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Is Time Restricted Eating (TRE) a practical way to help people lose weight?

Submission date
13/11/2017

Recruitment status
No longer recruiting

Registration date
14/11/2017

Overall study status
Completed

Last Edited
30/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Over a quarter of adults in England are obese, with obesity more prevalent in disadvantaged areas. The health burden from obesity is largely driven by an increased risk of type 2 diabetes, cancer and cardiovascular diseases. Simple and effective weight loss interventions that are easy for individuals to complete are lacking. Intermittent fasting (IF) involves restricting food intake for periods of time, and is one potentially promising approach. There is evidence showing that in animals, regular periods of IF accompanied by no other food restrictions, generates weight loss and improvements in health. In humans, IF can generate weight loss and a range of associated benefits, particularly promising in terms of heart health. In terms of clinical practice however, the approach has limitations. In existing human studies, a rather harsh form of IF is used, whereby individuals are expected to fast on two consecutive days and restrict calorie intake the rest of the week. Within tightly controlled trials, a proportion of clients are able to persist with this approach for the trial duration, but the approach is too difficult for most people and it is not used in clinical practice. IF, however, can be also implemented in less severe formats, one of which is 'Time-Restricted Eating' (TRE) or '16:8' diet. TRE requires people to consume food only within a specific 'window' period each day, typically over eight hours, and refrain from any eating outside of this window. The simplicity of the approach could be useful particularly to disadvantaged client groups that rarely engage with more intensive and demanding interventions. Some research has shown benefits of TRE. This study aims to evaluate the acceptability and short-term effects of TRE in an inexpensive and quick pilot study focusing on clients from areas of high social deprivation who are most likely to benefit from this particular approach, compared to other diets that require calorie counting and much more extensive behaviour change.

Who can participate?
Adults aged 18 and older who have a BMI over 30 kg/m2 or over 28 kg/m2 with comorbidities.

What does the study involve?
Participants attend an appointment with the study team where they complete questionnaires about their physical activity. They are measured for weight and blood pressure and provide a blood sample. Participants are asked to consume all their food during an eight hour period every day for three months. Out of the remaining 16 hours participants can drink non-calorie drinks.

Participants attend weekly follow ups for six weeks with the first one taking place at the clinical where they are weighted again and fill out a questionnaire about their experience in doing TRE. The next five weeks they are followed up by telephone. On week six, participants come back to be weighed and to fill out the questionnaire. At 12 weeks participants attend a last follow up where they provide the same measurements and complete a study questionnaire.

What are the possible benefits and risks of participating?
The benefit of taking part in the study is that it may help participants to lose weight and improve general health. Participants will receive payments of £10 at week 6 as compensation for time and travel and additional compensation of £10 for each blood sample taken at week 1 and 12. There is not expected to be any risks from trying TRE. There may be some discomfort when providing blood samples

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
November 2017 to November 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
1. Mrs Daniella Ladmore
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2. Dr Dunja Przulj

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
012075QM

Study information

Scientific Title
Time Restricted Eating as a weight loss intervention in obese adults: A pilot study

Acronym
TRE

Study objectives
The primary objective of this study is to determine the feasibility of 'Time Restricted Eating' (TRE) by examining adherence and retention rates. Secondary objectives include TRE effects on changes in weight, blood pressure and lipid profile, client feedback, and, provided the intervention is feasible and the efficacy results are encouraging, effect estimates to inform any future randomized trial of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Interventional non randomised study.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Obesity

Interventions
Eligible participants are asked to attend an appointment with the study team in which they are asked to complete a routine clinic questionnaire and complete a questionnaire on physical activity levels (IPAQ). Weight and blood pressure are measured and a blood sample is taken. Participants speak with an advisor about "Time-Restricted Eating" TRE and are given a guide to take home. They are asked to adhere to TRE every day for the next three months.

Participants are asked to consume all their food during an 8 hour period each day for the next three months. Over the remaining 16 hours each day, participants can drink, but only non-calorie drinks (e.g. water or coffee/tea with no milk or sugar). Participants are free to choose which 8-hour period they would like to eat in.

Participants are followed up weekly for the next six weeks. The first follow up takes place at the clinic, where their weight is taken, and they complete a questionnaire about their experience in doing TRE. Participants are then followed up over the telephone for the following five weeks. On week six, participants areasked to attend the clinic again to check their progress with TRE. They are asked to complete a questionnaire and are weighed.

At 12 weeks participants attend the final follow up at the clinic in which in which they have their weight and blood pressure measured and give a blood sample. They also complete a study questionnaire.

Intervention Type
Behavioural

Primary outcome measure
1. Adherence to TRE will be measured by asking participants to complete a questionnaire on how many days they completed the intervention. Adherence will be monitored weekly for 6 weeks, then a final adherence rating taken at week 12.
2. Estimates of effect size for future randomised trials, will be obtained using the mean weight change of TRE at 6 weeks and 3 months

Secondary outcome measures
1. Weight is measured using digital scales in kilograms at the baseline visit, weeks 1, 6 and 12. Self-reported weight will be asked at weeks 2-5.
2. Blood Pressure is measured using an Omron blood pressure monitor at the baseline visit and week 12
3. Lipid profile measured using a blood sample given by the participant at the baseline visit and week 12

4. Difficulty adhering to TRE and hunger ratings are measured on a questionnaire weekly from baseline to week 6, then again at week 12
5. Helpfulness of the intervention, TRE difficulty, readiness to continue, 8 hour eating time frames and ratings of hunger will be measured through participant feedback every week for 6 weeks and at week 12. Recommending TRE to friends will be asked at week 12. Participants will have the opportunity to use free text to give feedback about barriers and facilitators of TRE at week 1 and 6.

Overall study start date
01/11/2017

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. BMI over 30 kg/m2, or over 28 kg/m2 with comorbidities
3. Speaks, reads, and understands English

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. A Medical condition precluding fasting, including a history of eating disorders
2. Has a serious illness
3. Currently on psychiatric medication
4. Pregnancy or breastfeeding
5. Has lost more than 5% of body weight in the last 6 months
6. Is currently using TRE or another fasting approach to weight loss

Date of first enrolment
01/02/2018

Date of final enrolment
01/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
Health & Lifestyle Research Unit
2 Stayners Road
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Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office
5 Walden Street
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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Daniella Ladmore Research Health Psychologist daniella.ladmore@qmul.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/01/2021	01/02/2021	Yes	No
Dataset		28/01/2021	30/11/2022	No	No
Protocol (other)	1.0	06/10/2017	30/11/2022	No	No
Protocol (other)	2.0	07/08/2018	30/11/2022	No	No