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**PARTICIPANT INFORMATION SHEET**

**The Frail-LESS study**

**(****LEss Sitting and Sarcopenia to lower frailty in older adults)**

**Invitation Paragraph:** We are inviting you to take part in a study to see whether it is possible to deliver a new programme to reduce sitting behaviour in older adults to improve health and help them stay independent with everyday activities like standing up, walking and climbing stairs. This new programme is delivered remotely so we can see if it can help people to sit less during situations like the COVID-19 pandemic or other times when people find it difficult to leave the home. Please read this information sheet carefully before deciding whether to take part.

**How do I sign up to take part?**

[INSERT QR CODE

If you decide to volunteer to take part then either (a)email the research team at [INSERT EMAIL] or phone them on [INSERT NUMBER] (b) scan the QR code on this page or visit this website <https://tinyurl.com/Frail-less-study>, or (c) fill out the expression of interest slip below and post it or email it to the researchers.

**What is the purpose of the study?**

We all lose muscle and strength as we get older (this is called sarcopenia) and this can affect how well we can do everyday activities. Reducing the amount of time spent sitting down could help improve older people’s strength, balance, ability to carry out everyday activities (e.g. standing up from a chair, walking and climbing stairs) and help them to maintain their independence for longer. The purpose of this study is to test a new remotely delivered programme to reduce sitting behaviour in older adults to help them with doing these types of everyday activities. Visit this website to find out more information: <https://tinyurl.com/Frail-less-study>.

**Why have I been invited to take part?**

You have been invited to take part as you are aged 65 years or older and may be losing strength which could make it harder for you to do everyday activities. We are looking for people who may need help with some daily tasks like ‘heavy’ housework (e.g. hoovering, ironing, cleaning the floor) and getting about on public transport or getting in and out of your car. To be able to take part, you also need to be able to walk on your own with a walking aid, sit a lot during a usual day, and be able to communicate in English.

**Do I have to take part?**

No, your participation in the study is completely voluntary and you will not be at any disadvantage if you decide not to take part.

**What will happen to me if I take part?**

You will be involved in the study for approximately 6 months. We will first take a set of health and behaviour measurements from you, which are explained below. You will then be randomly put into either the control group or the intervention group. Regardless of which group you are in, we will repeat the health and behaviour measurements again 3 and 6 months later. After the last set of measurements at 6 months, your involvement in the study will end.

If you are in the intervention group, you will receive the Frail-LESS programme straight away, which will last for 6 months and will include the following:

* An education programme that will tell you about the health benefits of sitting less and ways that you can try to reduce your sitting time.
* You will be given a device that you can wear on your wrist throughout the 6 months to support you with sitting less. This device tracks your sitting time and sends you alerts to encourage you to get up and move more often. You will receive guidance from the researchers on how to use the device. This device will be loaned to you but the researchers take responsibility for any loss or damage.
* You will be offered five sessions with a health coach over the phone or by video call, at a time suitable to you, who will help you in meeting your targets for reducing your sitting behaviour.
* You will be able to join a Frail-LESS peer support group, which will have other members in it from the study. You will be able to support each other in reducing your sitting time during regular meetings and by keeping in touch by phone and email.

If you are in the control group you will be asked to continue with your normal daily behaviours for 6 months. You will take part in the same measurements as the intervention group during this time. After 6 months, your involvement in the study will end but you will have the opportunity to receive the Frail-LESS programme explained above (apart from the health coaching). You won’t take part in anymore measurements after this. It is important to have a control group so we can see how the Frail-LESS programme works compared to people who aren’t receiving it.

The measurements

You will be asked to complete a range of measurements on three occasions to see how your sitting levels, health and wellbeing might change during the study. It will take around 1 hour to complete all the measurements. **If you are unable to attend the University or prefer not to because of COVID-19, a member of the research team will visit you at your home to do the measurements with you.** We will be following government guidelines during the measurements to reduce the risk of spreading COVID-19, such as wearing a face mask and having regular COVID-19 tests. The measurements we take at each time point will include the following:

***Health and wellbeing measures:*** We will first measure how well your body functions physically by testing your balance, normal walking speed, how easily you can rise and stand up from a chair, and how hard you can grip with your hand. The amount of muscle in your body will be measured by sticking four small electrode pads to your hand and foot. We can work out your muscle levels by sending a very small safe electrical current through the body; this does not cause any pain. We will also measure your height and weight and ask you to complete some questionnaires around your health and lifestyle. We will stay a safe distance away from you while you do these measures, unless we think there is a risk of a fall in which case we will stand at an outreached arms distance away.

***Sitting and activity monitoring:*** At the end of the three measurement sessions, we will provide you with a small activity monitor that will be stuck to your thigh to be worn for the next 8 days. It is attached to your thigh using a dressing and this will keep the device waterproof. You can wear it continuously even when bathing or showering. It is important that you wear this continuously every hour of every day otherwise we will not know if the Frail-LESS programme has been successful. This device will be loaned to you but the researchers take responsibility for any loss or damage.



***End of study questionnaire and interview:*** At the end of your 6 month participation in the study, we will ask you to complete a questionnaire to find out what you thought about taking part, how you found the programme and what you thought about the measures we took. We will also invite some of the participants to take part in a one-to-one interview that will last about 30 minutes to find out about this in more detail. If you decide to stop taking part in the study, we will also ask you to complete a questionnaire so we can understand the reasons why people might not continue with this type of research.

**What are the possible benefits of taking part?**

You may experience improvements in your health from receiving the programme such as improved strength, balance and your ability to do everyday activities; this includes the control group who can have the Frail-LESS programme at the end of the study. We are hoping this study leads to a larger study that may help to change healthcare for older adults that encourages reducing their sitting time using this type of programme. By taking part you will be helping us with this. You will receive £10 of shopping gift vouchers for completing the measurements at each data collection point and if you return the activity monitor each time you have worn it (up to a maximum of £30). You will be reimbursed your travel expenses for any visits you make to the university to complete measurements as part of this study.

**What are the possible disadvantages and risks of taking part?**

There is a small chance of skin irritation from the dressing used to attach the activity monitor to your skin. If this happens, remove the activity monitor immediately and discuss the problem with the research team. When we measure how well your body functions there may be a risk of injury. During these measures, you will need to wear suitable footwear (flat heels) to minimise the risk of falling and do the tests without any obvious trip hazards. There is a small risk of experiencing some distress during an interview we may ask you to take part in. You can end the interview at any point without giving a reason why and you can seek support from your GP if you feel this is appropriate. To minimise the risk of data misuse, all information we collect about you will be stored in line with General Data Protection Regulation (GDPR) guidance. This includes storing paperwork in locked filing cabinets at Brunel University and storing electronic files on password protected computers.

**What if something goes wrong?**

If something goes wrong then please contact the research team as soon as possible to explain the problem. We will work with you to find a resolution. If you would like to discuss the problem with someone outside of the research team then please contact Dr Derek Healy, Chair of Brunel University Research Ethics Committee [Derek.Healy@brunel.ac.uk](mailto:Derek.Healy@brunel.ac.uk).

**Will my taking part in this study be kept confidential?**

Your GP will be notified of you taking part in this study. Other than this, your participation in the study will be kept confidential; nobody else outside of the research team will be informed.

**What if I want to withdraw from the study?**

If, at any stage you wish to leave the project, then you can. There is no problem should you wish to stop taking part and it is entirely up to you. There will be no disadvantage to you if you withdraw. If you lose capacity to consent during your participation in the study, you will be withdrawn from the study. Identifiable data already collected with your consent may be retained and used in the study.

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

The results of the study may be published in a scientific journal and presented at a conference so we can share the findings with other researchers and healthcare professionals. We will also send a summary of the findings to all of the participants who take part in the study.

**Who is organising and funding the research?**

The study is being organised by Brunel University London and is being funded by the Abbeyfield Research Foundation.

**What are the indemnity arrangements?**

Brunel University London provides appropriate insurance cover for research which has received ethical approval, like this study. In the event of a claim for which negligence cannot be demonstrated, the claimant may need to take legal action for which they would need to pay.

**Who has reviewed the study?**

This study has been reviewed and a favourable opinion provided by the Berkshire B NHS Research Ethics Committee.

**Research Integrity**

Brunel University London is committed to compliance with the Universities UK Research Integrity Concordat, which is a national framework for good research conduct. You are entitled to expect the highest level of integrity from the researchers during the course of this research.

**How will we use information about you?**

We will need to use information from you for this research project. This information will include your name, contact details, employment status, ethnicity, health conditions, the type of home you live in and your COVID-19 circumstances. 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. We will write our reports in a way that no-one can work out that you took part in the study.

As part of the study, you may be invited to take part in an interview. If you agree to this, the interview will be recorded and saved onto a password protected computer. The research team will type up the recording word for word and will use a fake name to protect your identity. The recordings will then be deleted. We may use quotes when writing reports for the study, but it will not be possible to link this quote back to you in any way. Only the research team will have access to any of the recorded data. Once we have finished the study, we will keep your personal data for 12 months. We will keep the anonymised research data for 10 years. 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.

**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. 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/](http://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to [data-protection@brunel.ac.uk](mailto:data-protection@brunel.ac.uk), or
* by ringing us on 01895 268273.

**Contact for further information and complaints**

**For general information**

Chief Investigator: Dr Daniel Bailey Email: [Daniel.bailey@brunel.ac.uk](mailto:Daniel.bailey@brunel.ac.uk)

Phone: 01895 265363

**For complaints and questions about the conduct of the Research**

Dr Derek Healy, Chair of Brunel University Research Ethics Committee [Derek.Healy@brunel.ac.uk](mailto:Derek.Healy@brunel.ac.uk).

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**EXPRESSION OF INTEREST SLIP** TheFrail-LESS Study

If you are interested in taking part in this study you can email [INSERT EMAIL] to express your interest, visit the website <https://tinyurl.com/Frail-less-study>, or complete this slip. We will then contact you to discuss the study further before you consent to take part. Please take care to ensure we can read your contact details clearly.

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please return this slip by email to [INSERT EMAIL] or by post to:

[INSERT NAME]

Department of Life Sciences

Brunel University London

Uxbridge

UB8 3PH