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The effects of early versus late time-restricted feeding on metabolic disease risk factors in adults at increased risk of developing type 2 diabetes: Is there an optimal time to eat?

Submission date
23/07/2019

Recruitment status
No longer recruiting

Registration date
01/08/2019

Overall study status
Completed

Last Edited
12/12/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
There is a rise in the number of people suffering from type 2 diabetes and a large proportion of the UK population are at increased risk of developing the condition. Some of the risk factors for type 2 diabetes include being overweight, having a family history of the condition, high blood pressure, abnormal blood cholesterol levels and ethnicity. This study seeks to investigate whether restricting dietary intake to a set number of hours in the day – either early in the day or late in the day – will make a difference to known risk factors for developing type 2 diabetes. By restricting dietary intake to a set number of hours in the day, this will increase the amount of time spent fasting (not eating) each day. This type of diet is known as time-restricted feeding. There is some evidence to suggest that time-restricted feeding may provide some health benefits in healthy individuals by helping to reduce the amount of energy consumed through food, lowering body weight and body fat, as well as improving markers of metabolic health. However, it is not yet known whether it is more beneficial to restrict our dietary intake to earlier or later in the day. Additionally, adherence to a change in diet is critical in predicting its success and long-term outcomes. However, when people find themselves in an environment with unlimited access to food during the day, it can be difficult to maintain successful behavioural changes. Therefore, the study will also look at how following this type of diet may impact on well-being, social life and the functioning of families (especially at mealtimes), to assess the suitability of the intervention for the general public, so that it does not negatively affect quality of life. Overall, this study will compare the effects of early versus late time-restricted feeding in adults at increased risk of developing type 2 diabetes.

Who can participate?
Adults aged 18-65 years old who are overweight

What does the study involve?
Participants are randomly allocated to one of three groups for 10 weeks:
1. A control group – where normal eating times are maintained

2. An early time-restricted feeding group – where eating is limited to between 7 am and 3 pm each day (± 1 hour)
3. A late time-restricted feeding group – where eating is limited to between 12 pm and 8 pm each day (± 1 hour)
Participants are asked to attend the University of Surrey for a total of five study day visits during this period for a variety of health assessments.

What are the possible benefits and risks of participating?
A variety of health assessments will be conducted as part of the study, including blood tests and scans to look at body fat distribution. All participants will receive one-to-one dietary support from a Registered Dietitian during the 10-week intervention period. There is a small risk of light bruising at the blood sample site, but all samples will be taken by trained phlebotomists the same way as during a blood test. Participants will also be asked to do an oral glucose tolerance test to look at how their body metabolises sugars. This will involve using a lancet device (used to collect blood samples) which will involve a short sharp prick to the tip of your finger. To measure the distribution of fat across the body, participants will receive a total of 2 dual-energy x-ray absorptiometry (DEXA) scans during the entire study. A DEXA scan exposes participants to ionising radiation, but the total radiation dose received from a DEXA is ~8 µSv per scan. This is equivalent to the amount of radiation that you would be exposed to if you spent 45 minutes on a transatlantic flight or the amount of radiation contained in 80 g of brazil nuts grown in Brazil. Although the dose of radiation participants are exposed to during the DEXA scan is minimal, there is a risk that even small doses of radiation can cause cancer.

Where is the study run from?
University of Surrey (UK)

When is the study starting and how long is it expected to run for?
May 2019 to June 2023

Who is funding the study?
University of Surrey (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
257999

Study information

Scientific Title
Early versus late time-restricted feeding: its effect on metabolic disease risk factors in adults at increased risk of developing type 2 diabetes

Study objectives
This study will test the primary hypothesis that 10 weeks of time-restricted feeding (TRF) will reduce insulin resistance and LDL-cholesterol in adults at increased risk of type 2 diabetes, as well as promote reductions in dietary energy intake, body weight and adiposity.
The secondary hypothesis will be that early-TRF will be metabolically superior to late-TRF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2019, London – Surrey Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8310; Email: nrescommittee.secoast-surrey@nhs.net), REC ref: 19/LO/0540, IRAS: 257999

Study design
Three-arm parallel randomised controlled dietary intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request PIS

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
After an initial 1-week baseline period, participants will be randomly assigned to one of three experimental groups for an intervention period of approximately 10 weeks.

The first (control) group will be asked to maintain their habitual sleep-wake and feed-fast routines throughout the intervention period.

The second, 'early-TRF', group will be asked to maintain their habitual sleep-wake routine, but restrict the duration of their eating times during the day to between 7am and 3pm (± 1 hour).

The third, 'late-TRF', group will also be asked to maintain their habitual sleep-wake routine, but restrict the duration of their eating times during the day to between 12pm and 8pm (± 1 hour).

Intervention Type
Behavioural

Primary outcome measure
1. Low-density lipoprotein (LDL) cholesterol measured using fasted blood tests at baseline, week 3, 5, 8 and 10
2. Insulin resistance measured using the homeostatic model assessment (HOMA) which utilises fasted glucose and insulin levels, at baseline, week 5 and week 10

Secondary outcome measures
1. Weight measured using scales at baseline, week 3, 5, 8 and 10
2. Adiposity measured using the gold standard dual-energy x-ray absorptiometry (DEXA) at baseline and week 10
3. Dietary intake assessed through the use of food diaries at baseline, week 2, 4, 7 and 9, as well as 24 hour dietary recalls at baseline, week 3, 5, 8 and 10
4. Food preferences assessed using questionnaires at baseline, week 3, 5 8 and 10, as well as eye tracking tests at baseline, week 5 and week 10

Overall study start date
03/05/2019

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Participants must:
1. Be aged 18 – 65 years old
2. Have a BMI ≥ 25 kg/m2
3. Have maintained a stable body weight for the 6 months preceding the study (± 2 kg)
4. Be at increased/moderate/high risk of developing type 2 diabetes, as per the Diabetes UK Diabetes Risk Score (scoring ≥ 7)
5. Be able and willing to give informed oral and informed written consent
6. Complete and meet the defined criteria of pre-study questionnaires
7. Be able and willing to complete daily sleep and food diaries during the study
8. Have an eating period of ≥ 12 hours a day
9. Agree to eat their meals within certain time periods during the day whilst participating in the study
10. Be willing and able to undertake laboratory tests on agreed dates during the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
51

Key exclusion criteria
Participants will be excluded if they:
1. Have a specific medical condition as confirmed by pre-study questionnaires – Type 1 or 2 diabetes, Polycystic Ovary Syndrome (PCOS), Schizophrenia, Bipolar illness, Depression or receiving treatment with antipsychotic medication, or have a history of Cardiovascular Disease (myocardial infarction or stroke)
2. Are currently on certain medications: weight loss, glucose- or lipid-lowering medication (e.g. 'Metformin' or 'Statins'), hypnotics or melatonin supplements
3. Are a smoker
4. Are pregnant
5. Have a history of any circadian or sleep disorder as confirmed by pre-study questionnaires
6. Have habitual irregular sleep patterns on more than 2 nights per week (bed time outside 22:00-1:00 h and wake up time outside 6:00-9:00 h) or a sleep duration on more than 2 nights per week < 7 or > 9 hours
7. Have donated over 400 ml of blood in the three months preceding the study
8. Exceed the defined criteria of pre-study questionnaires:
8.1. BMI: < 25kg/m2
8.2. 30 ≤ Horne-Östberg questionnaire ≥70
8.3. Pittsburgh Sleep Quality Index: > 5
8.4. Epworth Sleepiness Scale > 9

9. Have travelled across more than two time zones within a month before or during the study
10. Are currently taking part in a clinical trial or another research study or have taken part within the last 3 months
11. Have participated in rotating or night shift work for more than 6 months prior to or during the study

Date of first enrolment
02/01/2020

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
University/education

Funder Name
University of Surrey

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
At present, additional documents for this study are not available. However, the researchers do plan to publish the protocol in the near future. The researchers plan to publish the results in a high-impact peer reviewed journal approximately one year after the overall trial end date.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No