

National Centre for Sport and Exercise Medicine (NCSEM)
School of Sport, Exercise and Health Sciences
Loughborough University
Epinal Way, Loughborough, LE11 3TU
Contact: Usiju Shaldas U.shaldas@lboro.ac.uk



Loughborough
University

Dr Katherine Brooke-Wavell k.s.f.brooke-wavell@lboro.ac.uk
Study phone: [01509 227890](tel:01509227890)

Predictors of resilience and frailty

Participant Information Sheet – older participants

Contents

KEY INFORMATION	2
Who is needed for the study?	2
Measurements	2
Study sessions	3
What should I do, bring or wear before the sessions?	3
Possible benefits of participating	4
Possible disadvantages or risks in participating	4
Once I take part, can I change my mind?	4
I have some more questions; who should I contact?	5
FURTHER SUPPORTING INFORMATION	5
Who is doing this research and why?	5
Data protection and privacy	5
What if I am not happy with how the research was conducted?	7

Invitation and brief summary

We would like to invite you to take part in our study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please read the key information on pages 2-5. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study before making a decision if you wish.

This study will examine whether measurements from the breath can predict who ages more successfully. It involves having a sample of breath and some other simple measurements. You will then be invited to repeat the measurements once or twice over the subsequent year.

KEY INFORMATION

Who is needed for the study?

We are looking for **men and women aged 65-90 years**, who are able to attend the university for measurements.

Unfortunately, we cannot include you if:

- you smoke or vape,
- you have any communicable disease, lung or chest infection
- you have an acute or transient condition affecting the airways
- you know you have metastatic cancer.

What will I be asked to do?

You will be asked to come to the university for measurements at the beginning, middle and end of the twelve-month study (follow up measurements may be taken at home). Between the measurements, we will ask you to carry on as usual, but to complete a monthly calendar to let us know about any falls or changes to your health and wear a smartwatch that we will provide.

Measurements

The measurements taken at the university will include:

- **Breath test.** This involves wearing a face mask connected to an air supply. You will be asked to breathe normally throughout the test, whilst sitting comfortably in a chair.
- **Blood, saliva, and urine** to examine markers related to ageing. Around two tablespoons will be taken from a vein in your arm, and you will be asked to collect a small sample of urine in a container that we will provide. We will ask you to spit a small amount of saliva into a tube.
- **Bioelectrical Impedance (BIA) scan** to measure your fat and lean mass. This involves standing on a special scale without shoes and socks.
- Some simple **tests of physical frailty**, that involve activities that you may do on a regular basis, e.g. how hard you can grip, how long it takes you to stand up from a chair and walk across a room, how well you balance.
- **Questionnaires** about your background, medical history, physical activity level, lifestyle and cognitive function.

We will also ask you to complete the following at home for the twelve months after the baseline visit:

- You will be given a smartphone app and/or paper **calendar to record any falls or illnesses**. We request that you return this monthly, by postage paid

envelope, email, or text. It is up to you whether you prefer to use the paper calendar or app.

- We will give you the option of using a smartphone app and **smartwatch** to monitor your activity, sleep, and heart rate. If you are willing to use this, please wear it as much as possible until the end of the study but you can remove it for bathing and showering.

Study sessions

You will be invited to **two or three measurement sessions**.

- Everyone will be invited for measurements at the beginning of the study.
- If you have a fall, we will repeat measurements as soon as possible (at your home if needed) and then six months later.
- If you do not have a fall, we would like to repeat measurements after twelve months.

Each visit may last **up to two hours**. Sessions will be arranged at a mutually convenient time as far as possible.

We will reimburse reasonable travel costs. These expenses will be paid bi-monthly. Alternatively, we can provide transport if needed.

What should I do, bring or wear before the sessions?

Please **avoid**:

- **Food, drink (aside from water), exercise, alcohol, breath mints** for two hours before the visit
- **Swimming or wearing perfume in the 12 hours before** the visit.

Please bring a list of all **medication** and bring any medication that may be needed during the visit.

Please wear loose-fitting or stretchy clothes and comfortable footwear to allow you to move freely. A T-shirt with joggers, socks and trainers may be ideal. You will be asked to roll up a sleeve for the blood sample and to remove shoes and socks for some measurements.

We have toilet and changing facilities available.

You are welcome to bring a friend or relative if you wish.

Possible benefits of participating

You will receive information on your results after everyone has finished taking part in the study. We will also let you know the overall study findings.

We hope you will find it interesting to take part in the measurements.

Finally, but perhaps most importantly, you will be a part of research to increase our knowledge on how we can predict who will age successfully.

Possible disadvantages or risks in participating

Injury during physical frailty tests: Due to the physical nature of the activity being performed, there is a potential risk of injury (e.g. tripping) whilst performing physical frailty tests. Sessions will be supervised. To minimise risks, we will follow recommendations of the American Heart Association and American College of Sports Medicine. All sessions will be supervised by at least two investigators, at least one of whom will be a trained first responder.

Blood samples: Risks of collecting blood samples include bruising or feeling faint. The researchers are phlebotomy trained and have regular experience with blood collection. We will have a couch that you can lie on to reduce faintness.

Breath test: You may experience some initial discomfort or slight claustrophobia when wearing the mask. We will always be there during the breath test and will quickly remove the mask should you wish to take it off.

Potential data breach: There is a very small risk that there may be a data leak which may lead to your information being available to others and potential “scam” attempts. This risk will be minimised by storing all information on password protected documents on password protected university computers.

Once I take part, can I change my mind?

After you have read this information and asked any questions you may have if you are happy to participate, we will ask you to complete an Informed Consent Form. However, if at any time, before, during or after the sessions you wish to withdraw from the study, please just contact one of the main investigators (Katherine Brooke-Wavell). You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing.

However, once the results of the study aggregated (31 September 2026) it may not be possible to withdraw your individual data from the research.

If you are unable to consent for follow up visits, we will keep continue to use your previous data for the research unless you ask for it to be deleted.

I have some more questions; who should I contact?

Mr Usiju Shaldas, Doctoral Researcher. U.Shaldas@lboro.ac.uk, 01509 227890

Dr Katherine Brooke-Wavell, Senior Lecturer. K.S.F.Brooke-wavell@lboro.ac.uk, 01509 222749

FURTHER SUPPORTING INFORMATION

Who is doing this research and why?

This study is funded by the Wellcome LEAP Dynamic Resilience Programme (<https://wellcomeleap.org/dr/>). Measurements will be carried out by:

- Mr Usiju Shaldas (PhD research student), Loughborough University
- Dr Katherine Brooke-Wavell (Senior Lecturer in Human Biology), Loughborough University
- Researchers may be assisted by other Loughborough University students.
- The overall project is led by Professor Alexandra Stolzing (Wolfson School of Mechanical and Materials engineering) Loughborough University in collaboration with researchers from chemistry (Dr Matt Turner and Ayoung Kim), information science (Dr Andrea Soltoggio and Christos Peridis) and Professor Tahir Masud (Professor of Musculoskeletal Gerontology from Nottingham University Hospitals NHS Trust).

The project has been reviewed by Loughborough University Research Ethics Committee.

Data protection and privacy

Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

What personal information will be collected from me and how will it be used?

We will ask for your name, date of birth, contact information, and medical history. In addition, we will take measurements of body weight and height, blood pressure, body composition, physical frailty and will analyse your breath, saliva, blood and urine.

All data will be anonymised and stored securely in a database that could be accessed for this study and for use in future research on related topics. These will be stored separately from health information such as breath and fluid samples.

What is the legal basis for processing my personal information?

The data will be used to describe the characteristics of people taking part in research as a group. Individual results will not be reported in any conference, publication or thesis. Personal data will be processed on the public task basis. For further details on the data protection legislation see:

<https://ico.org.uk/your-data-matters/>

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as “sensitive data”. The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

How long will my personal information be retained?

We will keep your contact information for 10 years as we would like to apply for funding for a follow up study and would like to be able to contact you to invite you to take part if you are interested.

Will my personal information be shared with others?

Anonymised data may be shared with all investigators taking part in the study as well as other collaborating scientists in the Wellcome LEAP Dynamic Resilience programme at other institutions (<https://wellcomeleap.org/dr/>).

Data from the smartphone app will be downloaded by the company providing the app and stored anonymously. This data will include your date of birth, physical activity (steps) and calendar entries.

Samples will be stored at Loughborough University but may be transferred to collaborating scientists for specialist analysis.

Will my taking part in this study be kept confidential?

Yes. As soon as you take part in the study, you will be assigned a study code (such as WL001). This code will have no reference to your name or any other personal details and will be stored securely in a file only accessible to the

direct research team. All data and samples will be identified only by this code. Data will be stored in locked filing cabinets and/or university's cloud-based secure system. Information linking participants names and study numbers will be stored securely in a separate location. Smartphone app data will be downloaded and analysed by the company providing the app (Gero) and stored anonymously on a server based in the UK.

How will the anonymised data/results collected from me be used?

Data collected will be used as part of a research project at Loughborough University and may be shared with collaborating scientists. Then, the results of the study will be published in scientific journals and presented at relevant scientific and medical conferences. We will share results with you and be happy to explain our findings.

The tests and samples are not general health tests, and any health issues you are experiencing should be discussed with your doctor.

How long will the anonymised data and samples be retained?

We will keep anonymised data indefinitely as part of a data repository. We will keep samples for up to 10 years after the completion of the study (until 30/9/2036) to allow us to analyse different predictors of frailty and ageing. If you are willing, we would like your permission to use any spare samples for future research in the same research theme over this time, for instance researching other health conditions.

What if I am not happy with how the research was conducted?

If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Review Sub-Committee, Research & Enterprise Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: researchpolicy@lboro.ac.uk

The University also has policies relating to Research Misconduct and Whistle Blowing which are available online at <https://www.lboro.ac.uk/internal/research-ethics-integrity/research-integrity/>.

If you require any further information regarding the General Data Protection Regulations, please see: <https://www.lboro.ac.uk/privacy/research-privacy/>.