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Moving on up! Physical literacy and activity of older adults using a digital rehabilitation tool

Submission date	**Recruitment status**	[_] Prospectively registered
09/05/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/05/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Physical inactivity is a major cause of disease and premature death across the world, and older adults are more likely to be physically inactive. Giving people advice on being physically active does have positive effects on people's physical activity, but this doesn't last for long. This is likely because it is difficult to give tailored physical activity advice to older adults that meets their needs and helps them to navigate barriers to being inactive, such as pain. This pilot study aims to test the impact of a tool that uses rehabilitation principles, helping people to build strength across complex movements that are required in daily life. It will test how effective the tool is on a smaller sample of people, but also how easy it is to recruit people and how many people stick with the tool, and how many people drop out of the study. This will help us build a bigger study to properly assess tools such as this one.

Who can participate?
Older adults aged 60 years and over who are able to participate in gentle exercise

What does the study involve?
Participants will be asked to complete a consent form and to complete questions such as age, sex, financial status, social connections, physical activity levels, illnesses and alcohol and smoking habits, and perceptions of physical activity (physical 'literacy'). Participants will then be randomly allocated to see a link to either a digital physical activity intervention that is web-based (the intervention), or to an information sheet with advice and guidance on physical activity (the control group). They will be contacted to repeat the online questionnaires at 3 and 6 months.
Participants who are selected for the intervention group (web-based digital tool) will be asked to complete a baseline physical activity assessment (how many times they can stand from sitting in a chair over 1 minute) and allocated an exercise programme. Each week they will be given 2-4 sessions of exercises described on the app and will be able to select exercises from a range of options. Each day, as part of a daily 'wellbeing check', they will be asked to quickly score levels of fatigue, recovery, soreness, sleep and stress on the app itself, and these will help guide them through progression in physical activity. This should only take 1-2 minutes. The digital tool is expected to take around 13 weeks to complete in full.

What are the possible benefits and risks of participating?
There should be no disadvantages to taking part, apart from the time spent supporting the study. Physical activity is generally safe. There is the potential for injuries and it is therefore important for people to only do what they feel comfortable with, and stop and seek help whenever they feel there is something wrong. It is envisaged that participation in either arm of the study will help participants to become more physically active, which has direct benefits for their health. The results of the study will help the researchers to plan a formal and larger study using digital tools such as this one, and will help to contribute to helping older adults become more physically active.

When is the study starting and how long is it expected to run for?
March 2022 to December 2023

Who is funding the study?
1. Imperial College London (UK)
2. National Institute for Health Research (NIHR) Biomedical Research Centre (BRC) (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Dr David Salman

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Additional identifiers

Protocol serial number
ICREC 6494648

Study information

Scientific Title

Moving on up! A pilot randomised controlled trial on the impact of a digital rehabilitation tool on the physical activity and physical literacy of older adults

Acronym
MOU

Study objectives
Use of the digital tool will be safe and feasible for participants, with impacts on their physical activity and physical literacy at 3 and 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/04/2023, the Imperial College Research Ethics Committee (Imperial College Research Ethics Committee-ICREC, Imperial College London, Room 221, Medical School Building, St Marys Campus, London, W2 1PG, UK; +44 (0)207 594 1862; researchethicscommittee@imperial.ac.uk), ref: 6494648

Primary study design
Interventional

Study design
Single-centre interventional single (investigator) blinded randomized (1:1 allocation) controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Maintenance of physical activity in older adults

Interventions
The participants are randomised on a 1:1 ratio to either receive the intervention (link to a digital tool) or control (link to educational resources) in the survey questionnaire in Qualtrics.

Participants in the intervention group will receive links to access a digital rehabilitation tool as a web-based app. The Movement Foundations digital tool was initially designed and created in 2021 by an Imperial College London team supported by Imperial Health Charity Innovate funding (grant reference number II2021_7), and updated in 2022 to focus on older adults, supported by Imperial College London and National Institute of Health Research (NIHR) Biomedical Research Centre (BRC) funding (reference 5899469). The web-based rehabilitation platform Rehab Guru was commissioned to develop the platform for the digital rehabilitation tool in both instances.

The digital tool consists of low-impact and intensity exercises based on functional movement patterns, a graduated progression in terms of volume (number of sessions per week and number of repetitions of exercises) and intensity/load (difficulty of exercise). Users will be entered onto a starting level based on an algorithm adjusted for the number of sit-to-stand (STS) repetitions over 1 minute, and the perceived degree of effort this exercise requires (Borg CR10 scale). Levels of exercise are phased: each phase lasts 1 to 2 weeks and contains a variable number of sessions. For each phase, users are able to choose exercises ranging in difficulty and across

functional movement pattern domains. When users log individual exercise sessions, they are asked to rate their perceived effort, and their subjective assessment of adherence to the exercises (how much were they able to do of what they intended).

Users are asked to complete daily questionnaires on fatigue, sleep, muscle soreness and emotional stress, based on Hooper and McKinnon scoring criteria. An additional domain of recovery has also been added. At the end of each phase, scores from the daily questionnaires, the level of effort and degree of subjective and objective adherence to the sessions are combined by an algorithm developed by the study team to generate options to the user. These include: progressing to the next phase; consolidating the previous phase; regressing a phase; and signposting for medical advice. In addition, a resource hub provides participants with information on deconditioning, planning sessions, rest and recovery, fatigue, sleep and muscle soreness. Users will be encouraged and guided to set goals for physical activity development. Users have the option of sharing goals on a public noticeboard (without identifiable information), and providing encouragement to other users using a thumbs-up symbol. The combination of information, social, review and reward, action planning and instruction align with items from the CALO-RE taxonomy for behaviour change for physical activity interventions, and the Capability, Opportunity, Motivation-Behaviour (COM-B) model for behaviour change.

Those in the control arm will receive an online-accessible and downloadable document with educational resources, including the UK Chief Medical Officer guidance for physical activity in older adults, and links to NHS guidance for physical activity.

Intervention Type
Behavioural

Primary outcome(s)
Physical activity measured using the International Physical Activity Questionnaire (IPAQ) to provide self-reported MET minutes/week at baseline, 3 and 6 months

Key secondary outcome(s)
1. Physical literacy measured using the Behavioural Regulation in Exercise Questionnaire (BREQ-3), an exercise confidence scale, and the Senior Perceived Physical Literacy Instrument (SPPLI) at baseline, 3 and 6 months
2. Social connections measured using the Lubben social network scale (LSNS-6) at baseline, 3 and 6 months
3. Loneliness measured using the University of California, Los Angeles (UCLA) 3-item loneliness scale, plus one additional question as recommended by the Office of National Statistics (ONS) at baseline, 3 and 6 months
4. Frailty measured by the FRAIL scale at baseline, 3 and 6 months
5. Mood measured by Hospital Anxiety and Depression (HADS) scale at baseline, 3 and 6 months
6. Sleep quality measured by the Pittsburgh Sleep Quality Index (PSQI) at baseline, 3 and 6 months
7. Technology readiness measured by the Technology Readiness Index at baseline, 3 and 6 months

Completion date
15/12/2023

Eligibility

Key inclusion criteria
Participants will be recruited from the Cognitive Health in Ageing Register for Investigational and Observational Trials (CHARIOT) register. The CHARIOT Register (n ≈ 40,000) was initiated in 2011 through collaborative efforts between GP practices across West London with the Department of Primary Care and Public Health and the Ageing Epidemiology (AGE) Research Unit, both within the School of Public Health at Imperial College London. The register is comprised of a cohort of approx. 40,000 cognitively healthy older adults aged 50-85 years who expressed interest in being contacted for participation in studies relating to dementia prevention and healthy ageing. In addition, participants will be recruited through public advertisement including through social media. The inclusion criteria are:
1. Aged 60+ years
2. No dementia diagnosis (self-reported)
3. Has access to the internet and a suitable device
4. English competency and no significant visual or auditory disability (able to read, hear (including with a hearing aid) and write)
5. Able to ambulate safely with or without a walking aid.
6. Able to participate in gentle exercise without any contraindication from a healthcare professional (note that no permissions are needed; if they have not been told otherwise, it is assumed there is no contraindication to daily physical activity)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 Years

Sex
All

Key exclusion criteria
1. Dementia diagnosis or prescription of dementia-specific medicines, as per NICE guidelines
2. Severe loss of vision, hearing, or communicative ability; conditions preventing cooperation
3. Limited or no access to technology or insufficient confidence in doing so
4. Participation in another intervention study
5. Chest pain on exercise
6. Dizziness on exercise

Date of first enrolment
10/05/2023

Date of final enrolment
10/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College London
School of Public Health
Faculty of Medicine
Level 2, Faculty Building
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Biomedical Research Centre (BRC)

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans are to be confirmed, but in discussion with Imperial College London the researchers aim for de-identified data from this study to be stored in a publicly available repository - this is to be confirmed

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 5.0		31/05/2023	No	Yes
Protocol file	version 6.0		31/05/2023	No	No