Participant Information Sheet

Understanding blood glucose responses to eating

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You are being invited to take part in a research study. Before you decide whether or not you wish to take part it is important that you understand why the research is being done and what it will involve. Please read this information carefully and discuss it with others if you wish. Please do not hesitate to contact us if anything is unclear, or if you require more information. Take time to decide whether or not you wish to take part. Details about the conduct of the study are also explained which will help you to decide whether or not you wish to take part.

What is the purpose of this study?

Dietary lifestyle interventions are one proposed strategy in obese populations to assist in weight loss and improve metabolic health, in particular the control of blood sugar. An emerging strategy is time-restricted eating (TRE). This protocol prescribes to consume all daily calories within a fixed daily time window, followed by a prolonged period of fasting over a total 24 hour period. Currently, some research points at metabolic benefits when an 8 hour window to consume food is followed by 16 hours of fasting. The rationale for implementing an 8 hour feeding window comes from recent interest in how circadian rhythms (24-h light-dark cycle) tightly regulate metabolism.

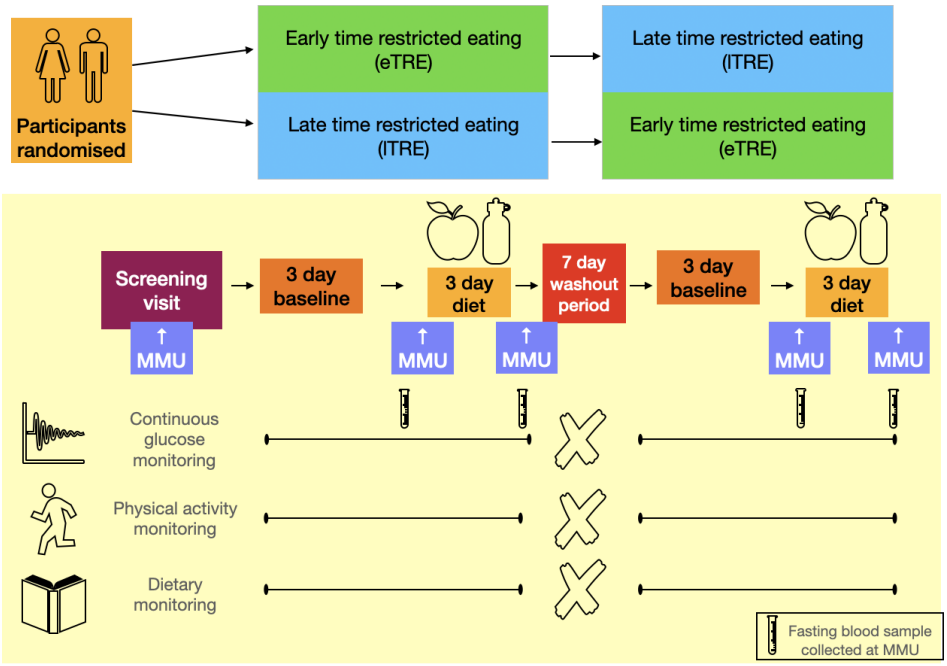
Previous research has shown benefits of TRE, however whether the 8 hour eating window yields improved metabolic health when applied early (i.e. 8:00 till 16:00) or late until later (i.e. 12:00 till 20:00) is still unclear. In addition, it is unknown whether these shown improvements are the result of an adaptive and cumulative effect of multiple days of TRE or can already be observed acutely. Thus, the aim of this study is to assess the effects of three days of both early or late time-restricted eating on 24 hour blood sugar levels.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to do so, you will be asked to sign a consent form. However, you will still be free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

We will contact you by phone or email to answer any questions you may have about the study. We will then ask you some questions about your medical history to check whether you can participate. You will not be able to participate in the study if you are a smoker, have type 1 or type 2 diabetes, are pregnant, alcohol consumption >14 units weekly, have food allergies or intolerances to any foods consumed in this study, have identified disturbed eating patterns or diagnosed eating disorders, recent major body weight change (+/- 3 kg in the last month), are a shift-worker, have any medical conditions or if you are taking medications that will affect the measurements in the study. If you are a suitable participant, we will invite you to attend the University research facilities on 5 separate occasions, lasting between 30 and 45 minutes per visit.



	Breakfast	Lunch	Dinner	Snacks
Early time restricted eating (eTRE)	8am	12pm	4pm	10am & 2pm
Late time restricted eating (lTRE)	12pm (noon)	4pm	8pm	1pm & 6pm

Figure 1: Explanation of study protocol, timing of measurements and timing of meals.

What will I have to do?

Visit 1 (Screening)

After contact via email or phone, you will be invited into the laboratory for a screening and familiarization trial. This visit will happen at a time that is suitable for you. At this visit you will be invited to ask any questions or raise any concerns before agreeing to take part in the study. Your participation will then depend on the satisfactory completion of a medical and exercise history questionnaire. If you are considered eligible and agree to take part you will sign an informed consent form.

You will then have your height, weight and waist circumference taken as well your body composition. You will be explained how to wear and use a continuous glucose monitoring device and an accelerometer. Next, we will place an accelerometer on your hip or wrist (your preference) which will measure your normal physical activity levels for three days. In these

three days, we will also ask you to keep a dietary diary and record all the food and times of food consumption. After the fourth day, you can take off the accelerometer and take the device and dietary diary with you to your next visit. At the end of the screening, we will schedule the next appointment for the start of the trial.

Visit 2

At least 4 days later (after wearing the accelerometer), you will attend the lab for the start of your trial. Attendance will be between 24 - 36 h before the start of the experimental protocol and has to happen in a fasted state (not having consumed food for several hours). We will collect a fasted blood sample upon arrival. The reason for the 24 - 36 h prior to the start is to place the continuous glucose monitor and let it stabilise before it records experimental data. We will provide you with the food that you will consume over the three days and explain when you are expected to consume the meals and snacks. You will undergo both conditions (early time-restricted feeding and late time-restricted), but the order will be based on randomisation. We will also place an accelerometer to measure physical activity levels over the three days and we will ask that you keep a dietary diary to indicate the timing when you consumed your meals and snacks. Throughout the three day intervention period, we will also send you automated text messages at appropriate times to remind you to consume your next meal or snack. Visit 2 should take approximately 30-45 minutes.

Visit 3

The morning after the three-day intervention, we will ask you to come to the lab in a fasted state. We will collect a blood sample and you will hand in the dietary diary, accelerometer and we will remove the continuous glucose monitor device. We will also schedule the next 3-day trial which is at least a week (7 days) later. Visit 3 will take approximately 30-45 minutes.

Visit 4 and 5

Visits 4 and 5 are identical to visit 2 and visit 3, except that you will be asked to follow the opposite eating pattern over the 3-day trial. Remember that the order of 3-day trial conditions (early or late) is randomised.

What are the possible benefits of taking part?

During the screening, we will measure your weight, height, body composition and measure some blood markers. This will give you insight in your physique and health and learn about your body. Additionally, we will provide you with the groceries needed to follow a predetermined diet on the two trials, which totals 6 days worth of food.

Will my participation involve any physical discomfort?

Yes, there are some possibilities that you experience physical discomfort. During the time-restricted eating trials, you will be asked to strictly adhere to food consumption at predetermined times of the day. This means that during the fasting phase you might experience a feeling of having an empty stomach. You are allowed to consume water without restrictions, that might help to suppress hunger feelings. We have designed the diet to mimic normal eating patterns and provide two snacks moments between the three main meals to reduce cravings.

Secondly, on the experimental days you will have to wear a continuous glucose monitor for 24 hours. A fine sensor will be inserted into the skin that will feel like a small prick. In extreme cases, an infection might develop around the site of insertion. An experienced researcher will handle the procedure of insertion. Lastly, on four (4) occasions, we will take a blood sample (15 mL). Thus a total of 90 mL of blood will be collected throughout the study. For comparison: during a blood donation 500ml blood is taken in one day. You may experience some mild discomfort when blood samples are being taken. This is not a painful procedure,

but you will feel a slight prick when the needle is inserted and you may have some very light, small bruising following, which is a completely normal response. However, all samples will be collected by appropriately trained personnel (certified phlebotomist/IV cannulation) to minimize this possibility. This will be discussed at the outset of the study and if you do not wish to take part on this basis then that is your choice.

What will happen if I feel unwell during the diet section of the study?

If you feel unwell at any point during the diet portion of the study, you may return to your normal diet and contact a member of the study team (emails at end of information sheet), you will then be withdrawn from the trial.

What will happen if anything goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you wish to make a complaint you can contact the principal investigator Kelly Bowden Davies whose details are on the front page on this information sheet.

Will my taking part in this study be kept confidential?

Yes. All information that is collected about you during the course of this research will be kept strictly confidential. You will be provided with a unique code so that any information collected will be unidentifiable to yourself.

What will happen to the study results?

The overall results of the study may be presented at scientific meetings or published in a scientific journal. You will not be identified in any of these presentations or publications. We will be happy to discuss the results with you when the study is completed and will let you know where you can obtain a copy of the published results.

Contact for further information

If you have any further questions, then please contact either Abigail Walker abigail.walker2@stu.mmu.ac.uk or Dr Kelly Bowden Davies K.Bowden.Davies@mmu.ac.uk

Thank you for having taken the time to read this information sheet and your interest in the study. If you do decide to take part in the study, you will be given a copy of the information sheets and a signed consent form for you to keep.