**Title of study: RESPONSE –** Breaking up prolonged sitting in people with type 2 diabetes: Optimising the response

**Chief Investigator: Prof Tom Yates**

*This study will form part of a PhD project being undertaken by Phil McBride (PhD candidate).*

*PhD Candidate: Phil McBride -* [*pm381@leicester.ac.uk*](mailto:pm381@leicester.ac.uk)

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**Participant Information Sheet**

We would like to invite you to take part in our research study. Before you decide whether you would like to take part, we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and talk to others about the study if you wish.

**Part 1** of this information sheet tells you about why we are doing this study.

**Part 2** gives you detailed information of what will happen if you decide to take part.

**Part 3** gives you information about the funding and support of the study, and potential risks/benefits to you.

Please contact us if there is anything that is not clear. Our contact details can be found at the end of this document.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it **AND/OR** for future research.   
We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

**Part 1**

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

Spending a large amount of time sitting during the day, and particularly in prolonged unbroken bouts is known to have a negative impact on blood sugar levels. The good news is that regularly breaking up sitting time by doing simple activities, such as standing, stretching, etc. for a few minutes can be very effective at improving blood sugar levels as well as many other aspects of health such as the ability to perform daily tasks, heart health, and risk of developing foot ulcers. For example, in people with type 2 diabetes, research has shown that doing simple activities every 30 minutes for 3 minutes over a 6-8-hour period significantly improves glucose control. We want to expand on this research by asking people with type 2 diabetes to take part in a 4-week programme designed to regularly break up sitting time throughout the day with a variety of simple activities. We want to test how well this programme works for improving blood glucose levels and various other indicators of your overall health.

**2. What does the study involve?**

With your signed consent, we would like to arrange a total of 2 video call-based assessments with our research team (e.g., over Skype, Zoom, or another platform that you may be familiar with). We would also like you to take part in a programme designed to regularly break up sitting time over a 4-week period. You do this programme in your daily life. There will also be two 8-day periods wearing activity monitors and a glucose monitor (which measures the amount of sugar in your blood) (one at the start and one at the end of the study). See Part 2 for full study details.

**3. Why have I been invited?**

You have been invited to take part in this research because you have a diagnosis of type 2 diabetes, are aged 40-75, and have previously taken part in research at the LDC, you have been referred to the study by your health care provider, or you have highlighted your interest based on promotional materials.

**4. Do I have to take part?**

No. Taking part is entirely voluntary and you can talk to others before deciding whether to take part. If you do decide to take part, or would like further information, we will describe the study and go through this information sheet with you. If you agree to take part, you will be asked to complete and sign a consent form. The consent form must be completed before we can schedule your first appointment. You will be given a copy of the signed consent form and this information sheet to keep. If you prefer not to take part, you do not have to give a reason, and this will not affect the standard of care you receive. If you agree to take part, but later change your mind, you may withdraw at any time, without giving a reason by contacting the research team. This will not affect your care in any way. If you do change your mind and withdraw, we will keep and use the data we have collected up to that point.

**Part 2**

**1. What will I have to do if I take part?**

***Video Call 1: 30-60 minutes***

The first video call will be for confirming eligibility and conducting baseline assessments. Depending on the information you have consented to us accessing, you may need to perform a fingerprick blood test using a monitor we send you. During this call we will explain all the study activities and measurements to you and ask you to perform the activities whilst we are on the video call. These activities and measurements are as follows:

Waist Circumference

We will provide you with the tape measure required to measure your waist circumference. Instructions on how to do this will be given during the video call.

Physical Function

We will ask you to perform some activities whilst we are on the call. We would like you to do the 30-second chair stand test. It includes standing up and sitting down as many times as you can from a sturdy chair (such as a dining chair) in 30-seconds.

We will ask you to watch a series of videos demonstrating different physical movements and indicate how capable you are of completing them.

Prior to the video call, we will send you a foldable marker which measures 4-metres. We will ask you to use this to mark out a clear 4-metre space at your home (inside or outside). We will then ask you to walk this 4-metre distance so that we can assess your walking speed.

Physical Activity and Glucose Monitors

Prior to the video call, we will post you two small activity monitors to wear, one on your wrist and one taped to your leg. These measure how much time you spend sleeping, sitting, and moving. You will also be sent a continuous glucose monitor to monitor the changes in your blood sugar throughout the day. They can be worn all day and night and whilst showering/bathing. We will also ask you fill out a wake and sleep log whilst wearing these devices. All these devices will be worn for 8 days, starting on the day you have your video call. During the video call we will talk you through how to wear the devices. At the end of the 8-day monitor wear period, the monitors should be returned to us in a pre-paid envelope (provided).

A picture containing person, sitting, table, woman

Description automatically generatedA hand holding a cell phone

Description automatically generatedA picture containing game, light

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Health Questionnaires

We will ask you to complete a small questionnaire booklet. This contains nine questionnaires. They will look at your functional ability, quality of life, breathlessness, anxiety and depression, chronotype (whether you are more of a morning or evening person), chronic pain, fatigue, and dietary intake. This can be completed on your computer and emailed to us, or we can send you a paper copy to be returned with your physical activity monitors.

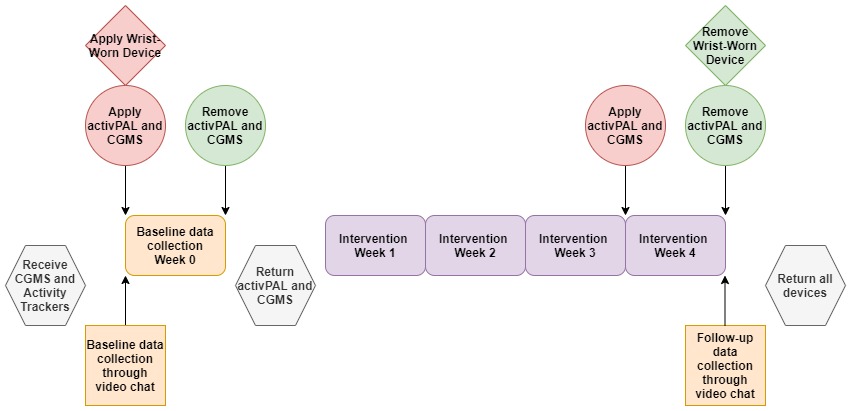
***Intervention***

The following phase of the study is the 4-week intervention. You will be given advice on strategies to break up your sitting time throughout the day. You will receive regular contact from the study team over the phone or via video chat to monitor your progress. You will also be given a choice from a variety of commercially available tool to help you to monitor your sitting time. These will range from wrist watches (like the Fitbit) to mobile apps or computer programmes which help you to keep track of your sitting time. This may require you to periodically upload data to a system which the research team can monitor. We will be using the information gathered on your usual activity patterns, patterns of changes in your blood sugar, and patterns of sleep to help us to offer you a personalised programme for breaking up your sitting time. Towards the end of the intervention, you will be sent another set of activity monitors and a glucose monitor. You should apply these during the final 8-days of the intervention and complete a new wake and sleep log. At the end of this 8-day period, the monitors should be returned to us in a pre-paid envelope (provided).

***Video Call 2***

Finally, you will have one further video session which will replicate Video Call 1.

Flowchart for study procedure



***To be returned to the study team at the end of the study:***

* ***All activity trackers provided to you by the research team (thigh-worn and wrist-worn)***
* ***All continuous glucose monitoring systems provided to you by the research team***

**Part 3**

**1. What will happen to the information and samples (data from the measurements) I provide?**

We will need to use information from you for this research project.

This information will include your ethnicity, age and measures collected as part of the study. 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 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.

Only the main research team have access to your personal details and know what your study ID is. The data will be analysed and compiled into a research project for submission as part of a PhD project.

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

If you choose to participate in the study, then you will be required to dedicate some of your time to the video calls and the intervention itself. You may experience slight irritation from the activity and glucose monitors, although this isn’t common.

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

While there is no direct monetary benefit to taking part in the study, you will receive data on your health which has been gathered from the study. You will be able to see any information which has been collected from you, including assessments of physical function, and your glucose responses over an extended period. You may also experience benefits to your health by taking part in the intervention and having structured support in reducing the amount of time you spend sitting.

**4. Will my taking part in this study cost me anything?**

There will be no direct costs to you taking part.

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

All the information that is collected about you during the course of the research will be kept strictly confidential. With your permission, we will contact your own doctor (GP) and they will be notified that you have participated in the above study and will be sent details of your results. It is possible that your results could have clinical significance. In this situation, these results will be highlight to you and your GP so that they may follow-up accordingly.

If you consent to taking part in the research study, members of the research team may request data from your medical records to supplement the data gathered during the study. They may also be looked at by the regulatory authorities or a representative of the sponsor (The University of Leicester) or host NHS organisation to check that the study is being carried out correctly. When the results are published, no names will be used, and it will not be possible to identify anyone who has taken part. 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.

Information collected may be used to support other research in the future and may be shared anonymously with other researchers. If you consent to this, we may share your data in an anonymous format with other organisations for research purposes. Only the main research team have access to your personal details.

**6. What will happen to my personal data?**

The University of Leicester is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake 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 properly. The University of Leicester will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at [www.hra.nhs.uk/information-about-patients/](about:blank) or <https://le.ac.uk/patient-gdpr-guidance> or by sending an email to <add your email>or by ringing us on <add your phone number>.

To speak to the University’s Data Protection Officer and In-House Commercial Lawyer (Elisabeth Taudi), University of Leicester, University Road, Leicester, LE1 7RH please email [ias@le.ac.uk](about:blank), or ring 0116 229 794.

Should you lose capacity to consent during the course of the study, you would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out on or in relation to you.

The University of Leicester will collect information about you for this research study from the central NHS database, NHS Digital. This information will include your name/ NHS number/ contact details and health information, which is regarded as a special category of information. We will use this information to track your visits to the GP, visits or admissions to hospital and, in the event of death, the date and cause of death.

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.
* **OPTION if data will be used for future research:** 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. [**Insert details of any specific bank/ repository**]

**7. Will the information obtained in the study be confidential?**

All details recorded in the study will be treated in the strictest confidence. The researchers involved in the study will keep your contact details in a secure database so that you can be contacted in the future should the need arise. This data will be held in compliance with the Data Protection Act 2018 and the General Data Protection Regulation (2018).

You can optionally agree to the researcher keeping your contact details to send you invitations to participate in other research projects in the future. You are under no obligation to agree to participate in these.

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

Once we have analysed the results, we will present the findings in a PhD thesis, at scientific meetings, across Leicester Diabetes Centre networks for educational purposes, and in medical research journals. All these results will be anonymous, and it would not be possible to identify you.

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

The data collected during this study forms part of a PhD project. The study is being run by investigators based at the Leicester Diabetes Centre at the Leicester General Hospital and is Sponsored by the University of Leicester. All student activity is being supervised by senior researchers within Leicester Diabetes Centre. This research is being funded by the Leicester Biomedical Research Centre. The researcher is not being paid for including participants in the study.

**10. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the safety, rights, wellbeing and dignity of its study participants. This study has been reviewed and given a favourable opinion by the RES Committee – London – Bromley. It has been reviewed by independent medical/research experts and the study sponsor, the University of Leicester.

**11. What if I am harmed by the study?**

It is very unlikely that you would be harmed by taking part in this type of research study. In the event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**12. What if I wish to complain about the way in which this study has been conducted?**

If you have a concern about any aspect of the study, please contact the Chief Investigator using contact details given at the bottom of this information sheet. If you remain unhappy and wish to make a formal complaint about any aspect of the study or how you have been treated during the study, the normal hospital complaints procedure is available to you. Please contact the following:

***Patient Information & Liaison Service at pils.complaints.compliments@uhl-tr.nhs.uk. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP***

***Freephone: 0808 1788337***

**13. What do I do now?**

Now that you have read the information leaflet, if you would like to take part, please complete the reply slip and pre-screening questionnaire and send back to the research team using the pre-paid envelope provided and we will then be in touch with you. If you would like to discuss this information with your family or friends, please do. The researcher’s details are given below. If you do not wish to take part, your clinical care will not be affected in any way.

**Contact for further information:**

**If you require any further information you can contact the following:**

**Phil McBride**

Leicester Diabetes Centre (Origin) email: pm381@le.ac.uk

Leicester General Hospital

Gwendolen Rd

Leicester

LE5 4PW

**Professor Tom Yates**  Tel: 07941456348

Leicester Diabetes Centre (Origin) email: ty20@le.ac.uk

Leicester General Hospital

Gwendolen Rd

Leicester

LE5 4PW

***Thank you for taking the time to read this information sheet.***

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to [**email**], or
* by ringing us on [**phone number**].