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How does restricting your food intake to 8 hours as either early or late in the day influence the regulation of blood sugar levels

Submission date
02/07/2025

Recruitment status
No longer recruiting

Registration date
10/07/2025

Overall study status
Completed

Last Edited
04/07/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Time-restricted eating (TRE) is a dietary strategy that limits the daily window of food intake without necessarily altering the overall energy consumed. Emerging evidence suggests that the timing of food intake may influence metabolic health, particularly glucose regulation. This study aims to investigate the short-term effects of early versus late TRE on blood glucose control in adults with overweight or obesity and a sedentary lifestyle. The findings will help to better understand how meal timing may support metabolic health.

Who can participate?
Adults aged 45 to 60 years, of any sex, who are classified as clinically overweight or obese (BMI ≥25 kg/m²) and who do not currently meet physical activity guidelines (i.e. perform less than 150 minutes of moderate-to-vigorous activity per week) are eligible to participate. Participants must also have a habitual eating pattern spread across more than 14 hours per day. Individuals must be generally healthy and not currently following a time-restricted eating or similar dietary pattern.

What does the study involve?
This is a randomised crossover study where all participants will undergo two conditions:
Early TRE (eating between 08:00 and 16:00 for 3 days)
Late TRE (eating between 11:00 and 19:00 for 3 days)

Participants will receive all meals during each 3-day period, with dietary intake standardised for energy and nutrient content based on national reference values. Each eating condition will be separated by a washout period.

Participants will wear a FreeStyle Libre 2 continuous glucose monitor for 3 days prior to and during each intervention period to measure free-living glucose profiles. Fasting blood samples will be collected before and after each 3-day eating condition to assess markers of glucose

regulation, including plasma glucose and insulin. Physical activity will be monitored using a wrist-worn accelerometer (GENEActiv), and participants will be asked to record the timing of all food and drink consumed to assess protocol adherence.

What are the possible benefits and risks of participating?
Participants may gain insights into their own glucose patterns and dietary behaviours, which could support healthier lifestyle choices. While there are no known major risks associated with the study, minor discomfort may be experienced during blood sampling or from wearing the glucose sensor and activity monitor. All procedures are non-invasive or minimally invasive and widely used in clinical and research settings.

Where is the study run from?
The study is being coordinated by Manchester Metropolitan University (ManMet), within the Institute of Sport (UK)

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

Who is funding the study?
The study is funded by Abbott Laboratories and ManMet (UK)

Who is the main contact?
Dr Kelly Bowden Davies, k.bowden-davies@mmu.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EthOS Reference Number: 44884

Study information

Scientific Title
The effect of early and late time-restricted eating compared to habitual eating on glycaemic variability in adults at risk of type 2 diabetes: a randomised crossover study

Study objectives
1. To assess how following a short-term (3 days) time-restricted eating protocol influences glucose homeostasis measured using continuous glucose monitoring (CGM), with additional outcomes including cardiometabolic blood markers when compared to 3 days of habitual food intake patterns.
2. To assess if there is a difference in the response when the time-restricted eating window is either earlier in the day (8am- 4pm) or later (12pm - 8pm).

The primary hypothesis is that time-restricted eating, irrespective of the timing of the eating window, improves glucose homeostasis compared to habitual eating patterns. It is further hypothesised that there will be no significant difference in glycaemic outcomes between early and late TRE protocols.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/06/2022, Science and Engineering Research Ethics and Governance Committee (Manchester Metropolitan University, Manchester, M15 6BX, United Kingdom; +44 (0)161 247 2000; ethics-scieng@mmu.ac.uk), ref: 44884

Study design
Interventional single-centre cross-over randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of glucose homeostasis in people at risk of type 2 diabetes.

Interventions
All participants completed two 6-day interventions with a wash-out of 7 days. Each 6-day intervention consisted of an initial 3-day habitual dietary intake phase (Non-TRE i.e. the control condition), immediately followed by a 3-day time-restricted eating phase (TRE). The TRE phase was either early (8am - 4pm; Early-TRE) or late (12pm - 8pm; Late-TRE). In which order a participant followed the two 6-day interventions was randomised. During TRE phase, participants were provided with foods to follow a eucaloric energy intake. During the non-TRE phase, participants were free to select their food intake.

Intervention Type
Behavioural

Primary outcome(s)
Glucose homeostasis - assessed using continuous glucose monitoring. Specific outcomes include 3-day average of mean 24h glucose, glucose area under the curve and glycaemic variability markers.

Key secondary outcome(s))
Fasted cardio-metabolic blood markers (insulin, HOMA-IR, ADIPO-IR, cholesterol) taken before and after each 3-day TRE phase.

Completion date
09/06/2025

Eligibility

Key inclusion criteria
1. Male and female adults aged 45-60 years
2. Classed as clinically overweight or obese (BMI ≥25 kg/m²)
3. Sedentary lifestyle (not meeting physical activity recommendations of 150 minutes of moderate to vigorous exercise per week
4. Typical dietary consumption pattern over the entire day (>14 h/day)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
60 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Currently classed as having diabetes (HbA1c ≥48 mmol/mol)
2. Enrolled in another lifestyle intervention or clinical research trial
3. History of substance abuse
4. Pregnant or considering pregnancy

5. Known cancer
6. History of myocardial infarction within the previous 6 months
7. Learning disability
8. Diagnosed with an eating disorder

Date of first enrolment
29/07/2022

Date of final enrolment
07/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Metropolitan University
All Saints
Grosvenor Square
Manchester
United Kingdom
M15 6BH

Sponsor information

Organisation
Manchester Metropolitan University

ROR
https://ror.org/02hstj355

Funder(s)

Funder type
University/education

Funder Name
Manchester Metropolitan University

Alternative Name(s)
Manchester Polytechnic, MMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Abbott Laboratories

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available upon request from K.Bowden.Davies@mmu.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	16/05/2022	04/07/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	15/08/2022	04/07/2025	No	No