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# Mind-body training with a mobile app for older adults

**Submission date**
08/04/2024

**Recruitment status**
No longer recruiting

**Registration date**
16/04/2024

**Overall study status**
Ongoing

**Last Edited**
13/05/2025

**Condition category**
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Training both the brain and body at the same time improves multitasking performance and mobility, thereby reducing the risk of falling. Some mind-body training programmes, delivered via mobile applications on tablets and smartphones, can improve mobility and the ability to multitask. Suitable cognitive (mind) and physical exercises can be pre-selected into a mind-body training programme, allowing people to self-direct their exercise independently while at home. This study proposes a blended method combining both a supervised and a self-directed mind-body training programme, with the use of technology via a mobile app. This project will examine how acceptable this new programme is likely to be to older people at risk of falling and will evaluate the feasibility of delivering it within the NHS.

Who can participate?
Older adults aged 65 years old and over who have had a fall in the past year

What does the study involve?
The study involves a 24-week mind-body exercise training programme. The programme has two phases: phase 1 (12 weeks) involves older adults undertaking the programme delivered via a mobile app with supervision from a physiotherapist in the community that aligns to the standard care; phase 2 (12 weeks) is self-directed, with participants independently exercising at home using the app.

What are the possible benefits and risks of participating?
Participants may improve strength and balance by undertaking regular exercises as part of the study.

There may be risks associated with undergoing balance exercises as these tend to be challenging. Clear instructions on how to undertake these exercises safely at home will be provided. Participants can contact the research team if they need help with using the app during the study.

There might be conditions that were previously unknown being noticed during exercise or assessments (e.g., pain during a certain movement, declined cognition); this could be considered

both a benefit or risk. In this case, we will notify the participant's GP about the conditions, who may be advised to arrange further management or to refer to appropriate specialities.

Where is the study run from?
School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham

When is the study starting and how long is it expected to run for?
August 2023 to December 2025

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

Who is the main contact?
Dr Shin-Yi (Chloe) Chiou, s.chiou@bham.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
327056

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 55683, IRAS 327056

# Study information

## Scientific Title
Feasibility and acceptability of a supervised and self-directed technology-based Dual Task training programme for older adults at risk of falling

## Study objectives
It is hypothesised that a blended technology-based dual-task training programme would be acceptable to older people at risk of falling.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 24/04/2024, East of England - Cambridge East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048181; CambridgeEast.REC@hra.nhs.uk), ref: 24/EE/0059

## Study design
Single-arm non-randomized feasibility study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Community, Fitness/sport facility, Home, Internet/virtual, Medical and other records

## Study type(s)
Treatment

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Generic health relevance in ageing older adults who have had a fall in the past year

## Interventions
This is a single-arm, non-randomised feasibility study. There are two phases in the study:
Phase 1 – supervised group exercise 1 day/week + self-directed exercise at home 2 days/week for 12 weeks.

Supervised group exercise.
Group exercise classes will be led by a qualified physiotherapist and delivered in the community (e.g., studios in fitness/leisure/wellbeing centres in Birmingham and Solihull).
The DT training programme requires participants to undertake concurrent cognitive and physical (balance and strength) exercises. Cognitive exercise will be delivered via a commercialised brain training app, PEAK. The content of the strength and balance exercises will align with the

standard care.
Before the face-to-face exercise class in week 1, all participants will receive online questionnaires to complete as their baseline data (see Outcomes below for details).
Week 1 exercise class will consist of a physical assessment of Timed Up and Go (TUG) with and without a cognitive task (see Outcomes below for details), app installation, the main DT exercise training, instruction on how to undertake the same exercises at home, and refreshment. The subsequent classes (week 2 to week 12) will consist of the DT exercise training, collecting self-reported adherence and app usage, refreshment, and individual technology support if needed.
With support from the physiotherapist, the PEAK app will be downloaded from the App Store or Google Play and installed on participants' phones/devices. A study-specific account will be created so no personal data will be shared with the app providers. To start using the app, participants will take a cognitive assessment provided by the app and receive a brain score. The app will be set up to send notifications to the participants to remind them to exercise, supporting exercise engagement and adherence to the programme. Subscription fees for using the app will be purchased for all participants.
In the supervised exercise class, all participants will undertake 10 minutes of strength and balance exercises alone (without concurrent use of the app), as part of the warm-up to familiarise themselves with the movement of the exercises. This will be followed by 30 minutes of DT exercises where they will be doing the same strength and balance exercises while performing cognitive games with their device. The device will be placed on a height-adjustable music stand placed in front of the participants at an appropriate distance that allows them to use the app. The physiotherapist will provide individual support to the participants during the class to ensure everyone can engage with the DT exercise training. The class will conclude with 5 minutes of cool-down exercise.
At the end of the first group exercise class, the physiotherapist will provide each participant with a printout of the balance and strength exercises with pictures and instructions and instruct the participants to perform the same DT exercise training at home by themselves, a music stand will be provided to each participant. All participants will be provided with an exercise calendar and shown how to document their exercise adherence outside of the exercise class.
Refreshments will be provided at the end of each exercise class to promote attendance and contribute to participants' social well-being.
Participants will attend group exercise classes once a week for 12 weeks; their travel expenses for attending the classes will be paid. The class size will be 5-10 people.

Self-directed, home-based exercise.
Participants will be instructed to perform the same DT exercises at home for another two days per week. To record adherence, participants will be asked to tick the days that they have completed the DT exercise on their exercise calendar. The PEAK app will store data on when and which cognitive exercises are undertaken and completed. The exercise calendar will be returned to the physiotherapist at the end of each month.

End of phase 1 – educational session.
Prior to the educational session, all participants will be sent an online EXIT survey (see below Outcomes section for details) and asked to complete the survey prior to the educational session.
All participants will attend an educational session for fall awareness scheduled in week 13 at the same time and place as the exercise classes. Their travel expenses for attending the educational session will be paid. The app usage recorded from the two self-directed sessions in week 12 and the month 3 exercise calendar will be collected at the educational session. The content of the second phase of the intervention will also be explained in this session (see below for full description). Participants will be given an exercise booklet containing instructions for strength and balance exercises week-by-week and a 3-month exercise calendar. They will continue to have access to the PEAK app which will record their app usage and adherence from weeks 13 to

24.
Participants will be asked to consider ways that may help them stay motivated in doing the exercise in the next 12 weeks, such as creating WhatsApp groups or using Facebook Messenger, the most common messaging apps used by adults in the UK31, and supplemented by face-to-face "coffee shop" get-togethers to stay in touch with other participants in the same age and/or living in the same area. The researchers will evaluate the impact of this informal peer support on engagement and sustainability of exercise as well as assess how peer support occurs in this age group, e.g., mostly in person or via social media in the planned focus groups (see below Qualitative interviews and focus groups section for details).

Phase 2 – self-directed, home-based DT training programme 3 days/week for 12 weeks.
Participants will undertake 30 minutes of self-directed DT exercises at home 3 times per week for 12 weeks. They will perform the DT exercise using the PEAK app and the strength and balance exercises in the exercise booklet. Usage and engagement of the app of the participants will continue to be recorded by the app. Participants will record their exercise adherence in the exercise calendar.
All participants will be contacted in week 24 to attend a post-assessment session in week 25. Their travel expenses for attending the post-assessment will be met.

End of Phase 2 (Week 25) – post-assessment and app data extraction session.
Participants will be invited back to the same place as the exercise classes to undergo the TUG assessment. The physiotherapist will perform the TUG assessment and document the app usage data from week 13 to week 24 from participants' phones/devices. The exercise calendars will also be collected from the participants. All participants will be sent the same online questionnaires as they completed at baseline and the end of phase 1 and asked to complete the questionnaires within 2 weeks from the post-assessment.

Qualitative interviews and focus groups
Face-to-face focus groups (FGs) with a total of 30 participants who have completed the programme (4-6 participants per group for 45-60 minutes) will be conducted. Participants (30) will be purposefully sampled, based on the demographic information, geographic location, exercise adherence, and results of the EXIT survey, to attend the focus groups.
Additionally, the researchers will conduct five online FGs with a total of 30 healthcare professionals, including GPs, district nurses paramedics, and physiotherapists who are part of the NHS falls prevention care pathways in Birmingham and Solihull, via MS Teams. Clinicians and physiotherapists involved in this study will be invited to take part.
The purpose of conducting the FGs is to allow for an in-depth exploration of the results obtained from the feasibility study as well as to capture attributes of the acceptability and feasibility which are unable to be recorded by outcome measures stated in the feasibility study above. Questions will be developed based on the framework for qualitative research in feasibility studies for trials and input from the PPI group. Specifically, questions will cover 4 main categories:
o Intervention content and delivery
o Study design, conduct and processes
o Outcomes (e.g., are they important to service users?)
o Measures (e.g., are the process valid for the service users?)
Descriptive data from the adherence, usage of the app, and the EXIT survey will be used as prompts. The FG will be led by two members of the study team. The reason to have two people leading the FGs is to ensure both verbal and non-verbal interactions and group dynamics during the discussions can be documented.

FGs will be voice recorded and later transcribed and analysed using a deductive thematic approach with Nvivo9 software; data for the study participants and the stakeholders will be analysed separately.

### Intervention Type
Behavioural

### Primary outcome measure
Feasibility outcomes:
The following will be assessed at the end of the study:
1. Recruitment rate measured using the screening log and the consent record by calculating the percentage of participants recruited
2. Adherence measured using self-reported diaries by the number of actual exercise days /number of exercise days offered (x100%) at the end of weeks 12 and 24
3. Attrition measured using the REDCap week 24 questionnaire by the number of withdrawals from the study and/or no follow-up data available
4. Usability, perceived effectiveness and satisfaction measured using a self-reported online EXIT survey at weeks 12 and 24 (moved from secondary outcome measures on 08/11/2024)

### Secondary outcome measures
Exploratory outcomes:
1. Physical assessment measured using the Timed Up and Go (TUG) test at week 12 and 24
2. Everyday Cognitive Score measured using the Measurement of Everyday Cognition (ECog 12) questionnaire at baseline and 24 weeks
3. Fear of Falls measured using the Falls Efficiency Scale-International at baseline and 24 weeks
4. Quality of life is measured using the EuroQol health-related quality of life EQ-5D-5L questionnaire at baseline and 24 weeks
5. Self-reported number of falls measured using the REDCap questionnaire reported by participants during the study period
6. Use of healthcare services evaluated using the ModRum questionnaire at baseline and 24 weeks (added 08/11/2024)

### Overall study start date
01/08/2023

### Completion date
31/12/2025

## Eligibility

### Key inclusion criteria
1. Are aged 65 years and above
2. Can give informed consent
3. Demonstrate sufficient cognition/hearing/vision to follow instructions of the assessment and the exercise programme
4. Can stand with one hand support on the current walking aid for at least 60 seconds
5. Can stand up from a chair independently and walk independently with the current walking aid for 6 meters
6. Are self-toileting
7. Own or have access to a smartphone/iPad/iPod touch/tablet
8. Have fallen more than once in the last 12 months

### Participant type(s)
Patient

### Age group
Senior

### Lower age limit
65 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

### Total final enrolment
43

### Key exclusion criteria
1. Have an unstable or acute medical condition that precluded exercise participation
2. Suffer from a progressive neurological condition (such as Parkinson’s disease or multiple sclerosis)
3. Are not recommended to undertake any forms of unsupervised exercise by their GPs or secondary healthcare team; for example, having uncontrolled blood pressure, postural hypotension, acute/unstable cardiac issues, and dizziness brought on by exercise or changing posture, or
4. Are currently participating in a different research study for managing their fall risks

### Date of first enrolment
01/05/2024

### Date of final enrolment
27/05/2025

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Birmingham**
School of Sport, Exercise and Rehabilitation Sciences
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**Study participating centre**
**Queen Elizabeth Hospital**
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# Sponsor information

**Organisation**
University of Birmingham

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**Sponsor type**
University/education

**Website**
https://www.birmingham.ac.uk/

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care 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
The study protocol will be submitted to a peer-reviewed journal for publication. We anticipate submitting a protocol manuscript within 2 months after completion of the trial registration. Full results will be published in peer-reviewed journals after completion of the study. Full publications are expected to be available within two years from the end of the study.

### Intention to publish date
31/12/2026

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

### IPD sharing plan summary
Published as a supplement to the results publication

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 4 | 26/04/2024 | 03/07/2024 | No | Yes |
| Protocol article | | 24/03/2025 | 13/05/2025 | Yes | No |