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Investigating the effect of time-restricted eating on sperm quality

Submission date
22/04/2025

Recruitment status
No longer recruiting

Registration date
30/04/2025

Overall study status
Completed

Last Edited
08/05/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
During the past 50 years, there has been a worldwide decline in male fertility, however, there has not been a subsequent increase in research or treatments available. Hence, there is an urgent need to explore anything that could improve fertility rates in men. Time-restricted eating (TRE) means that you only eat during a set time each day (usually an 8-10 hour window), and for the rest of the day, you can only drink water or black tea/coffee. Doing this appears to have a number of health benefits, including weight loss, better blood sugar regulation, improved levels of hormones and a healthier gut. We think that because TRE has these positive effects on the body, it might also improve sperm production, however, this has not yet been investigated.

Who can participate?
Male patients aged 18-44 years undergoing fertility investigations in three outpatient fertility clinics

What does the study involve?
Participants will have a semen analysis to assess their semen volume, sperm count, motility, and appearance of the sperm, as well as a test to assess the oxidative stress in the semen. They will then be asked to undertake TRE for a period of 3 months, eating in an 8-hour window between 11 am and 7 pm. After 3 months, the sperm tests will be repeated to see whether there has been any change. Additionally, semen samples will be frozen and analysed to look for changes in composition, including sugars and amino acids.

What are the possible benefits and risks of participating?
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.
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 will 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.

Where is the study run from?
Bristol Centre for Reproductive Medicine Limited (UK)

When is the study starting and how long is it expected to run for?
November 2022 to May 2025

Who is funding the study?
NHS England (UK)

Who is the main contact?
Jennifer Nisbett, jennifer.nisbett@bcrm.clinic

Contact information

Type(s)

Contact name
Mrs Jennifer Nisbett

ORCID ID
http://orcid.org/0009-0002-9296-0131

Contact details
Bristol Centre for Reproductive Medicine
135 Aztec West
Almondsbury
United Kingdom
BS32 4UB
+44 (0)117 2591159
jennifer.nisbett@bcrm.clinic

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327685

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58798

Study information

Scientific Title
The effect of time-restricted eating on the sperm parameters and seminal oxidative stress of a cohort of male patients attending a fertility clinic

Study objectives
Causal hypothesis:
Following a schedule of time-restricted eating (TRE) for 3 months will result in increased sperm concentration, motility, morphology and decreased seminal oxidative stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/01/2024, Bradford and Leeds REC (Bradford Leeds Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8083; bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0015

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Sperm quality

Interventions
Following their usual clinic appointment, participants who meet the eligibility criteria and wish to take part in the study will give their consent and complete a questionnaire about their lifestyle and medical history. This questionnaire will be reviewed by a clinician to ensure that they do not have any medical conditions which would make it unsafe for them to participate. At least 24 hours later, participants will be contacted and invited to attend the Bristol Centre for Reproductive Medicine (BCRM) for an initial appointment. This appointment will last

approximately 1-1.5 hours, and patients will be advised that they should have a 2-3 day abstinence period prior to the sperm testing at this appointment. We will also measure their height, weight, waist circumference and blood pressure. The first 10 consenting participants will also have a small sample of blood taken. All participants will then 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. A small portion of the semen sample will then be stored for analysis. The results of the sperm test and the MiOXSYS test will be available to the participant via email within 5 working days. They will be provided with our contact details in order to discuss the results with a scientist, if required.

Due to the natural variation in sperm parameters, more than one test is required to establish a baseline. Therefore, results from two samples will be averaged to give a baseline for each participant. If participants have had a semen analysis at a UKAS or HFEA licensed centre within the previous 12 months, the results of this can be used. Participants who have not had a previous test will be asked to drop off a second sample for testing prior to starting the TRE schedule.

Each participant will take part in TRE for 12 weeks, following a schedule of 16 hours fasting and 8 hours eating between the hours of 11 am and 7 pm. They will be given a fasting log to record the duration of fasts, and the importance of recording honestly will be emphasised. During this time, the research team will send text message reminders and phone every 4 weeks to check how participants are getting on, answer any questions they may have and provide ongoing support. Participants can contact us at any point if they have questions.

After 12 weeks, participants will be asked to attend the BCRM again for repeat height, weight, blood test and semen analysis. This appointment will last less than 1 hour. Again, the results of the semen analysis and MiOXSYS test will be available via email after 5 working days and the option to discuss the results with a scientist will be given.

The frozen semen samples will be sent to the University of Manchester Biological Mass Spectrometry Core Research Facility for metabolomic analysis (https://www.bmh.manchester.ac.uk/research/platforms/mass-spectrometry/). This analysis will identify the profile of small molecules, commonly known as metabolites, induced by TRE. The samples will be sent securely and will only be labelled with unique participant ID numbers, no personal details.

The blood samples will be sent to Southmead Hospital, and the level of testosterone will be measured. The sample will be coded using unique participant ID numbers and will not be labelled with identifiable details.

Once the testing has taken place, the samples will be destroyed.

Taking part in this study does not prevent participants from embarking on fertility treatment or trying to conceive.

Intervention Type
Behavioural

Primary outcome measure
Seminal fluid analysis including concentration, motility and morphology according to WHO guidelines at baseline and 3 months

Secondary outcome measures
1. Testosterone level measured by blood test at baseline and 3 months
2. Metabolomic analysis of seminal fluid collected at baseline and 3 months, using gas chromatography-mass spectrometry (GC-MS)

Overall study start date
01/11/2022

Completion date
28/04/2025

Eligibility

Key inclusion criteria
1. Male
2. Aged between 18-44 years
3. Body mass index (BMI) of at least 18.5 kg/m2
4. Non-smoker
5. Men who have sperm in their ejaculate
6. Non-diabetic
7. No previous eating disorders
8. Participants capable of giving informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
44 Years

Sex
Male

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. A history of eating disorders
2. BMI below 18.5 kg/m2
3. Aged 45 years and over
4. Smoker
5. Men who have no sperm in their ejaculate

6. Diabetic
7. On any medication which needs to be taken with food
8. Previous bariatric surgery

Date of first enrolment
23/02/2024

Date of final enrolment
14/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Centre for Reproductive Medicine (Almondsbury)
135 Aztec W
Almondsbury
Bristol
United Kingdom
BS32 4UB

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Sponsor information

Organisation
Bristol Centre for Reproductive Medicine Limited

Sponsor details
Brunel House
11 The Promenade
Clifton
Bristol
England
United Kingdom
BS8 3NG
+44 (0)1172591159
paul.wilson@bcrm.clinic

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
This trial is forming part of a professional doctorate (DClinSci) for the main study contact and will be submitted in a thesis to Manchester Metropolitan University.

Also, planned publication in a high-impact peer-reviewed journal following completion of the DClinSci (anticipated in 2026).

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of male infertility results, and participant information stated that the results would only be used in the management of this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1		28/04/2025	No	Yes