PARTICIPANT INFORMATION SHEET

The ACTIVE-FAB intervention to reduce sitting time and increase physical activity in adults with Fabry disease.

We would like to invite you to take part in our research study. Joining the study is entirely up to you, and before you decide we would like you to understand why the research is being done and what it would involve for you. Please read this information sheet to help you decide whether you would like to take part. Please feel free to ask the research team any questions you may have and talk to others about the study if you wish.

This study will form part of an educational project undertaken by Miss Sarah Gosling as part of her PhD that she is doing at Brunel University London.

Part 1 of this information sheet tells you the purpose of the study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part. Please be assured that there will be no disadvantage to you if you decline to take part.

Part 1

How do I sign up to take part?

If you would like to take part in this study, then please email Miss Sarah Gosling: sarah.gosling@brunel.ac.uk

What is the purpose of the study?

Currently, treatment of Fabry disease is focused on medication to help manage physical symptoms. We don't know much about treatments other than medication for managing mental health and quality of life in Fabry disease. Limiting sedentary behaviours (like watching TV, using a computer, and browsing social media) and increasing physical activity (e.g. walking, housework and gardening) can improve physical health, mental health, and quality of life in the general population. We have designed a new sedentary behaviour and physical activity intervention with patients and healthcare professionals to support adults with Fabry disease improve their physical health, mental health, and quality of life.

The purpose of this study is to test this new intervention, called ACTIVE-FAB, to see if it is acceptable and safe for adults with Fabry disease and what their experiences are when taking part in it.

Why have I been invited to participate?

You have been invited to join this research study as you are an adult with Fabry disease. To be eligible, you must be at least 18 years old, live in the United Kingdom, able to walk without the help of another person, and able to communicate in English.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. There will be no disadvantage to you if you decide to not take part or withdraw at any time.

What would taking part involve?

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

If you are in the intervention group, you will receive the ACTIVE-FAB intervention straight away, which will last for 3 months and include the following:

- An initial consultation with a physiotherapist to discuss your sedentary behaviour and physical activity, and set goals.
- Two progress consultations with a physiotherapist to discuss your engagement with the intervention, and review your goals.
- An educational website, which covers the importance of limiting sedentary behaviour and engaging in physical activity, and examples of physical activities for people with different capabilities.
- A smartwatch (see image) that tracks sedentary behaviour and physical activity. You will receive guidance from the research team on how to use the device. You can keep the smartwatch after the study has ended.
- You will have the option to join an ACTIVE-FAB peer support group, which will have other members in it from the study. You will be able to support each other during monthly meetings, and by keeping in touch by phone and email.

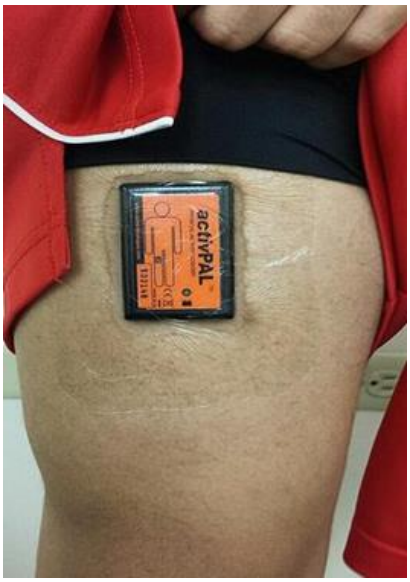
If you are in the control group, you will be provided with a leaflet providing healthy lifestyle advice and will continue to get your normal healthcare as usual for 3 months. . You will take part in the same measurements as the intervention group during the study. After 3 months, your involvement in the study will end but you will have the opportunity to use the ACTIVE-FAB website and smartwatch, which you can keep afterwards. It is important to have a control group so we can see how the ACTIVE-FAB intervention works compared to people who aren't receiving it.

The measurements

You will be asked to complete a set of measurements on two occasions to see how your sedentary behaviour, physical activity, mental health, and quality of life might change during the study. The measurements will include the following:

Mental health and quality of life questionnaires: Two online questionnaires to measure your anxiety, depression and quality of life. Completing these two questionnaires will take approximately 15 minutes.

Sedentary behaviour and physical activity monitoring: You will be provided with a physical activity monitor called an activPAL, which will be attached to the front of your thigh and worn for the next 8 days. It is attached to your thigh using a dressing and this will keep the device waterproof. It is very important that you wear it continuously, even when bathing or showering. It is important that you wear the activPAL every hour of every day otherwise we will not know if the ACTIVE-FAB programme has been successful. We will also ask you to complete a daily diary to record the time you wake up and get out of bed and the time you get into bed and go to sleep, as this will help us to know when you are asleep and awake. The activPAL will be loaned to you, but the researchers take responsibility for any loss or damage. We will provide you with a pre-paid envelope to send the activPAL back to us so we can download your data from it.



End of study questionnaire and focus group: At the end of your 3-month participation in the study, we will ask you to complete a questionnaire so you can give feedback on your experiences of the measurements we took. We will also invite some participants to take part in a focus group that will last about 90 minutes to find out about their experiences with the ACTIVE-FAB intervention.

What are the possible benefits of taking part?

You may experience improvements in your health and quality of life by taking part in the study. We will use the findings from this study to design a larger study in the future to test how effective it is and if it is value for money. The larger study may lead to changes in healthcare for adults with Fabry disease to include an intervention like ACTIVE-FAB for managing this condition. By taking part you will be helping us with this.

Once we receive the activPAL from you at each time we take measurements, you will receive a £50 shopping voucher as a token of appreciation for your involvement in the study.

You will also be able to keep the smartwatch after the study has ended.

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 activPAL monitor to your skin. If this happens, remove the activPAL immediately and discuss the problem with the research team.

Although a clinician will check it is ok for you to take part in the study, there is a small risk of experiencing some worsening of symptoms of Fabry disease that you may have (e.g. chest pain or severe shortness of breath). If you experience symptoms such as this, immediately stop the physical activity that you are doing and contact your GP (or call an ambulance if you feel very unwell and symptoms do not go away when you stop the physical activity). There is also a risk of injury while doing physical activity. To reduce this risk, please wear suitable clothing and footwear and complete any exercises in a space free from any trip hazards. If you experience any adverse events during the study, please report it to the research team.

There is a small risk of experiencing some distress during the focus group if you take part in this. You can take a break from the discussion and re-join the group if you feel able to or leave the focus group at any point without giving a reason why. If you experience distress, you can seek support from your GP, if you feel this is appropriate.

How will data be taken from medical records?

Records will typically be kept by your hospital in paper or electronic, scanned form. We will collect data from relevant sections of your medical records and store this data anonymously using a participant ID number.

Will my taking part in this study be kept confidential?

Responsible members of Brunel University London or regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure the study is being carried out correctly and complying with regulations. Access to paper and electronic files would be given to authorised people, which would be set up on a limited basis for the duration of their visit. These people will have a duty of confidentiality to you as a research participant.

Will I be recorded, and how will the recording be used?

If you take part in a focus group, this will be recorded using the recording feature of Microsoft Teams. The recording will be saved onto a University password protected laptop or computer. The recording will be typed up word for word and a fake name will be used to protect your identity. Following this, the recordings will be deleted.

What will happen if I don't want to carry on with the study?

If you wish to leave the study, then you are free to do so and without giving a reason. There will be no disadvantage or detriment to you if you withdraw. With your permission, we would like to keep data collected from you up until you withdraw from the study, but we would not continue to collect data from you. If you would like us to, we will destroy all of your identifiable data as soon as you withdraw.

<u>Part 2</u>

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 conferences so we can share the findings with other researchers and healthcare professionals. We will also send a summary of the findings to you by email or post if you consent to this.

What if there is a problem?

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 Chair of the Research Ethics Committee: Professor Christina Victor (christina.victor@brunel.ac.uk).

Who is organising and funding the research?

The study is being organised by Brunel University London. Funding from the Society for Mucopolysaccharide Diseases (MPS Society) is supporting the research.

What are the indemnity arrangements?

Brunel University London provides appropriate insurance cover for research which has received ethical approval. 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 given favourable opinion by the [INSERT REC NAME] NHS Research Ethics Committee and the College of Health, Medicine and Life Sciences Research Ethics Committee at Brunel University London.

Research Integrity

Brunel University London is committed to compliance with the Universities UK Research Integrity Concordat, which is a national framework for good research. 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 and from your medical records for this research.

This information will include your: name, contact details, age, sex, ethnicity, height, weight, education level, employment status, occupation, marital status, age when diagnosed with Fabry disease, disease genotype (genetic variant), disease phenotype (classic or late-onset), LysoGb3 (biomarker), comorbidities, level of mobility, type of therapy (enzyme replacement therapy or chaperone therapy), and therapy duration.

People 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 have procedures in place to keep all information about you safe and secure.

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.

If you take part in the focus group, 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.

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 London and storing electronic files on University password protected laptops and computers.

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.

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 data-protection@brunel.ac.uk

Contact for further information and complaints

For general information

Principle Investigator: Dr Daniel Bailey Email: daniel.bailey@brunel.ac.uk

Doctoral Researcher: Miss Sarah Gosling Email: sarah.gosling@brunel.ac.uk

For complaints and questions about the conduct of the research

Professor Christina Victor, Chair of Brunel University London Research Ethics Committee

Email: christina.victor@brunel.ac.uk

Thank you for taking the time to read this information sheet. If you would like to take part, you will be asked to sign a consent form.