successful ageing is to find effective ways of helping older people to maintain greater levels of physical activity to break the downward spiral into disability that is increasingly characteristic of old age. This in turn would provide considerable benefit in terms of human welfare and savings in social and health care cost.

Active ageing programmes help older people who are at risk of such decline to improve or maintain their mobility through physical activity. However, nationally and locally resources to support such programmes are scarce. The voluntary sector is ideally placed to mobilise older adults to act as volunteers to deliver these programmes. Unfortunately, little evidence exists as to whether volunteer-driven, community-based active ageing programmes actually work and are cost-effective. This is what this study is designed to test.

Who can participate?

ACE is a low-cost programme where up to 150 older volunteers (aged 55 years +) will support older people (65 years +) to improve their mobility by becoming more active within their communities. The 515 older people recruited to the study will be sedentary and community living, with functional limitations (i.e. who are at risk of major mobility limitations), but who can still walk independently (including walking with a walking stick). This will be measured using a physical function test to assess balance, walking speed and the ability to go from a sitting to a standing position. The researchers are targeting a non-disabled but at-risk population. Participants will mainly be recruited via invitations sent by GPs to patients who meet the inclusion criteria. A small-scale feasibility study conducted several years ago confirmed that ACE was well-received by both participants and volunteers and appeared to deliver a positive impact on the physical and mental well-being of both groups.

What does the study involve?

During the ACE programme, volunteers will meet with participants twice to get to know each

other, find out about and discuss local community-based activities that the participant would like to join, and identify and address any barriers to taking part (weeks 1 and 2). Then, over a 3-month period, the volunteer-participant pair will attend at least three local activities chosen by the participant, together. Over the following 3 months volunteers will support the participant to continue attending these activities independently through regular phone calls, with further joint visits to activities scheduled if needed. Volunteers will attend a two-day ACE training course prior to taking part.
Participants will be randomly assigned to either the ACE programme or a comparison group who will receive information about healthy ageing, attend two social events including a health ageing presentation. but will not be paired with a volunteer. All participants and volunteers will complete a set of measures at the start of the study and then 6 and 18 months later. These measurements will include tests of mobility (a balance test, a 'sit-to-stand' test and a walking speed test), physical activity and questionnaires to measure mental wellbeing, quality of life and how much people use health and social care services. The results from those taking part in the ACE programme and those in the comparison group will be compared so the researchers can assess whether the programme is effective and cost-effective.

What are the possible benefits and risks of participating?
Getting out and about more has been shown to increase levels of physical activity in older adults. A recent UK Chief Medical Officer's report said that "engaging in physical activity carries very low health and safety risks for most older adults. In contrast, the risks of poor health as a result of inactivity are very high". ACE is designed to help people who take part to gradually become more active. Government safety guidelines in relation to COVID-19 will be followed at all times for any face-to-face meetings.
People in the intervention group will get out and about more, with a volunteer for support and encouragement. This will help people to become more active, which could help improve their ability to perform daily activities, increase strength and stamina and help maintain the physical function needed to continue living independently. It also means they will have the chance to socialise with other people. Older adults often find being involved in research a positive experience, finding it interesting and stimulating. Participants will also be contributing to a large pioneering study that will provide very important information for the NHS and, if successful, may improve the health of many other older adults in the future.

Where is the study run from?
The Universities of Birmingham and Manchester and Cardiff Metropolitan University (UK)

When is the study starting and how long is it expected to run for?
February 2019 to May 2025

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

Who is the main contact?
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Scientific

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Integrated Research Application System (IRAS)
290332

Central Portfolio Management System (CPMS)
49549

Study information

Scientific Title
A multi-centre randomised controlled trial of a peer-volunteer led active ageing programme to prevent decline in physical function in older people at risk of mobility disability: the ACE (Active, Connected, Engaged) study

Acronym
ACE

Study objectives
Compared with an information-only control group, participants allocated to the ACE programme will have significantly reduced mobility-related limitations, as indicated by SPPB score, at 18 months of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/08/2021, London - Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048276; surrey.rec@hra.nhs.uk), REC ref: 21/LO/0433

Primary study design
Interventional

Study design
Randomized; Both; Design type: Prevention, Psychological & Behavioural, Complex Intervention, Physical, Health Economic

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Physical function in older people at risk of mobility disability

Interventions
The ACE study is an individually randomised, parallel-group, single-blind randomised controlled trial with an internal pilot phase, a whole-systems oriented process evaluation and an economic evaluation.

Participants, who will be 65 years old or older, will mainly be recruited via a letter of invitation from their GPs. 515 patients who meet the study inclusion criteria will be randomised to receive either the ACE intervention, delivered over a period of 6 months by peer volunteers, or a minimal control intervention. Peer volunteers will be recruited and managed by volunteering organisations such as the Royal Volunteering Service.

ACE is a low-cost programme where older volunteers (55 years +) support older people (65 years +) to improve their mobility by becoming more active within their communities. The 515 older people recruited to the study will be sedentary and community living, with functional limitations (i.e. who are at risk of major mobility limitations), but who can still walk independently (including with a walking stick). This will be measured using a physical function test to assess balance, walking speed and the ability to go from a sitting to a standing position. The researchers are targeting a non-disabled, but at-risk population.

During the ACE programme, volunteers (n=150) will meet with participants twice to get to know each other, find out about and discuss local community-based activities that the participant would like to join, and identify and address any barriers to taking part (weeks 1 and 2). Then, over a 3-month period, the volunteer-participant pair will attend at least three local activities chosen by the participant, together. Over the following 3 months volunteers will support the participant to continue attending these activities independently through regular phone calls, with further joint visits to activities scheduled if needed. Volunteers will attend an ACE training course prior to taking part.

Participants will be randomly assigned to either the ACE programme or a comparison group in a 1:1 ratio stratified by site using a centralised web-based system run by the Cardiff Centre for Trials Research (CTR). The comparison group will receive information about healthy ageing and will be invited to two social events which will include a health ageing presentation, but will not be paired with a volunteer. The researchers will run an internal pilot study with 90 participants to test our recruitment procedures and to allow (if needed) fine-tuning of our recruitment and the intervention. They will make the decision whether to go ahead with the full trial based on the success of this pilot.

All participants and volunteers will complete a set of measures at the start of the study and then again 6 and 18 months later. These measurements will include tests of mobility (a balance test, a ‘sit-to-stand’ test and a walking speed test), physical activity and questionnaires to measure mental wellbeing, quality of life and how much people use health and social care services. The

results from those taking part in the ACE programme and those in the comparison group will be compared to assess whether the programme is effective and cost effective. The researchers will also telephone participants and volunteers at 12 months and ask them to answer some of the questions from the 6 and 18-month questionnaire over the phone. Some participants in the intervention group and some volunteers will be interviewed or attend a focus group to provide feedback on ACE.

Intervention Type
Behavioural

Primary outcome(s)
Lower limb physical function assessed using a Short Physical Performance Battery (SPPB) at baseline, 6 and 18 months

Key secondary outcome(s)
Participants and volunteers:
1. Weekly volume of physical activity accounting for both physical activity intensity and duration, measured using accelerometry at baseline, 6, 12 and 18 months
2. Average number of times a participant transitions from sitting to standing per hour of the day, measured using accelerometry at baseline, 6, 12 and 18 months
3. The number of times a participant transitions from sitting to standing each hour of the day, measured using accelerometry at baseline, 6, 12 and 18 months
4. Average proportion of each waking hour spent in active events, measured using accelerometry at baseline, 6, 12 and 18 months
5. Average proportion of each waking hour spent inactive, measured using accelerometry at baseline, 6, 12 and 18 months
6. Adherence to Chief Medical Officers' recommendations for strength training exercise measured using Muscle-Strengthening Exercise - Adherence scale at baseline, 6 and 18 months
7. Psychological functioning and well-being measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, 6, 12 and 18 months
8. Subjective well-being measured using the Ageing-Well Profile at baseline, 6 and 18 months

Participants only:
1. Health-related quality of life measured using EQ-5D-5L, ICECAP-O at baseline, 6, 12 and 18 months
2. Capability measured using ICECAP-O at baseline, 6, 12 and 18 months
3. Activities of daily living measured using EQ-5D-5L, ICECAP-O at baseline, 6, 12 and 18 months
4. Medical history, medications, health and social service usage measured using medical history and medications, health and social care usage questionnaires at baseline, 6, 12 and 18 months
5. Frequency of trips out of the house measured using a questionnaire item on trips out of the house (previously used in the OPAL study) at baseline, 6 and 18 months
6. Frequency of falls, injurious falls and fear of falling measured using Falls Inventory, Short Falls-Efficacy scale-international (Short FES-I) at baseline, 6 and 18 months
7. Pain measured using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, 6 and 18 months
8. Progression of frailty assessed using the Fried Frailty Phenotype score at baseline, 6 and 18 months, including the following components:
8.1. Grip strength in kg (highest score out of three trials), measured using a dynamometer
8.2. Gait speed (4 m walk from Short Physical Performance Battery)
8.3. Physical activity measured using the International Physical Activity Questionnaire-Elderly (PASE) (9)

8.4. Exhaustion measured using exhaustion questions from the Centre for Epidemiological Studies Depression Scale
8.5. Unintentional weight loss
9. Cognitive function measured using the Montreal Cognitive Assessment (MoCA) at baseline, 6 and 18 months
10. Loneliness measured using the 3-item Revised UCLA loneliness scale at baseline, 6, 12 and 18 months
11. Social networks assessed using Lubben's Social Network Scale at baseline, 6, 12 and 18 months

Peer volunteers only:
1. Motivation to volunteer and volunteering outcomes measured using Short Volunteer Functions Inventory at baseline, 6 and 18 months
2. Amount of intervention-related contact between participants and volunteers measured using diary of contacts with ACE participant(s) at 6 months

Process evaluation measures:
1. Motivation to adhere to the CMO recommendations for strength training measured using Muscle-Strengthening Exercise - Perceived importance (single-item) and confidence (single item) scales at baseline, 6, 12 and 18 months
2. Motivation (based on the satisfaction of basic human needs (competence, autonomy and relatedness) to adhere to the CMO recommendations for aerobic activity measured using the aerobic activity perceived confidence, autonomy, and relatedness scale at baseline, 6, 12 and 18 months
3. Motivation (based on the satisfaction of basic human needs (competence, autonomy and relatedness) to participate in community activities measured using Community activities - Perceived confidence, autonomy, and relatedness scale at baseline, 6, 12 and 18 months
4. Perceived benefits of participation in aerobic activity measured using Physical activity – Perceived Benefits scale at baseline, 6, 12 and 18 months
5. Perceived benefits of participation in community activities measured using the Community Activity Perceived Benefits scale at baseline, 6, 12 and 18 months
6. Evaluation of natural and built local environment characteristics measured using the Quality of the Local Community scale at baseline, 6, 12 and 18 months
7. Feedback on the ACE programme (intervention group only) collected using qualitative interviews and group discussions at 6 months
8. Engagement in local community activities using the activities in the local community scale (3 items) collected at 6,12, and 18 months
9. Intervention fidelity/quality of intervention delivery assessed by applying a checklist to a purposive sample of audio-recordings of intervention contacts between the volunteer and the participant collected at 6 months

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Short Physical Performance Battery (SPPB) score between 4 and 9 inclusive. This is based on definitions of physical frailty from the European Medicines Agency for identifying people with

(or at risk of) physical frailty in clinical trials. This guidance defines pre-frailty as an SPPB score of 8-9 and frailty as an SPPB score of 7 or less
2. Planning to reside in the target area for intervention delivery for at least 18 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 Years

Sex
All

Total final enrolment
528

Key exclusion criteria
1. Self-reported inability to walk across a room without help (use of a stick for support is acceptable)
2. Being too physically active (defined by four verbal screening questions (How would you find walking across a room? How easy would you find getting out of a low chair? How easy would you find walking up a flight of stairs with no handrail or wall to lean on? How easy do you find walking on uneven pavement without losing your balance? Responses easy/a little difficult/very difficult)
3. Having an existing major mobility limitation (SPPB of 3 or less)
4. Living in residential or nursing care; e) Having any serious medical conditions that would preclude participation

Date of first enrolment
01/11/2021

Date of final enrolment
28/02/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University of Birmingham
School of Sport, Exercises and Rehabilitation Sciences
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Study participating centre
University of Manchester
Oxford Road
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Study participating centre
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR130156

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Afroditi Stathi (A. Stathi@bham.ac.uk). The de-identified data will become available after the publication of the core publications and the NIHR Library report related to the grant, and they will be available for 5 years. Consent from participants for use of data for future research has been obtained. The researchers do not forsee any ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/11/2023	01/12/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		13/06/2024	28/02/2025	Yes	No
Participant information sheet	version 1.1	21/06/2021	24/09/2021	No	Yes
Protocol file	version 5	22/07/2022	03/08/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes