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The effect of fasted and non-fasted cycling at different times of the day on appetite regulation, digestive function and metabolism in healthy overweight individuals

Submission date
07/12/2018

Recruitment status
No longer recruiting

Registration date
10/12/2018

Overall study status
Completed

Last Edited
13/09/2021

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
Growing interest in nutrition and the circadian system has produced many insights within recent years, with research suggesting circadian rhythms, nutrition and metabolism to be intimately linked. Intermittent fasting has become an increasingly popular intervention for metabolic health and combining intermittent fasting with exercise may lead to benefits for weight management. Therefore, the aim of this study is to investigate the effect of fasted versus fed exercise at different times of the day on gastrointestinal function, metabolic responses, and appetite responses, in overweight individuals.

Who can participate?
Males aged 18-40 years who are non-smokers and have a body mass index (BMI) class of 25-29.9 kg/m2 but otherwise healthy.

What does the study involve?
The participants will visit the laboratory on 5 occasions, once for a preliminary visit and on four other occasions to complete four separate experimental trials, two in the morning and two in the late afternoon. Experimental trials will consist of cycling exercise under 4 conditions; morning fed (AM-F), morning fasted (AM-NF), late afternoon fed (PM-F) and late afternoon fasted (PM-NF). Each experimental trial will last approximately 5.5 hours and begin at 0800 h for AM trials and 1500 h for PM trials. The AM-F and PM-F trials will consist of ingestion of a standardised breakfast meal one hour in advance of the exercise, whilst in the AM-NF and PM-NF trials, participants will not ingest the breakfast meal and remain fasted for the exercise. After the exercise participants will be provided with a standardised semi-solid meal. Regular breath and blood samples will be taken throughout the trials.

What are the possible benefits and risks of participating?
Participants will be able to receive data on their current aerobic fitness, body composition, and dietary analysis. Apart from this, there will be no immediate direct benefits to participants

taking part. However, the results and participants' experiences in the study will aid the research team in understanding the effect of fasting and exercise on the regulation of appetite and help develop further research on interventions that may help people improve their health. There is a small risk of muscle soreness and discomfort after each exercise session and a small risk of infection and discomfort from blood sampling.

Where is the study run from?
Manchester Metropolitan University.

When is the study starting and how long is it expected to run for?
December 2018 – September 2019

Who is funding the study?
Manchester Metropolitan University and The Physiological Society (research grant)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VJM_0878

Study information

Scientific Title
Implications of fasted cycling exercise on metabolic responses, gastrointestinal function, and appetite, in overweight individuals

Acronym
FastExOverweight

Study objectives
1. Fasted exercise will result in differences in gastric emptying rate compared to fed exercise.
2. Fed or fasted exercise in the morning will result in differences in gastric emptying rate compared to fed or fasted exercise in the evening.
3. Fasted exercise will result in different gastrointestinal hormone responses, metabolic responses and appetite responses compared to fed exercise.
4. Fasted or fed exercise in the morning would result in differences in gastrointestinal hormone responses, metabolic responses and appetite responses compared to fasted or fed exercise in the evening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Manchester Metropolitan University faculty of Science and Engineering Research Ethics and Governance Committee, 10/2018, ref. 0878.

Study design
Interventional, repeated measures design with randomised crossover

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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

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

Interventions
The participants will complete four experimental trials in a randomised crossover design. Experimental trials will consist of 60 minutes of cycling under 4 conditions; morning fed (AM-F), morning fasted (AM-NF), late afternoon fed (PM-F) and late afternoon fasted (PM-NF). Each experimental trial will last approximately 5.5 hours and begin at 0800 h for AM trials and 1500 h for PM trials. Trials will be separated by a minimum of 7 days. The AM-F and PM-F trials will consist of ingestion of a standardised breakfast meal one hour in advance of 60 min of cycling exercise at approximately 60% peak maximal oxygen uptake, whilst in the AM-NF and PM-NF trials, participants will not ingest the breakfast and remain fasted for the same exercise. After the exercise in all four trials participants will be provided with a standardised semi-solid meal to ingest. Regular breath and blood samples will be taken throughout the trials. In the 24 hours following the end of each trial, participants will be asked to record their dietary intake. There will be no long term follow up following completion of the study.

Intervention Type
Other

Primary outcome measure
1. Gastric emptying rate of a semi-solid meal that will be provided 30 minutes following the cessation of the cycling exercise will be measured using the 13C breath test method.
2. Breath samples will be collected every 15 min for a two-hour period.
3. Circulating levels of key gastrointestinal hormones and metabolic markers. Venous blood samples will be collected at baseline, post breakfast ingestion period, 1-hour post breakfast ingestion period (pre-exercise), immediately post 60-min cycle, 30 min post cycle (pre meal ingestion), then at 30 min intervals post meal ingestion for two hours.
4. Subjective feelings of appetite will be assessed using 100 mm visual analogue scales at baseline, post breakfast ingestion period, 30 min post breakfast ingestion period, pre-exercise, post exercise, pre semi-solid meal ingestion, then every 15 min post semi-solid meal ingestion for two hours.
5. 24h post trial energy intake using weighed food intake dietary record.
6. Substrate oxidation will be measured using a breath-by-breath gas analyser at baseline, post breakfast ingestion period, 30 min post breakfast ingestion period, pre-exercise, continuously throughout exercise, pre semi-solid meal ingestion, then every 30 min post semi-solid meal ingestion for two hours.

Secondary outcome measures

1. Salivary melatonin concentration at the start of the trials.
2. Ratings of perceived exertion using the Borg scale and heart rate using telemetry will be recorded pre-exercise and every 15 min during the exercise.

Overall study start date
28/02/2018

Completion date
24/05/2019

Eligibility

Key inclusion criteria
1. Male.
2. Aged 18-40 years.
3. Non-smokers.
4. Classified as overweight according to body mass index (BMI) class of 25-29.9 kg/m2 and body fat %.
5. Able and willing to comply with study procedures.
6. Willing to undertake required fasting duration, and with the capacity to provide informed consent
7. Free from injury prior to commencing the trials (6+months), with 1+ year free from any injury (such as, lower limb musculoskeletal injuries) that may have prevented and/or affected the participant. from performing cycling previously.
8. Classified as moderate or intermediate chronotypes according to the questionnaire of Waterhouse et al (2001).

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Male

Target number of participants
12

Total final enrolment
12

Key exclusion criteria

1. Regular medication or any known history of gastrointestinal, respiratory, cardiovascular, or endocrine disease.
2. Early circadian phase also known as extreme morning chronotypes and extreme evening chronotypes.
3. Involved in shift work and report any disturbances to their normal sleep-wake cycle during the two weeks prior to data collection.
4. Cannot consume the test meals due to intolerance's/dietary preferences.

Date of first enrolment
12/12/2018

Date of final enrolment
03/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Metropolitan University
John Dalton Building, Chester Street
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Sponsor information

Organisation
Manchester Metropolitan University

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Sponsor type
University/education

ROR
https://ror.org/02hstj355

Funder(s)

Funder type
Other

Funder Name
Manchester Metropolitan University

Alternative Name(s)
MMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Physiological Society

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned communication of results at a scientific conference.
Planned publication in a high impact peer reviewed journal within 12 months of the completion of the study.

Intention to publish date
31/05/2022

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 conditions of the ethical approval granted for this study.

IPD sharing plan summary
Not expected to be made available