

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

Participant Information Sheet

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.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study

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?

In this study we would like to test the impact of a digital web-based physical activity tool on the ability to be physically active and quality of life of people aged over 60 years. We would like to learn as much as possible about the tool, but also about the study and how people progress, so that we can plan and refine a larger study.

Why have I been invited?

We are asking you to think about joining this study because you are part of the CHARIOT cohort. Specifically we are looking for people aged over 60 years who have:

- No diagnosis of dementia
- Access to the internet and a suitable device (eg a mobile phone)
- English competency and no significant visual or auditory disability (able to read, hear (including with a hearing aid) and write)
- Able to ambulate (walk around) safely with or without a walking aid.
- Able to participate in gentle exercise without having been told otherwise by your doctor or other healthcare professional

Unfortunately, we would have to exclude participants who have:

- A diagnosis of dementia or are prescribed medicine for dementia
- Severe loss of vision, hearing, or the ability to communicate

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- Limited access to technology (such as a phone that can connect to the internet), or are not confident using it.
- Participation in another intervention study (where you are being asked to do something different to what you would normally do in day to day life)
- Chest pain on exercise
- Dizziness on exercise

Being physically active is an important part of daily life, and there is evidence to suggest that it is more safe to be physically active than not even if you have multiple health conditions. The benefits generally outweigh the risks, providing that you only increase your physical activity gradually, and that you only continue only as you feel comfortable. We anticipate recruiting a maximum of 1000 people in total for this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to complete the consent form below. If you decide to take part, you are still free to withdraw at any time and without giving a reason. You can withdraw using the opt out link sent to you on the email invite, or by emailing us at: moustudy@imperial.ac.uk

What will happen to me if I take part?

If you are thinking of taking part in the research, but have questions for the research team, you can discuss with us by contacting us at moustudy@imperial.ac.uk. Here, you will have the opportunity to ask any questions that you might have. If you decide to take part, you will be asked to complete a consent form underneath this statement. Please note that, even if you complete the consent form and agree to participate, you can withdraw your consent at any time by contacting a member of the research team at moustudy@imperial.ac.uk or by clicking on the opt-out link in the invitation email. If you withdraw your consent, no further data will be collected from you although we will still use data collected from you to that point.

The next stage of the study is divided into a few parts:

1. You will be asked to complete some questions about yourself on the questionnaire below. These will include age, sex and questions about financial status, social connections, physical activity levels, illnesses and alcohol and smoking habits. We also ask about your perceptions of physical activity (your physical 'literacy'). Although we ask for your postcode to get a better idea of the socioeconomic background of people participating, none of the questions ask anything that could identify you or anyone you know. We analyse all the data together, so no-one would be able to identify you from the results. We anticipate it will take 30 minutes to complete this.

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2. After the questionnaire you will 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). We ask you to follow the guidance in these tools only for as long as you feel comfortable doing so – you are not obliged to do anything or follow any of the guidance. We simply want to know how well these things work. We will describe the specifics of the digital tool below.

3. We will contact you to repeat the online questionnaires at 3 and 6 months, and ideally we would like to follow you up much further down the line, if you are happy for us to contact you again in several years time.

You will be selected for either the intervention or control group at random, and unfortunately you won't be able to choose which group you would like to join. If you are selected for the intervention group (web-based digital tool) you will be asked to provide an email address to which notifications to complete a daily 'wellbeing' check-in can be sent. This will be securely stored, and will not be shared with anyone else. Once the study is completed, this will be securely deleted.

You will then be asked to complete a baseline physical activity assessment (how many times can you stand from sitting in a chair over 1 minute) when convenient for you, and be allocated an exercise programme. Each week you will be given 2-4 sessions of exercises described on the app, and you will be able to select exercises from a range of options. These are body weight-type exercises designed to help you develop strength across your whole body, such as pressing up against a wall, or balancing while holding the back of a chair. Each session should last approximately 30 minutes. Each day, as part of a daily 'wellbeing check', you will be asked to quickly score your levels of fatigue, recovery, soreness, sleep and stress on the app itself, and these will help guide you through progression in physical activity. This should only take 1-2 minutes. Data will only be collected under your study number and cannot be linked to you except by a member of the study team. The digital tool is expected to take around 13 weeks to complete in full, although you can stop using it whenever you wish. The aim is that you use this tool to guide your physical activity progress for as long as it is useful for you.

What are the possible disadvantages and risks of taking part?

There should be no disadvantages to taking part, apart from the time spend kindly helping us. Physical activity is generally safe, and the benefits of being physically active almost always outweigh the risks. There is the potential for injuries, just as in any activity from daily life. It is therefore important to only do what you feel comfortable with, and stop and seek help whenever you feel there is something wrong. We will ask you to tell us about any injuries or issues you had when we follow you up at 3 and 6 months. If you do have any concerns about any aspect of this study, then please do not hesitate to contact a member of the study team as above. We will not ask you to do anything you are not comfortable doing.

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What are the possible benefits of taking part?

It is envisaged that participation in either arm of the study will help you to become more physically active, which has direct benefits for your health. The measurements we will get from you will allow us to learn more about physical activity tools we use for older adults.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. 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 (David Salman d.salman11@imperial.ac.uk). If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk).

- **What will happen to the results of the research study?**

At the end of the study, all participants will be sent a summary of the data we find (of everyone together – not data that can identify individuals). We aim to present the data in journals and at conferences, and will let you know when we have done so.

Who is organising and funding the research?

This work is funded by Imperial College London and the National Institute of Health Research (NIHR) Biomedical Research Centre (BRC).

Who has reviewed the study?

This study was given favourable opinion by Imperial College Research Ethics Committee (ICREC) and Research Governance and Integrity Team.

Contact for Further Information

Please contact David Salman: moustudy@imperial.ac.uk

Thank you for taking part in this study!

A copy of this written information and signed Informed Consent form will be given to you to keep.

Transparency Notice

How will we use Information about you?

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

Study number: 6494648

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in **December / 2023 and data deleted by December 2032.**

For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information (including personal data and data created as part of the study) from **you** for this research project.

This information will include your **name and contact details, and your study identifier**. People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

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 unique study number instead.

We will keep all information about you safe and secure.

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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.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), **Imperial College London relies** on “scientific or historical research purposes or statistical purposes.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the [UK Policy Framework for Health and Social Care Research](#).

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Samples / data from the study may also be provided to [organisations not named in this participant information sheet](#), e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample analysis having the potential

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to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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 that we already have because some research using your data may have already taken place and this cannot be undone.

- We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
- [If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.](#)

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

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

- by asking one of the research team
- by sending an email to d.salman11@imperial.ac.uk, or moustudy@imperial.ac.uk
- by ringing us on (0)20 7594 2956.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to d.salman11@imperial.ac.uk, or by ringing us on (0)20 7594 2956.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or

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via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.