**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).*

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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 or if you would like more information. Our contact details can be found at the end of this document.

**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 for 3 minutes every 30 minutes over a 6-8 hour period significantly improves blood sugar 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 sugar levels and various other measures of your overall health.

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

With your signed consent, we would like you to attend a total of 4 visits to our research centre to have measures of your health taken. 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, not at our research centre. There will also be two 8-day periods of wearing activity monitors and a glucose monitor (which measures the amount of sugar in your blood) (once at the start and once 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 Leicester Diabetes Centre, 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. 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 need to do if I take part?**

***Visit 1: 4-5 hours***

The first time you come to the research centre will be for consent and baseline measurements. You will need to refrain from eating food and drinking anything other than water from the night before your appointment. You will also need to avoid alcohol, caffeine, and exercise 48 hours prior to the visit, and avoid vigorous   
exercise 72 hours before the visit. We encourage you to take a finger prick test before travelling, and if there is a risk of this please call us to reschedule your appointment. First, we will review the inclusion and exclusion criteria with you and check that there are no issues. This may require a small fingerprick blood sample to be taken. After this has been confirmed, the baseline measurements are as follows:

Anthropometric Measures

We will measure your body composition (body weight and how much of your body is made up of muscle, fat, etc.) using bioimpedance assessment. This device is very similar to a set of weighing scales. A small (un-noticeable) electric charge will pass through your body. We will also measure your height, and waist circumference.

Resting Metabolic Rate

This will tell us how much energy you use when at rest. From this we will also be able to see how many calories your body needs. This will involve lying as still as possible (whilst remaining awake) under a clear hood. The test takes around 30 minutes.

A person standing in a room

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Blood Sample

We will take approximately 11ml (around 2-3 teaspoons) of blood from a vein in your arm so that we can measure the amount of sugar and fat in your blood. We will also freeze 9ml of blood to allow us to measure other markers of health related to type 2 diabetes.

Health Questionnaires

We will also ask you to complete a questionnaire booklet which should take around 30 minutes to complete. This contains nine questionnaires. They will ask you about your ability to perform various daily tasks, quality of life, breathlessness, anxiety and depression, chronotype (whether you are more of a morning or evening person), chronic pain, fatigue, and dietary intake.

Mixed Meal Challenge

The research team will give you a standard breakfast – options will be provided. They will then take approximately 11ml (around 2 teaspoons) blood samples at intervals up to 3 hours (15, 30, 45, 60, 90, 120, 150, 180 minutes). These samples will be taken via cannulation. Cannulation involves connecting a tube to your vein so that blood can be taken multiple times without having to repeatedly use a needle (see image below). These blood samples will allow us to test your body’s response to food.

A close up of a hand

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The total volume of blood taken through this visit – including all samples will be approximately 108ml. This is a relatively small amount and it is unlikely that there will be any side effects to losing this much blood. For example, when you give blood for donation, they typically take around 470ml of blood.

Physical Function

We will measure your standing balance, usual walking speed, ability to stand from a chair, hand grip strength, and ask you to perform a selection of activities which include: walking 50ft, putting on and removing a coat, picking up a penny, standing up from a chair, lifting a book, climbing one flight of stairs, and safely turning in a circle. We will also ask you to do a simple fitness test that involves walking between two points, 10 metres apart. The speed at which you walk will be set to a recorded “beep”. The beep will get progressively faster until you are no longer able to maintain the pace. These tests should take a total of around 20 minutes.

Physical Activity and Glucose Monitors

We will give 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 given a continuous glucose monitor to monitor the changes in your blood sugar throughout the day – attached to your arm. You will not be required to do anything to these monitors, and they will be recording measurements without your input. They can be worn all day and night and whilst showering/bathing. We will also ask you fill out a wake and sleep log. All these devices will be worn for 8 days, starting on the day you come to the research centre.

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A hand holding a cell phone

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Flowchart for Visit 1

**A screenshot of a cell phone

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***Visit 2: 6 hours***

Your second visit to the research centre will be to undergo a 5.5-hour period of sitting down with simple 2-minute physical activity breaks occurring every 20 minutes to break up the sitting. This will give us a good understanding of how your body responds to different types of breaks in sitting. Once again, you should attend this visit having not consumed food or drinks other than water since the previous evening and breakfast will be provided. You will also be provided with a snack during the visit, but lunch will not be provided. If necessary/desired, you should bring lunch to consume at the end of the experiment. You will return your two activity devices (wrist and thigh) and be given two new ones to wear during the visit. You will keep the same continuous glucose monitor on until the end of this visit.

At various points throughout the day at the visit, we will be taking measurements for the following:

Muscle Activation

You will be given a pair of “smart shorts” to wear for the duration of the session. These shorts have electrodes embedded into the fabric which allow us to assess which of your muscles are being activated and how much during each of the physical activity breaks. These are similar to cycling shorts and can be worn under your normal clothes. If you are not comfortable with this, then you can opt-out of this element of the study.

A picture containing person, indoor, table, chair

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Breath Analysis

Around 5 minutes before the start of each physical activity break, you will be fitted with a mask which covers your mouth and nose. You should keep your normal breathing pattern. This will allow us to measure how difficult the activity is for your body. The mask will be removed at the end of the activity break. You will wear this mask 16 times.

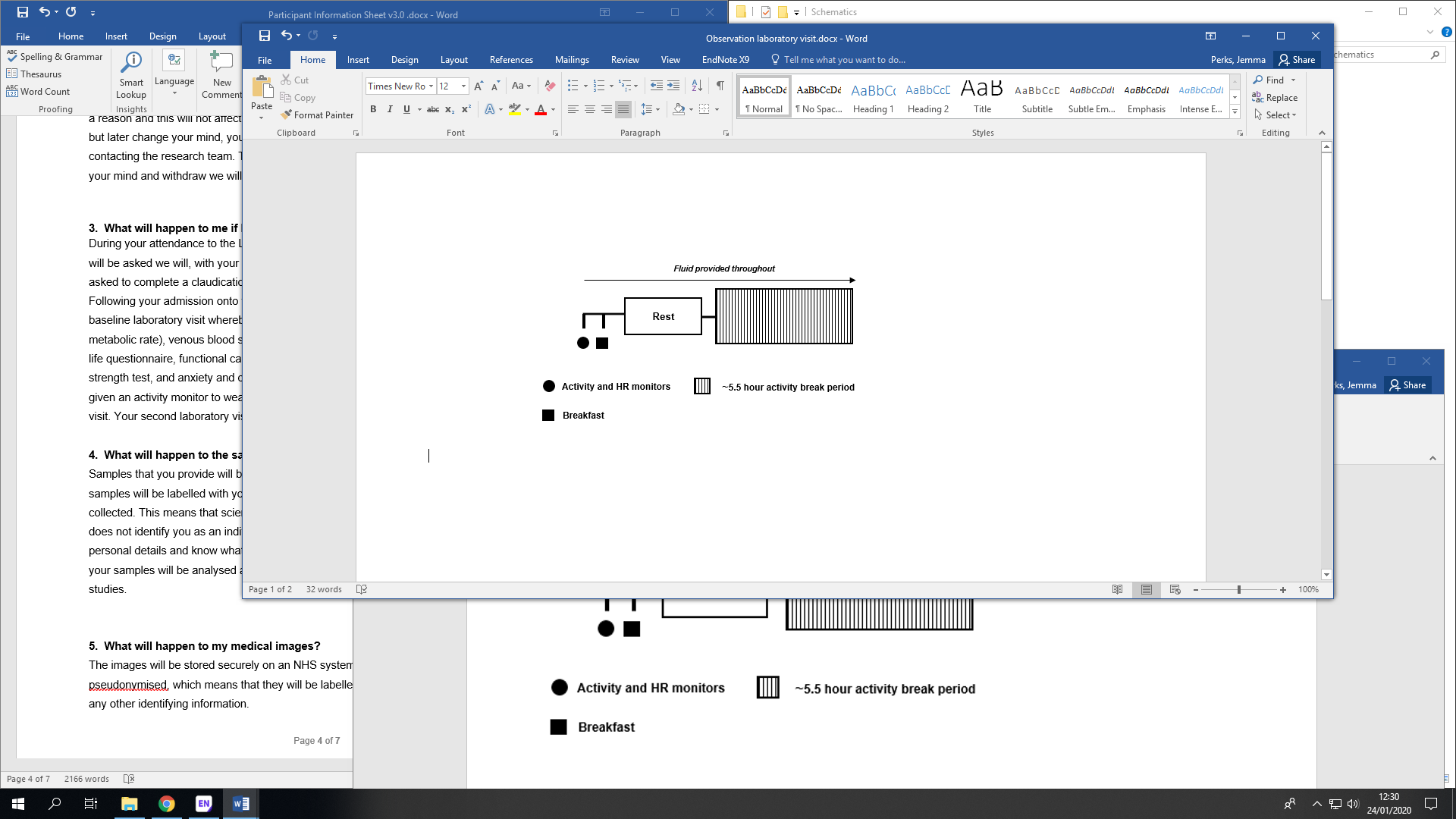
A picture containing person, building, outdoor, man

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Exertion, Pain, and Feelings

Towards the end of each physical activity break we will ask you to rate how difficult you think the activity was, how much pain the activity caused you, and how pleasant/unpleasant you feel the activity was. The activities are simple movements, many of which you will be familiar with already, and include stretches, squeezing a stress ball, and balancing on one leg.

Flowchart for breaks procedure

A picture containing food

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***Intervention***

The following phase of the study is the 4-week intervention. You will be randomly assigned to one of two groups: a control group who will receive generic advice on how to reduce sitting time; and another group who will receive personalised advice based on the data collected in the previous two visits. 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. The research team will review the measurements that were taken in your previous visits to design a personalised programme for you to reduce your sitting time. This will include looking at your sleep patterns, responses to food, and the reactions you had to different types of activities used to break up sitting. All participants will receive weekly contact from the study team to keep track of your progress.

***Visit 3: 10 minutes***

During the final 8-days of the intervention period, you will come back into the research centre for a short visit to be fitted with new activity devices and a continuous glucose monitor. These should be worn until the end of the intervention. If preferable, it can also be arranged for the devices to be posted to you and the research team will schedule a video call with you to guide you through how they should be worn.

***Visit 4: 4-5 hours***

Finally, you will attend the research centre for one further session which will replicate Visit 1. Once again, you will need to come to this visit in a fasted state and breakfast will be provided. You will also need to avoid alcohol, caffeine, and exercise 48 hours prior to the visit, and avoid vigorous exercise 72 hours before the visit.

***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.

Blood samples that you provide will be stored in a secure facility at the University of Leicester until all data has been collected, at which point they will be analysed. The samples will be labelled with your ‘study ID’ not your name, and the date they were collected. This means that scientific personnel will only work on your samples in a way that does not identify you as an individual. 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 being at the research centre. You may experience some bruising from the blood tests. You may experience slight irritation from the activity and glucose monitors, although this is not 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 blood analysis, assessments of physical function, and your glucose responses to consuming a meal.

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

There will be no direct costs to you taking part. You will be repaid for travelling expenses that you incur as part of attending the study centre. Upon production of receipts, you will be reimbursed up to £10 per visit to cover costs of travel e.g. parking, taxi.

**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 in the UK and abroad 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 the 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**].