

Participant Information

Investigating the effect of time restricted eating (TRE) on sperm quality

Invitation and Summary

Thank you for your interest in this study. Please read the following information to decide whether you wish to take part. Please take the time to discuss this with your partner and ask the research team and your doctor any questions you may have.

Time restricted eating (TRE) is a form of intermittent fasting which involves eating during a window of 8 hours within a 24-hour period. The remaining time in the day is fasting, taking only water, black coffee or tea. TRE is an emerging field with a growing range of health benefits including weight loss, better blood sugar regulation, improved hormone levels and a healthier gut. As TRE has a positive effect on a number of systems in the body, including female reproductive systems, there is potential that it could influence sperm production, however, this has not yet been investigated. This study aims to discover whether a 3-month period of TRE has a benefit on sperm quality.

Who can take part?

Men between the ages of 18 – 44 with a BMI of at least 18.5 kg/m².
You cannot take part if you are diabetic, a smoker, have struggled with an eating disorder in the past or have had bariatric surgery.

What would taking part involve?

If you decide to take part in this study, you will be asked to complete a consent form. You will also be asked to fill in a questionnaire about your lifestyle and medical history which will be reviewed by a doctor to check that it is safe for you to take part.

You will be contacted by telephone and invited to attend the Bristol Centre for Reproductive Medicine (BCRM) for an initial appointment which will last approximately 1 – 1.5 hours. At this appointment we will measure your height, weight, waist circumference and blood pressure. For the first cohort of participants, a small sample of blood will be taken to check testosterone levels. We will need to collect 2.5mls which is less than a teaspoon. You will also be asked to produce a semen sample in one of our private sample production rooms. The clinical team will perform a semen analysis including sperm count, motility and normal forms.

In addition, the semen will be tested for levels of oxidative stress using a system called MiOXSYS. The results of your sperm test and MiOXSYS test will be available to you via email within 5 working days. If you wish to discuss the results with a scientist, our contact details will be provided with the results. A small portion of the semen sample will also be frozen for metabolic analysis, looking at the small molecules which are present.

Due to the variability in sperm parameters, we will ask you to provide a second semen sample before starting the fasting, so that we can calculate your baseline results. If you have had a semen analysis at an accredited laboratory within the last year, we can use these results to calculate your average instead.

We will ask you to take part in TRE for 12 weeks, eating only between the hours of 11am and 7pm. You will be given a fasting log to record the duration of your fasts, it is very important that you document honestly, even if you have not completed the fasting. During this time, the research team will send text message reminders and phone you every 4 weeks to check how you're getting on, answer any questions you may have and provide ongoing support. You can contact us at any point if you have questions; our details are at the end of this document.

After 12 weeks, you will be asked to attend the BCRM again for repeat height, weight, waist circumference and semen analysis. If you were in the initial cohort of participants who had their blood tested for testosterone levels, this will also be repeated. Again, the results of the semen analysis and MiOXSYS test will be available to you via email after 5 working days. If you wish to discuss the results with a scientist our contact details will be provided with the results.

Taking part in this study does not prevent you from embarking on fertility treatment or trying to conceive. Being part of this study will not affect your treatment.

What will happen to the samples?

Once a semen analysis has been performed on the fresh sample, a small amount will be frozen for analysis. The frozen sample will then be sent to the University of Manchester Biological Mass Spectrometry Core Research Facility, where the composition of the semen will be tested using specialised equipment for the purposes of this research project.

Your blood sample will be sent to Severn Pathology at Southmead Hospital and the level of testosterone measured.

All samples will be sent securely and will only be labelled with a code number, none of your personal details. Once the testing has taken place, all samples will be destroyed.

What are the potential benefits of taking part?

You will be given the results of all semen analyses and the MiOXSYS tests at no cost to you and can discuss these with a member of the embryology team. Self-funding these tests would cost more than £500. TRE has been shown to have a range of health benefits, offering positive effects on physical health and wellbeing. Aside from the personal benefit, we hope that conducting this research will improve our knowledge of the effect of diet and lifestyle on male fertility. If beneficial, this could provide a useful tool to improve male fertility. There is no payment for taking part in this study.

What are the possible disadvantages and risks of taking part?

Undertaking TRE for 3 months could be restrictive, as we are asking you to stick to the schedule as closely as possible and record your eating window over a long period. Support will be provided and you can withdraw from the study at any time.

There is a chance that TRE may have no effect or may negatively affect sperm production. We anticipate that any decline in sperm parameters would be temporary, returning to baseline measurements within 3 months. A Trial Management Group will be monitoring participants carefully and if a significant decline is identified, the study would be stopped early.

You will be required to attend the BCRM to produce a semen sample before commencing the study and after a period of TRE. As far as possible, we will try to schedule these appointments at a time that is convenient to you.

How will we use your information?

We will need to use information from you for this research project. This information will include your initials, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. Your information will be treated as strictly confidential and will only be used in the management of the study. This personal information will be stored in a separate, password protected document so that 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, with paper records stored in a locked filing cabinet and electronic records in a password protected folder on a secure server. 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 wish to have the results of your sperm test sent to you, you will be registered on the BCRM patient portal so that they can be communicated to you securely.

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.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ ; <http://www.hra.nhs.uk/patientdataandresearch> by asking one of the research team or by contacting the BCRM Data Protection Officer, Paul Wilson on **0117 2591159** or paul.wilson@bcmr.clinic

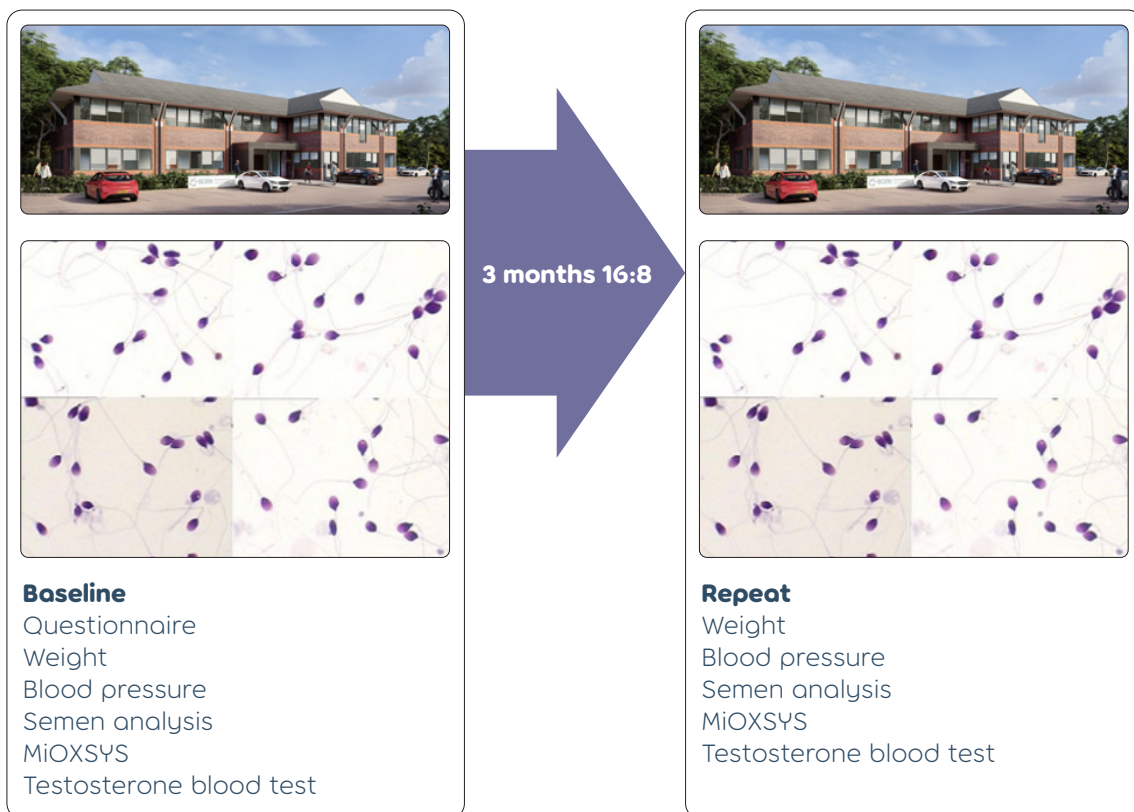
Where will the results of this study be shared?

This study is being conducted by the BCRM in collaboration with Manchester Metropolitan University. The results will be published in a DClinSci thesis and may also be published in academic journals and at scientific conferences. These results will be presented in an anonymised data set, so that no identification of participants is possible. Please let the research team know if you would like to receive a summary of the study results.

If you have any further questions regarding this study and what is involved, please contact Jennifer Nisbett, Senior Clinical Embryologist:
jennifer.nisbett@bcmr.clinic

Complaints

If you wish to make a complaint you can contact the Quality Manager at BCRM by emailing quality@bcmr.clinic and/or PALS at Southmead Hospital: pals@nbt.nhs.uk, **01174144569** or St Michael’s Hospital: PALSandcomplaints@ubhw.nhs.uk, **0117 3422015**



This costs of this study are covered with funding from NHS England and the study has been given favourable opinion by the Bradford Leeds Research Ethics Committee.