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Moving on up! Physical literacy and activity of older adults using a digital rehabilitation tool: a pilot randomised controlled trial

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Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Research Governance and Integrity.

This protocol describes *Moving on up! Physical literacy and activity of older adults using a digital rehabilitation tool: a pilot and feasibility randomised controlled trial* and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

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1. INTRODUCTION

1.1 Background

Physical inactivity is a major global driver of non-communicable disease and all-cause mortality.[1] It is associated with increased frailty,[2]dementia risk,[3]and reduced physical function,[4]is a condition of socio-economic inequality, and is more prevalent in older adults.[5] Moreover, physical activity (PA) and inactivity is related to social relationships: our previous work in the CHARIOT Covid Rapid Response (CCRR) study suggested that older adults who were lonely or who had markers of social isolation reduced their physical activity during the Covid-19 pandemic.[6,7] In contrast, people in more active social networks and in relationships are more likely to be physically active,[8] and social support that is specific to physical activity is associated with increased PA levels in older adults.[9]

Physical activity interventions in older adults improve balance, muscle strength and reduce the risk of falling, and can also help older adults perform activities of daily living.[10–12] Moreover, digital interventions specifically can increase physical activity levels in older adults. A systematic review suggested that such interventions increase moderate to vigorous PA by approximately 35% of recommended amounts. However, it is unclear how long this effect might last.[13] Generally, studies assessed the impact of an intervention when it ends, and systematic reviews suggest that most non-digital approaches to increase PA, although effective, have an unknown duration of impact beyond one year.[14]

One concept that might bridge the gap between intervention and longer-term impact is that of physical literacy. This encapsulates the competence and confidence with physical skills, motivation towards physical activities, and the value a person attributes to physical movement.[15] It is still not understood how physical literacy in older adults translates into increased and sustained physical activity.[16] This pilot and feasibility study of a digital rehabilitation tool, that follows rehabilitation principles using the principles of key movement domains, aims to assess the impact on physical activity levels, markers of physical literacy, the physical and mental health, wellbeing and function over a 6-month period, with the aim to extend to longer time-periods as resources and capacity allow. This aligns with the Medical

Research Council (MRC) guidance for the development and evaluation of complex interventions, with feasibility testing an integral and important component.[17]

1.2 Study Rationale

Aims:

- This project aims to pilot, and assess the feasibility of, a randomised controlled trial using a digital rehabilitation tool to enhance physical activity and literacy in older adults

Research questions:

- What are the impacts and effect sizes of the intervention on the proposed primary outcome (self-reported physical activity levels (MET minutes/week) at 3 and 6 months) and secondary outcomes (mood/physical literacy scores/frailty/quality of life)?
- What is the acceptability of the digital tool for participants?
- For how long do people use the tool, and how frequently (adherence)?
- What is the recruitment rate?
- What is the attrition rate to follow-up?
- What issues are encountered when cleaning and analysing data?
- What are outcomes at longer time intervals (1-2 years)?
- What is the safety profile of the tool for participants?
- What are the perceptions of participants on the usability and acceptability of the digital tool?

Hypothesis:

- 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

2. STUDY OBJECTIVES

The primary study objective is to pilot a randomised controlled trial of a digital rehabilitation tool and to assess the feasibility for a larger randomised controlled trial. Objectives will cover:

(i) Impact on effect sizes (pilot RCT): for both the proposed primary outcome on self-reported physical activity (MET/minutes per week) and secondary outcomes of physical literacy and mood

(ii) Safety: self-reported safety profile

(iii) Feasibility: recruitment rate, attrition rate, follow-up rate for questionnaires; adherence and usage of the digital tool

(iv) Usability: perceptions of usability and impact; perceived barriers to inclusion

3. STUDY DESIGN

The study design is a pilot and feasibility randomised controlled trial for the impact of a digital tool for physical activity in older adults on their physical activity and physical literacy versus simple educational resources alone. Participants will be recruited from the Cognitive Health in Ageing Register for Investigational and Observational Trials (CHARIOT) register: a cohort of over 40,000 cognitively healthy (without a known diagnosis of dementia) adult volunteers aged over 50 years, recruited from 172 GP surgeries across West and North London as part of a collaboration between regional GP practices and the School of Public Health, at Imperial College London.

Upon expression of interest and informed consent, participants will be:

1. Asked to complete questions using the qualtrics platform on: financial status, social connections, physical activity levels, illnesses and alcohol and smoking habits and perceptions of physical activity (physical 'literacy') (all described in more detail below). Postcode will be asked to understand socioeconomic background of those participating.

2.Randomised to either the intervention or control group.

3. Receive either a link to a digital physical activity intervention that is web-based (the intervention), or an information sheet linking to advice and guidance on physical activity (the

control group). They will be asked to follow the guidance in these tools only for as long as they feel comfortable doing so.

4. Asked to repeat the online questionnaires at 3 and 6 months, and to consent to longer-term follow-up.

Further details on the specific aspects are described below.

3.1 Intervention and control

3.1.1 Movement Foundations digital rehabilitation tool

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 between 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) (Figure 1). 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 one to two 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.[18] 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,[19] and the Capability, Opportunity, Motivation-Behaviour (COM-B) model for behaviour change (Figure 2).[20]

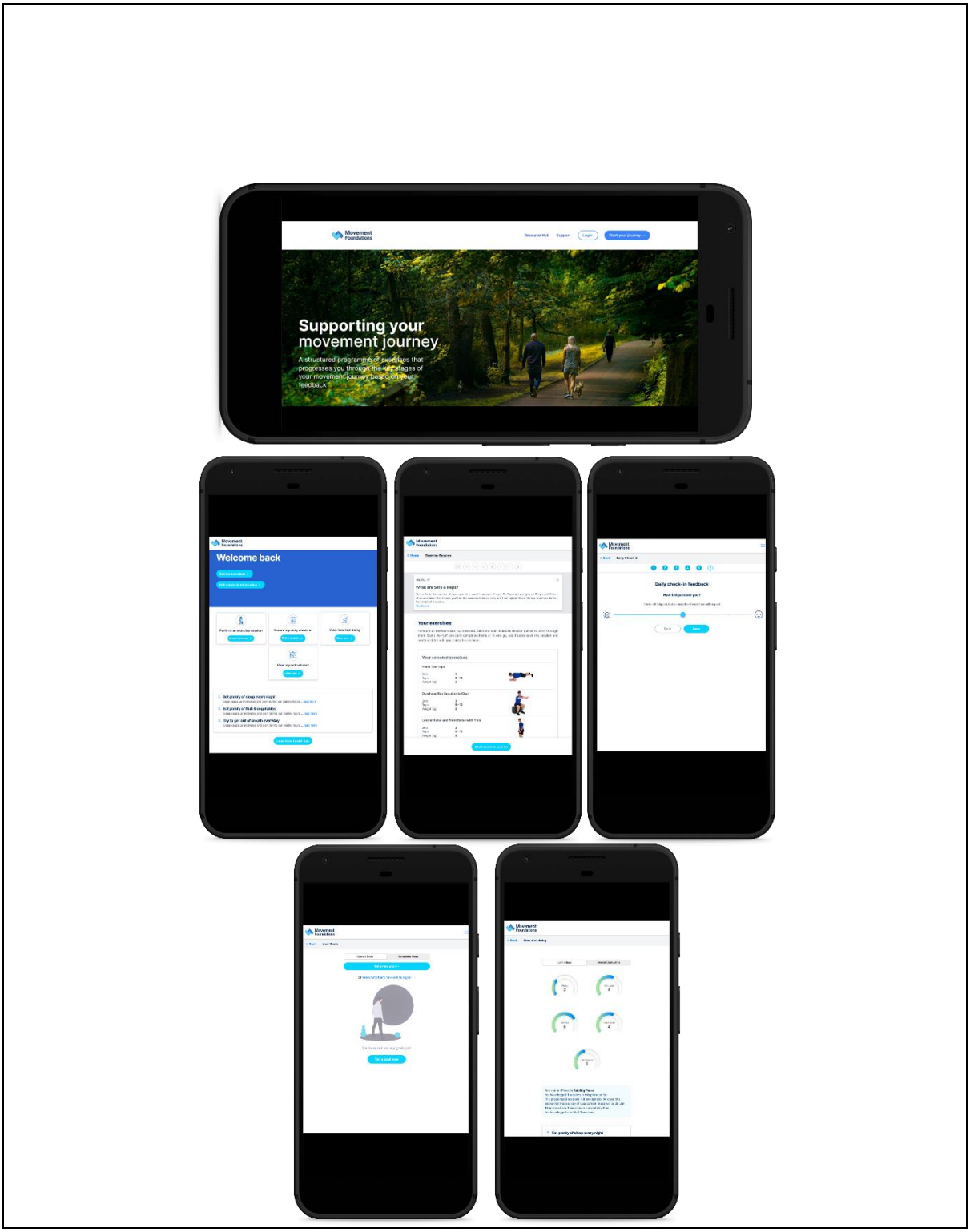

Figure 1: The digital tool supports the user with exercises across movement domains, daily feedback on user responses, goal setting, and visual feedback on progress

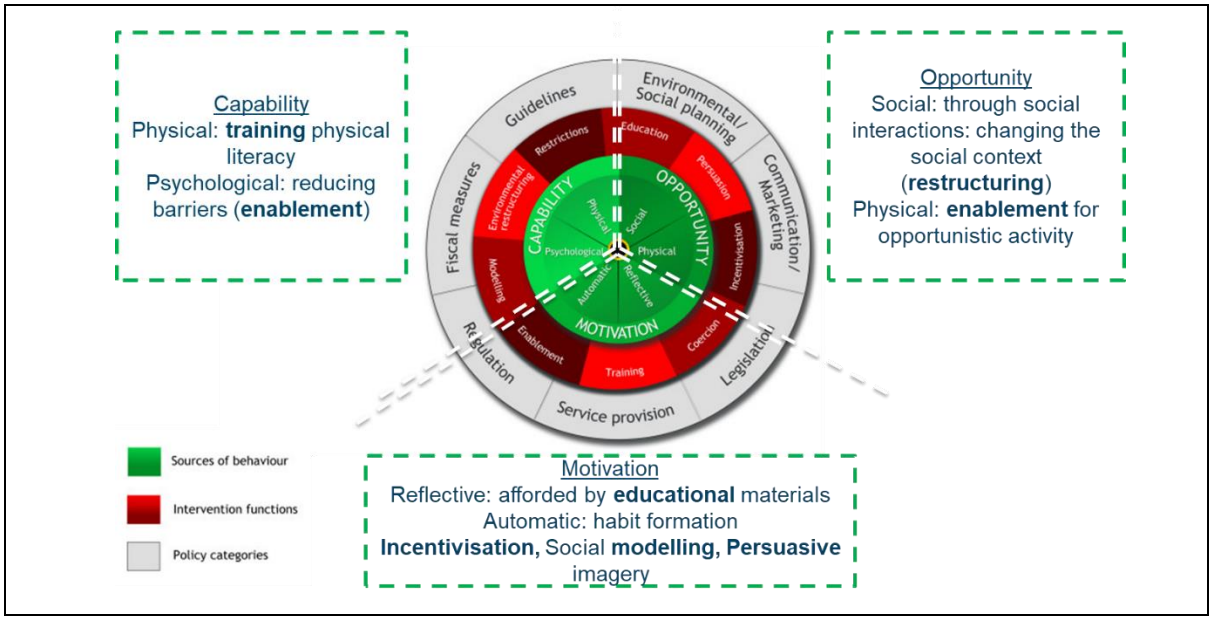

Figure 2: **Alignment with the Capability, Opportunity, Motivation-Behaviour (COM-B) model**

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.

Follow-up will be at 3-months initially, but we will ask participants to consent to subsequent follow-up at 6-months, and again at 1-year and 2-years as funding and research capacity allow.

4. PARTICIPANT RECRUITMENT

4.1 Pre-recruitment evaluations

4.1.1 Study population, recruitment strategies and baseline pre-screening

Figure 3 depicts the flow of recruitment, screening and baseline assessment procedures. 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. Participants will be recruited over a period of 1 month from ~~1st March~~May 2023 and halted at a maximum of 1000 participants across both groups (500 per group).

All participants will be invited to join the study through an email of a flyer on an invitation email distributed through the secure Imperial Qualtrics platform to eligible people on the CHARIOT register. The distribution list will be managed such that automated follow-ups will be sent at 3 and 6 months, provided the participant has not opted out of the study. . If no response is received, an automated follow up email will be sent. A study-specific email address will be provided to potential participants (moustudy@imperial.ac.uk) should they wish to ask any further questions, and it will be made clear to participants that they can opt out or withdraw from the study by clicking the dedicated link. The invitation flyer on the email / letter will include a unique link connected to a participants study (CHARIOT) ID number, which will direct them to the Qualtrics Platform, and will also contain an~~d~~ embedded, dedicated study ID also to pseudoanonymise respondents. Distribution will be managed via Qualtrics by the AGE team. On clicking the link/scanning the QR code, participants will receive a welcome message and will be prompted to read the Participant Information Sheet. The welcome message and Participant Information Sheet will outline the pilot's eligibility criteria for participants to do a self-screening assessment and will request participants to only progress onto completing the Informed Consent Form (ICF) if they fulfil all eligibility requirements. Prior to the ICF,participants will be asked to confirm that they meet the eligibility requirements.

4.1.2 Randomisation

Once consent is complete, the participant will be provided with the baseline questionnaire, and then randomised evenly by the Qualtrics platform to either receive [21]a link to the digital Movement Foundations physical activity tool (intervention arm), or to download the educational resources (control arm).

4.1.3 Blinding

Although it will be difficult to blind informed participants from their allocation to intervention or control, single blinding of analysts will be performed until all data at 3 and 6 months have been cleaned. Therefore, the study IDs allocated to the intervention or control group will be withheld from the study team cleaning and analysing the data, and held only by the data controller at the Ageing Epidemiology Unity (AGE).

4.1.4 Follow-up and study flow

Follow-up questionnaires (the same as baseline questionnaires but without demographic information, and with added components on safety and feasibility) will be sent to each participant at 3 months from completion of the baseline questionnaire, and again at 6 months using the Qualtrics platform Funding will be sought to send further follow-up questionnaires at 1 year and again at 2 years, and these follow-up windows will be included in consent process at the start of the study.

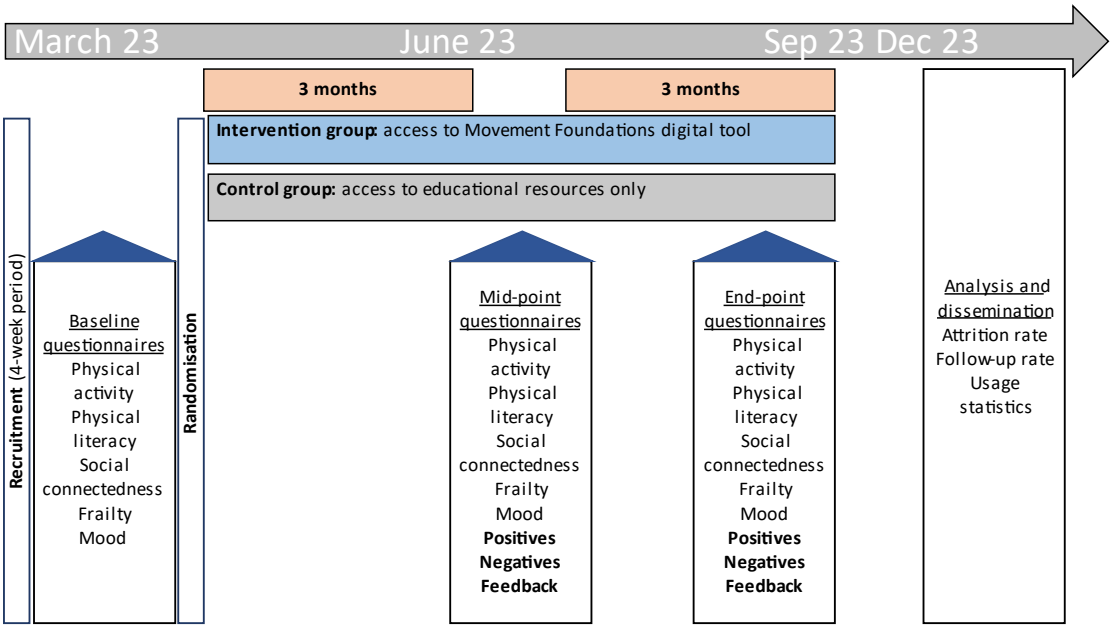

Figure 3: Study flow
Participants will be recruited and randomised following informed consent. Randomisation will be to intervention (Movement Foundations digital tool) or control groups (educational resources only) at a 1:1 rate. All participants will receive baseline questionnaires at time=0, mid-point questionnaires at time=3 months, and end-point questionnaires at time=6 months.

4.1.5 Data analysis

The primary outcome is change in self-reported physical activity (MET minutes per week) from baseline to 3 and 6 months. The effects on secondary outcomes including physical literacy, mood, frailty and sleep will also be assessed, as will participant usage of the digital tool, and drop out rates. An intention to treat analysis will be used. Although this study is designed to assess effect sizes for primary and secondary outcomes, using a previous study with of a physical activity intervention with similar outcomes,[22] we performed a power calculation for two-sided t-test of means of two samples with alpha error of 5%. Standard deviation of both groups was assumed to be ~550 (*). The 95% confidence interval sizes for the control and test groups are about 43 (48.7 - 5.7) and 27 (136.6 - 109.7), respectively. This translates into group standard deviations of (43/4) * sqrt (3000) and (27/4) * sqrt (3000). For conservativeness, we used a higher value of 15 * sqrt (3000) for both groups.
The results are shown in Figure 4 and Figure 5. For a mean difference of 150 MET minutes/week between groups, which would be clinically significant, and power of 0.8, approximately 5700 participants between groups would be required.

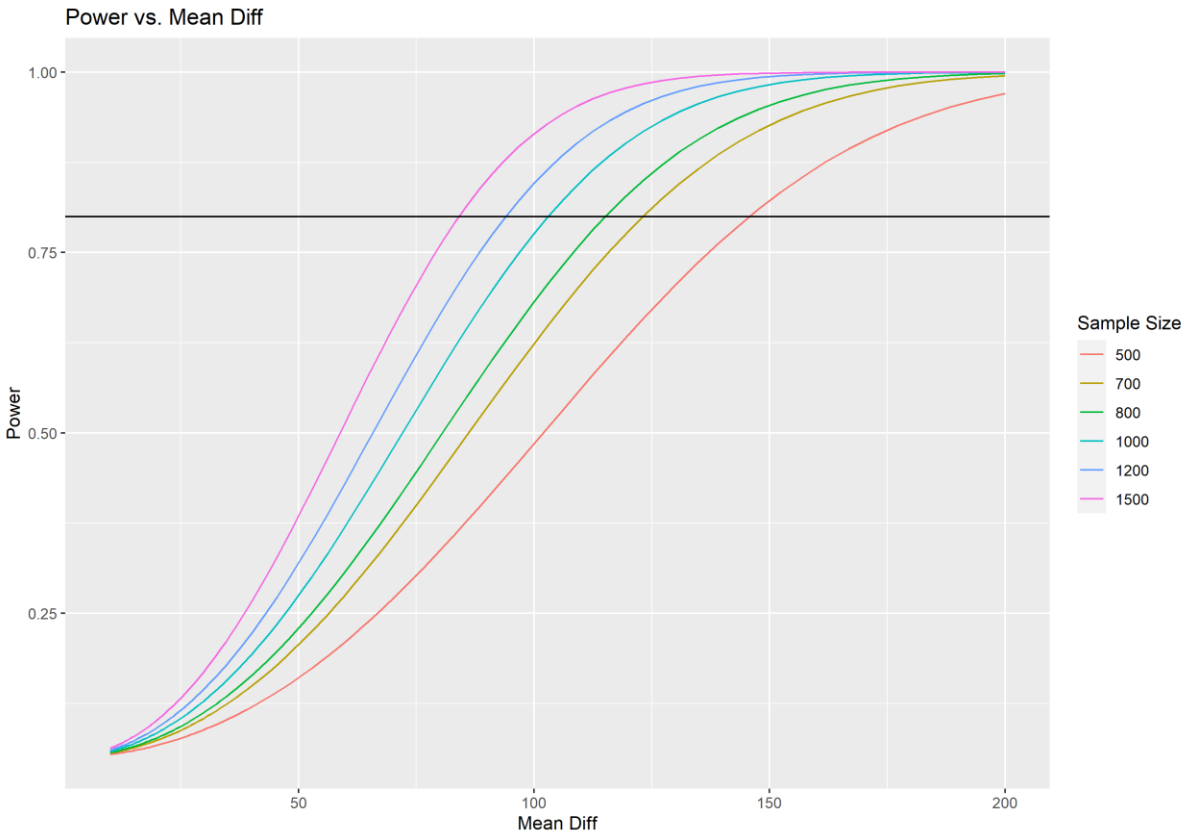

Figure 4: Power vs Mean Difference
Y-axis is the study power between 0 and 1 (100%). The x axis shows the assumed values for the difference of the group means. We tried various combinations of the sample size of each group (assumed to be equal) and effect size.

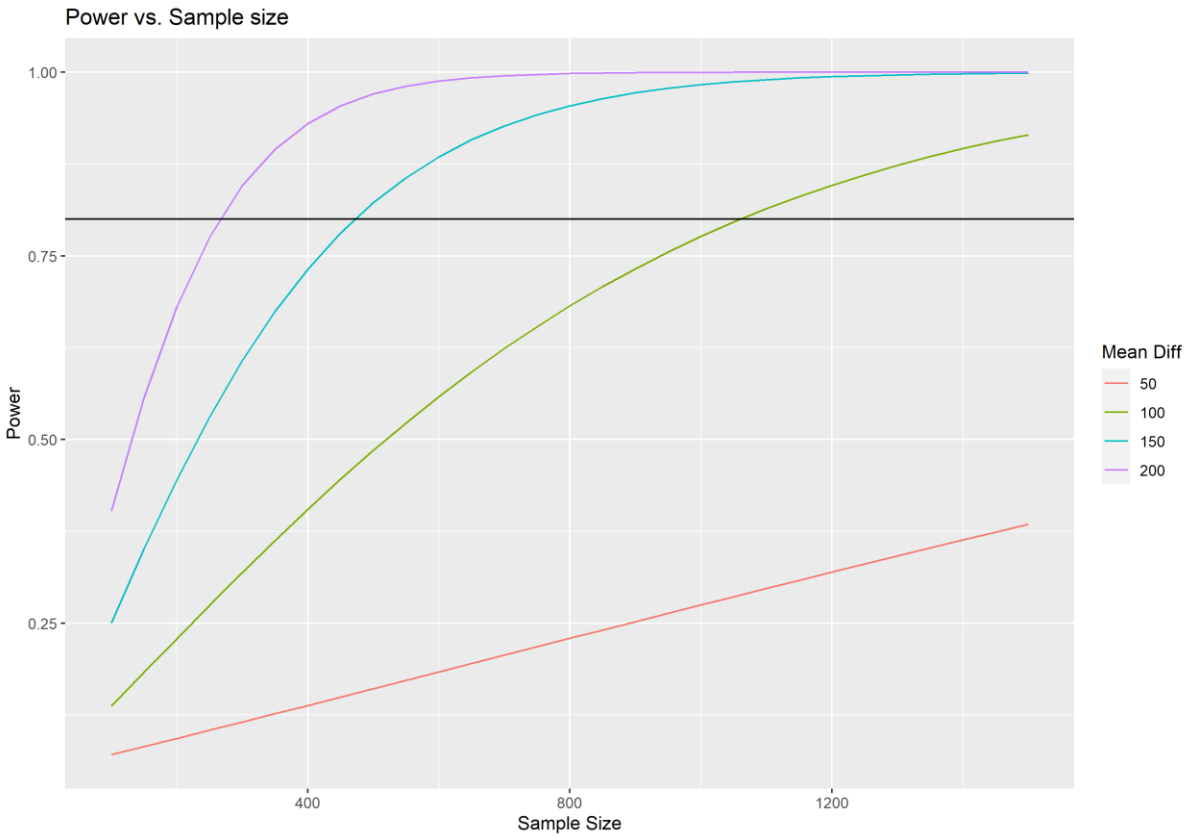

Figure 5: Power vs. sample size
Y-axis is the study power between 0 and 1 (100%). The x axis shows a range of sample sizes between 100 to 1500. We tried various combinations of the sample size of each group (assumed to be equal) and effect sizes.

4.2.1 Eligibility Criteria

Prior to inviting participants into the pilot study, we will screen the CHARIOT Register volunteers for exclusion criteria based on available information recorded against their register profile. Screening eligibility will also be self-assessed upon study invitation. To facilitate ease of assessment, the inclusion/exclusion criteria are brief and specific. The study welcome message and Participant Information Sheet will detail the eligibility criteria for potential participants to review and make a self-assessment as to whether they meet the eligibility criteria. Prior to completing the Informed Consent Form, participants will be asked to confirm their eligibility. If they select 'no' next to any inclusion or 'yes' next to any exclusion criteria, they will be notified of their non-eligibility at that time. We understand that volunteers may be disappointed if they do not meet the eligibility criteria. If a volunteer does not meet screening eligibility, they will be informed of the decision, thanked for their time and

be provided with a description of the exclusion criteria and why these criteria are considered exclusionary for the purposes of this study. The excluded individual will also be provided with links to resources on topics relating to physical activity and NHS recommendations for maintaining a healthy lifestyle (which form the resources provided to the control group).

4.2.2 Inclusion Criteria

- Aged 60+ years
- No dementia diagnosis (self-reported)
- Has access to the internet and a suitable device
- English competency and no significant visual or auditory disability (able to read, hear (including with a hearing aid) and write)
- Able to ambulate safely with or without a walking aid.
- 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)

4.2.3 Exclusion Criteria

- Dementia diagnosis or prescription of dementia specific medicines, as per NICE guidelines (16)
- Severe loss of vision, hearing, or communicative ability; conditions preventing cooperation
- Limited or no access to technology or insufficient confidence in doing so
- Participation in another intervention study
- Chest pain on exercise
- Dizziness on exercise

4.4 Withdrawal Criteria

All participants have the right to withdraw from the MOU pilot study at any time, without providing a reason. Participants may withdraw by contacting the study team directly or they can select to withdraw electronically by following a link provided to them within each study email. At the time of withdrawal, participants may be asked whether they would like to share any comments of their experience on the study and their reason for withdrawing. The

participant is not obliged to provide this information, but if they do provide a reason, this information will be recorded. All information already collected as part of the study will be retained for analysis, but no further data will be collected from them.

Only those participants who discontinue participation in all study activities will be considered as withdrawn. All discontinuations, including transient, will be automatically documented during the study. Participants who withdraw voluntarily will also have the possibility to return to the study, or to return to the study activities, provided they are still ongoing.
At time of any future protocol amendment notification, if a participant fails to re-consent after receiving a reminder email to do so, they will be considered withdrawn unless they contact the study team to notify of their interest in re-participation.

5. ADVERSE EVENTS

All the physical activities suggested in the digital tool are of low-impact, and designated as safe for participants in this age group by the research team including: sport and exercise medicine professionals, physiotherapists and exercise rehabilitation instructors. Moreover, participants embarking on either the control or intervention arms will be reminded that they should not participate in anything with which they feel uncomfortable or incapable, and that participation is at their own risk.

Collecting and reporting study events will help to protect the safety of clinical study participants and fulfill regulatory responsibilities. This section describes the requirements and procedures for study event reporting, even though no specific investigational medicinal products are being studied. Participants will be provided with a link to a form to complete in the event of any adverse event, so that these may be logged and followed-up.

5.1 Definitions

Adverse Event (AE): any untoward occurrence in a participant. These might include injuries form participation in the activities suggested by the digital rehabilitation tool.

Serious Adverse Event (SAE): any untoward and unexpected occurrence or effect that:

• Results in death

• Is life-threatening – refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe

• Requires hospitalisation

• Results in persistent or significant disability or incapacity

Medical judgement will be exercised in deciding whether an AE is serious and/or severe in all situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one of the other outcomes listed in the definition above, will also be considered serious.

5.2 Reporting Procedures

Any events that are reported by the participant to have taken place from the time of signing the informed consent to study termination will be reported as adverse or serious adverse event, depending on which criteria are being met. Depending on the nature of the event the reporting procedures below will be followed. All adverse events (AEs) should be reported. Any questions concerning adverse event reporting should be directed to the Principal Investigator in the first instance. Adverse events will be recorded by participant study ID

numbers. No identifiable information in relation to any adverse events reported will be disclosed outside of Imperial College London.

Non-serious Adverse Events (AEs)

All such events, whether expected or not, should be recorded. This will include concerns raised by participants from completing the questionnaires, including anxiety, or events that occur during the course of the study that the participant feels may affect their participation.

Serious Adverse Events (SAEs)

A Serious Adverse Event (SAE) form should be completed and emailed to the Principal Investigator within 24 hours.

Contact Details for Reporting SAEs:

Phone: [(0)20 7594 2956]

Email: a.mcgregor@imperial.ac.uk

FAO: Professor Alison McGregor

Note that hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs

All SAEs should be reported to the Ethics and Research Governance Coordinator where in the opinion of the Principal Investigator, the event was:
• 'related', i.e. resulted from the administration of any of the research procedures; and
• 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Local investigators should report any SAEs as required by their Local Research Ethics Committee,
Sponsor and/or Research & Development Office.
SAE Forms must be sent to the JRCO administrator in the Joint Research Compliance Office – Email:
jrco@ic.ac.uk

6. ASSESMENT AND FOLLOW UP

6.1.1 Questionnaires

Questionnaires provided as part of the baseline, mid-point and end-point assessments for all participants will consist of a combination of previously validated tools and stand-alone questions. Below provides a summary of each component within the questionnaire. The questionnaire has been designed in alignment with that used in other studies within the CHARIOT register, such as the CHARIOT COVID-19 Rapid Response study (CCRR) (April 2020) and includes:

Demographics

Sociodemographic variables include age, sex, ethnicity, education, occupational status and history, annual gross household income, household composition, marital status and postcode.

Medical history and biometrics

Existing co-morbidities and medications will be collected via self-reporting. Baseline biometrics including weight, height and most recent record of blood pressure measurement (where available) will be included. Participants will be asked to report on their current mobility status and frequency of access to primary care.

Mood

Anxiety and Depression: The Hospital Anxiety and Depression Scale (HADS) tool will be utilised for this study.[23] HADS includes 14 questions on feelings related to anxiety and depression rated on a 4-level Likert scale from “most of the time” to “not at all”. The HADS tool has face validity, with questions that are easy to relate to and appropriate to the current social isolation situation. The tool is also widely used and easy to score.

Sleep Quality

Physical activity has impacts on sleep quality [24] and reduced quality of sleep is a risk factor for the development of cognitive deficits and dementia.[3]

The Pittsburgh Sleep Quality Index -PSQI [25] measures sleep quality with good validity and test-retest reliability.[26]

Physical Activity

The International Physical Activity Questionnaire (IPAQ), short form, will be used for assessment of physical activity. IPAQ is a brief self-reporting tool designed to collect data on physical activities and has been validated across diverse participants up to the age of 65 years,[27] with further evidence of validity and efficacy in older age groups.[28] The questionnaire includes a question each on time spent partaking in moderate activities and vigorous activities, sitting and walking. Vigorous activities are defined in the questionnaire as those which require hard physical effort and result in much heavier breathing than moderate exercise such as heavy lifting or running. Moderate activities are defined in the questionnaire as those which require physical effort resulting in somewhat heavier breathing than walking such as carrying light loads.

Activities of Daily living

The Functional Activities Questionnaire (FAQ) will assess the ability of participants to carry out essential activities of daily living.

Frailty

A short screening tool for frailty, the FRAIL scale, will be used to assess vulnerability to physical frailty in this cohort, and ask questions relating to fatigue, resistance, aerobic capacity, co-morbidity and weight loss. This will categorise patients into robust (score=0), pre-frail (score=1-2) and frail (score = 3-5). This short tool correlates with other markers of frailty, and risk for difficulties with activities of daily living and mortality and has been used in diverse populations of older adults.[29–31]

UCLA Loneliness scale (short form)

This three-item loneliness scale is widely used and validated among older adults. Four additional questions on loneliness are added as well to capture different aspects of loneliness. The first three questions are from the University of California, Los Angeles (UCLA) three-item loneliness scale. The last is a direct question about how often the respondent feels lonely, as recommended by the Office of National Statistics (ONS).

Lubben social network scale (LSNS - 6)

The 6-item scale is a self-report measure of social engagement including family and friends. The Lubben Social Network Scale correlates with mortality, all case hospitalization, health behaviours, depressive symptoms, and overall physical health.[32]

Technology Readiness

The Technology Readiness Index (TRI)[33] is a 2-page questionnaire designed to assess participants' level of comfort with, and frequency-of-use of novel technology, and will be collected to understand participant receptiveness to this digitally enhanced study. The TRI has been used in other pilot studies of online questionnaires with CHARIOT register participants.

Physical Literacy

The Behavioural Regulation In Exercise Questionnaire (BREQ-3) gives information on how people's behaviour with regards physical activity is regulated, and helps us understand their motivations with regards exercise and movement. We have also added the **Exercise confidence based scale** and **Senior Perceived Physical Literacy Instrument – SPPLI** which has been validated in older adults.[34]

7. REGULATORY ISSUES

7.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and [approval from the Research Governance and Integrity Team (RGIT). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. Participant consent will be obtained through the Qualtrics platform. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time.

Those wishing to volunteer, in response to invitation, will be contacted by the research team. A participant information sheet and contact details of research team will be made available to potential participants, who can then contact the research team for further information.

7.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

Participant data will be pseudonymised by study ID (linked th CHARIOT ID), and the pseudo-anonymisation key held securely by the data management team at the Ageing Epidemiology team at Imperial College London. The research team do not have access to this. Only pseudo-anonymised data (i.e. containing no participant identifiable data) will be used in analysis. These data will be held in password protected databases on secure Imperial College computers on site at the Sir Michael Uren Hub in White City.

7.4 Indemnity

Imperial College London holds negligent harm insurance policies which apply to this study.

7.5 Sponsor

Imperial College London will act as the main sponsor for this study.

7.6 Funding

This study is not funded.

7.7 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor.

8. PUBLICATION POLICY

Data from this study will be published in peer-reviewed journals and presented at international scientific conferences, such as the British Association of Sport and Exercise Medicine (BASEM). No identifiable data will be used.

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