

## PARTICIPANT INFORMATION SHEET

**Study title:** The REgulate your Sitting Time (RESIT) study

**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 people with Type 2 diabetes. Please read this information sheet carefully before deciding whether to take part.

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

If you decide to volunteer to take part then either (a) email the research team at [INSERT NAME] or phone them on [INSERT NAME], (b) scan the QR code at the top of this page, or (c) fill out the expression of interest slip below and post or email it to the researchers.

### What is the purpose of the study?

The purpose of this study is to test a new programme to reduce sitting behaviour in people with Type 2 diabetes. The programme is person-focused meaning that participants get to choose different options within the programme based on their own preferences. Visit this website to find out more information and watch a video about the study: [tinyurl.com/RESIT-information](https://tinyurl.com/RESIT-information).

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

You have been invited to take part as you have Type 2 diabetes. To be eligible, you need to be able to stand and walk unassisted (with or without the use of a walking aid) and able to communicate in English. You must be aged 18-85 years old. You must not be on insulin medication or be pregnant. You should also not take part if you have any blood borne disease or infection e.g. HIV, hepatitis.

### 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?

Each participant will be randomly put into either the control group or the intervention group and will be in the study for 6 months. If you are in the intervention group, you will receive the RESIT package, which will include the following:

- An online education programme that will tell you about the health risks of sitting, ways that you can try to reduce your sitting time, and tools that you can use in the RESIT programme to help reduce your sitting time.
- You will be offered four sessions with a health coach at a time suitable to you who will help you in meeting your targets for reducing your sitting behaviour.
- You will get to choose from a selection of phone apps, computer apps and wearable devices to support you to sit less. These tools track your sitting time, help you to set goals, and send you alerts to encourage you to get up and move around more often. You will receive guidance from the research team on how to use each of the tools available to you.

If you are in the control group you will receive the above (apart from the health coaching), but this will be delayed by 24 weeks from the start of the study. During the first 24 weeks you will need to continue with your normal daily behaviours. It is important to have a control group so we can see how the programme works compared to people receiving usual healthcare.

### The measurements

You will be asked to attend Brunel University on three occasions at the start of the study, 3 months into the study, and 6 months at the end of the study. This is to have a range of measurements taken so we can monitor sitting levels, health and wellbeing. You will need to come to our laboratory in the morning after an overnight fast. It will take around 1 ½ hours to complete all of the measurements. If you are unable to attend the University because of restrictions in relation to the COVID-19 pandemic, we will get you to

complete the measurements by yourself at home during a video or phone call with the research team. If this happens, you won't need to fast overnight.

**Sitting and activity monitoring:** We will provide you with a small activity monitor that will be stuck to your thigh to be worn for 8 consecutive days after your visit to our laboratory. It is attached to your thigh using medical 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 activity monitor continuously every hour of every day otherwise we will not know if the intervention has been successful.



**Health and wellbeing measures:** We will take a small finger prick blood sample to measure your blood sugar and cholesterol levels. Blood pressure will be measured by inflating a cuff around the arm. Body fat levels and weight will be measured by standing on a scale with two metal plates and by measuring your waist circumference. We will 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. We will ask you to complete some questionnaires around your health and lifestyle as well. At the end of the study we will ask you to complete a questionnaire to find out what you thought about taking part, how participants found the intervention 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.

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

You may experience improvements in your health from receiving the programme; this includes the control group who can have the programme at the end of the study. We are hoping this study leads to a larger study that may help to change healthcare for people with Type 2 diabetes that encourages reducing their sitting time using this type of programme. By taking part you will be helping us with this. You will receive £30 of shopping gift vouchers if you take part in all of the data collection and return the activity monitor each time you have worn it. You will be reimbursed your travel expenses for any visits you make to the university as part of this study.

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

There is a very small risk of cross-infection when taking blood samples. We will take these samples in line with best practice guidelines to minimise this risk. There is a small chance of skin irritation from the dressing used to attach the activity monitor to your skin. If this happens, the activity monitor can be removed immediately and the problem discussed 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 as to 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 GDPR guidance. This includes storing paperwork in a locked filing cabinet at the 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 Professor Christina Victor, Chair, College of Health and Life Sciences Research Ethics Committee [Christina.victor@brunel.ac.uk](mailto:Christina.victor@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 Diabetes UK.

### **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 approved by the West of Scotland NHS Research Ethics Committee.

### **Research Integrity**

*Brunel University London is committed to compliance with the Universities UK [Research Integrity Concordat](#). 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 and contact details. 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. 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.

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 using a phone app called 'Otter' and saved onto a password protected computer. The research team will type up the recording word for word and will use a pseudonym (fake name) to protect your identity. 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. If we need you to take measurements at home because of the COVID-19 pandemic, we will record you doing some of the measurements using Zoom and save these recordings on a password protected computer. Only the research team will have access to any of the recorded data. We will not collect any data from you from any of the apps or wearable devices you use during the 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 [Dipa.Gorsia@brunel.ac.uk](mailto:Dipa.Gorsia@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**

Professor Christina Victor, Chair, College of Health and Life Sciences Research Ethics Committee  
[Christina.victor@brunel.ac.uk](mailto:Christina.victor@brunel.ac.uk)

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**EXPRESSION OF INTEREST SLIP**

Regulate your Sitting Time (RESIT)

If you are interested in taking part in this study you can email [INSERT NAME] to express your interest 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