The University of Birmingham
Edgbaston
Birmingham B15 2TT
United Kingdom
Chief Investigator: Dr Shin-Yi (Chloe) Chiou
Associate Professor in Motor control and Rehabilitation
School of Sport, Exercise & Rehabilitation Sciences
Telephone: 0121 414 5315
Email: s.chiou@bham.ac.uk

UNIVERSITY OF BIRMINGHAM

NHS
University Hospitals Birmingham
NHS Foundation Trust

Technology-based dual-task training in older adults

Research Participant Information Sheet

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Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

It is known that our ability to multitask reduces as we get older and this in turn increases our risks of falling. The purpose of this study is to test a programme of training for balance and mobility in people aged 65 years and over, who have fallen in the last 12 months. The training programme is called technology-based mind-body, or dual-task (DT) mind-body training.

Why have I been chosen?

You are someone who is 65 years and above, who has had more than one fall in the last 12 months.

Am I eligible to take part?

You are eligible to take part if you:

1) Are 65 years or above;
2) Give informed consent to the study participation;
3) Understand and can follow instructions for both 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 metres,
6) Are able to use the toilet without help,
7) Own or have access to a smartphone or iPad or tablet.

You won't be able to take part if you:

1) Have a medical condition that precludes you taking part in exercise; this may be case-by-case and we can discuss it with you;
2) Are not recommended to undertake any forms of exercise by your GP or medical care team; or

3) Are currently participating in a different research study for managing your fall risks.

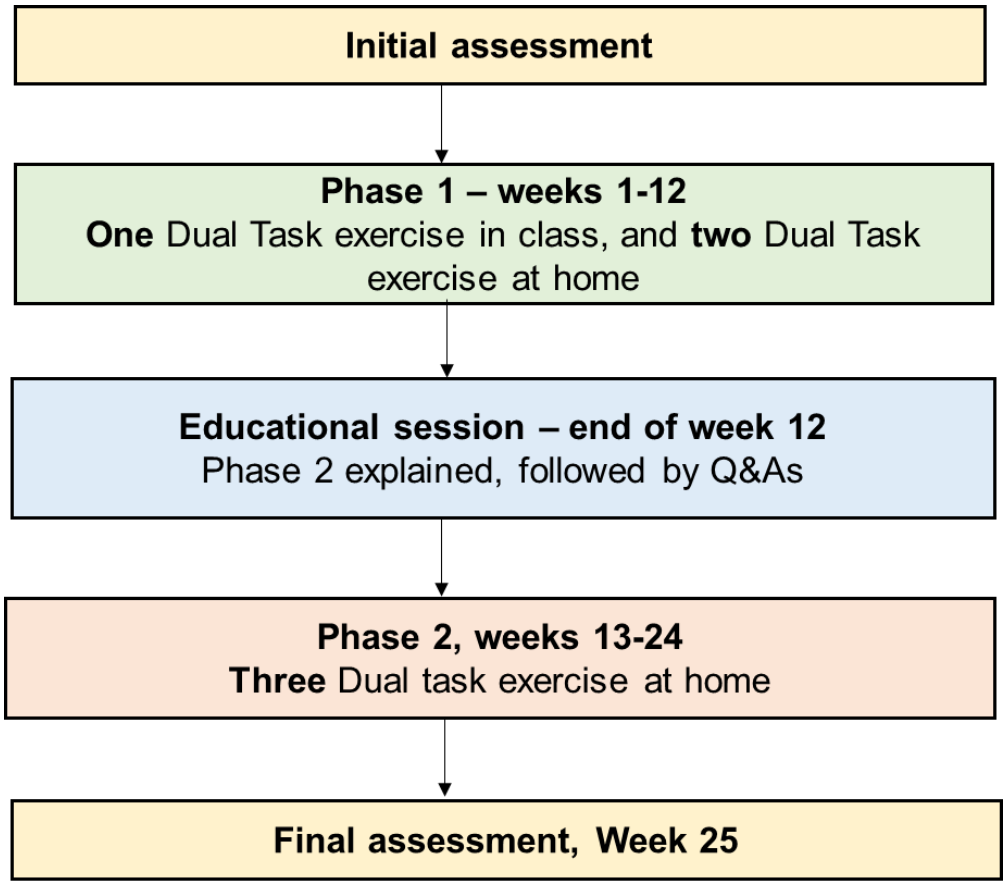
Do I have to take part?

No. It is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to take part in the study, you are free to withdraw from the study ***at any time without your treatment being affected.***

Once you have decided to take part in this research, a member of our research team will discuss the study with you and answer any questions you may have.

What will happen to me if I take part?

If you are happy to take part, you will be asked to sign a consent form, followed by an initial assessment before you start the programme. See the study diagram below:



Initial assessment – this will consist of a face-to-face meeting with a member of the study team, for each individual (potential) participant, in which you will have the overall purpose of the research programme explained and will be able to ask questions about the Dual Task (Mind/Body) exercises, and how they will be delivered via a smart phone or tablet or computer. You will be asked to download an app onto your touch screen device to do the exercise.

Phase 1 – weeks 1-12

Phase 1 will last for 12 weeks, and each week you will undertake 1 x 45 minutes Dual Task (mind/body) exercise all together in class, and 2 x 45 minutes Dual Task exercises on your own at home. The physiotherapist leading the classes will provide you with instructions related to how to exercise safely at home. You can also contact the research team if you have concerns about exercising at home and need additional support.

Educational Session - End of week 12

In this session, you will again be all together, and will have Phase 2 explained, and then you will be able to ask questions about Phase 2

Phase 2 - weeks 13-24

Phase 2 will consist of 3 x 45 minutes Dual Task exercise sessions a week for a further 12 weeks, in which you will be working at home on your own, although you will also be able to contact one another (and members of the study team), through a mutually agreed way (e.g., WhatsApp Group). You will also be able to meet up occasionally face-to-face in a small group, if you think that will be helpful in keeping you motivated, and it will also enable you to raise further questions as you work through the Dual Task exercises on your own, at home.

Final Assessment – Week 25

There will be a final assessment for each participant in week 25, to measure your progress by the end of the whole programme, and to advise you how you might be able to carry on with the Dual Task or similar exercises, into the future.

Assessments (30 minutes)

1. **Online questionnaires**: we will ask you to fill in some questionnaires to assess your state of mind, fear of falling, quality of life, use of healthcare services, and satisfaction with the training programme. The questionnaires are online, and you will be sent a link to access them.
2. **Timed Up and Go (TUG) test**: we will ask you to stand up from a chair and walk to a floor marker 3 meters away, turn, and walk back to the chair. While you are walking, we may ask you some questions to challenge your brain. We will record the time to complete the task.

Optional: to help us verify how accurate and feasible it is to run the TUG test remotely, we will invite you to an additional assessment where you will be shown how to perform the test at home in front of a camera.

Focus group (60 minutes)

At the end of the study, you may be contacted by a member of the research team who will invite you to attend an in-person focus group where you will be sharing your experience of taking part in this study and discussing your views on the intervention you undertook. It will be an informal discussion which will be audio recorded and transcribed by members of the research team. The conversation will focus on your own experience of undertaking the intervention. The discussion will last no longer than 60 minutes and will be audio recorded for transcription purposes. No personal identifiable information will appear in the transcriptions. The original audio recordings which contain identifiable information will be deleted within 15 working days after completion of the transcription. We may publish direct quotes from you

but only your study ID will be included, and not your name or any other information that could identify you, in the publication.

What are the risks involved in taking part?

There may be risks associated with undergoing balance exercises as these tend to be challenging. We will provide you with clear instructions on how to undertake these exercises safely at home. You can contact the research team if you 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, declining mental ability); this could be considered both a benefit or risk. In this case, we will notify your GP about the conditions, who may be advised to refer to an appropriate specialist.
Current government guidelines and local safety procedures in relation to respiratory diseases such as flu and coronavirus will be adhered to, in order to minimise any risk of exposure to these viruses.

What are the possible benefits of taking part?

We hope that your strength and balance will improve by undertaking regular strength and balance exercises as part of the study. At the end of the study, you can choose to continue with the training programme, or move on to do something else.

Will I be paid for taking part in the study?

You will not be paid for your participation in the study, but you will be reimbursed of travel expenses incurred by taking local buses/trains for undertaking study-related activities. Please keep the tickets/receipts/proof of purchase for your journey as these will be required for your reimbursement. You can claim up to £10 towards your

travel costs, but more could be reimbursed if needed (e.g., payment for a care giver to support you, a taxi or car mileage if you are unable to use public transportation)

Contact for further information about this study.

If you would like to consider this study further before you make your decision, please take your time to do so. You may ask for further information by telephoning 0121 414 5315. The person to speak to is the chief investigator, Dr Chloe Chiou. Alternatively, you may also send an email to s.chiou@bham.ac.uk to request further information.

Turn to the next page if you wish to read about the information related to data protection and security and your rights as a research participant.

How will we use information about you?

In order to carry out the research project described above, we will need to collect information about you, and some of this information will be your personal data including:

- your name and initials
- date of birth
- contact detail
- demographic details
- medication
- fall history.

The research team will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you, i.e., both identifiable and non-identifiable data already collected with consent, that we already have. No further data will be collected from you. If you decide to stop taking part in the study your treatment will not be affected.

If you lose capacity to consent during the study, you will be withdrawn from the study. Data collected up to that point with consent will be retained and used in the study.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team

- by contacting our Data Protection Officer:
  The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT
  Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

What if something goes wrong?

In the extremely unlikely event that anything goes wrong while you are taking part, local hospital facilities are available (A&E department). You should call 999 if there is a medical emergency when undertaking the study during the group class or at home. You should also contact the research team in any situation and update them. If you feel distress when undertaking the study, you should contact the research team.

University of Birmingham holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that University of Birmingham is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Chloe Chiou, 0121 414 5315 or email: s.chiou@bham.ac.uk) in the first instance. Alternatively, you can contact the Patient Liaison Services (PALS) at <*Insert local PALS contact details here – delete this text on completion*> if you wish to complain to an independent point of contact.

The normal National Health Service complaints mechanisms are also available to you.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at neuroscience, neurological and other health care conferences and published in scientific journals. No individual subject will be identified in any report or presentation arising from the research. Data may be shared with our NHS partners; however, no data will be shared with the app providers.

Who is organising, insuring and funding the research?

The study is funded by the National Institute for Health and Care Research and run by a research team based at University of Birmingham.

The University is the sponsor for this study and has in place indemnity coverage for this study, which provides cover for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the study and may alternatively, and at the discretion of the University provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical study and the normal NHS complaints mechanisms will still be available to you.

Who has reviewed the study?

This study has been approved by the East of England – Cambridge East Research Ethics Committee.