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Is it more beneficial for appetite and weight management to exercise once or twice a day?

Submission date	Recruitment status	[X] Prospectively registered
07/12/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/12/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/02/2021	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

There is a growing amount of literature committed to understanding if being more active will have beneficial effect on health. However, less is known on whether performing exercise twice a day is more beneficial than exercising once when matched for workload. Therefore, the aim of this study is to identify if workload matched exercise split over the day, will result in possible changes in gastrointestinal function, metabolic responses and appetite.

Who can participate ?

Healthy males (age 18-40 years; body mass index <29.9 kg/m2; non-smokers, no history of GI symptoms not consuming prescription medication and subsequently be physically active, in order to complete the trials.

What are the possible benefits and risks of participating?

1. Full fitness assessment
2. Information about the participants diet
3. Knowledge about how gastric emptying may affect exercise
4. Experience within a research laboratory

What does the study involve?

The study involves two non-consecutive test days in a randomised order. After a 24 hour standardisation period and overnight fast. Participants come to the laboratory and exercise; either split over the day (two, 30min cycles) or a one-off bout (60-min cycle) before consuming a milk-shake and a standardised semi-solid meal. Throughout the trial, measurements of subjective feelings of appetite, gastric emptying rate, substrate utilisation and 24-hour energy intake. Blood samples will also be taken regularly throughout the trials.

Where is the study run from?

Manchester Metropolitan University , Manchester (UK)

Who is funding the study?

Manchester Metropolitan university

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

Who is the Main Contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LRM-1089

Study information

Scientific Title
The effect of exercising once vs. twice a day on gastrointestinal function, metabolic responses and appetite in healthy males: a randomised cross over trial.

Acronym
Split exercise

Study objectives
1. Exercising twice a day will result in differences in gastric emptying rate and metabolic responses compared to a single workload-matched bout of exercise.
2. Exercising twice a day will result in differences in appetite and gut hormone responses compared to a single workload-matched bout of exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Faculty of Science and Engineering Research Ethics and Governance Committee at Manchester Metropolitan University, 11/2018, ref. 1089

Study design
Interventional, repeated measures 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 participants information sheet

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

Interventions
Participants will complete two 7h experimental trials in a randomised cross-over design, where each participant will complete both trial arms; exercise once and twice a day separated by a minimum of 7 days. One trial will consist of a one off 60-min cycle at 70% peak maximal oxygen

uptake. After completion of this single bout of exercise, participants will ingest a milkshake containing 30% of their estimated energy expenditure through the trial. Following a rest period the remaining 70% of their estimated energy expenditure through the trial will be provide as a semi-solid meal. The second trial will consist of a 30-min cycle before participants will ingest a milkshake followed by the same rest period before completing the remaining 30-min cycle and ingestion of a semi-solid meal. There will be no follow up session apart from all participant will record 24-h food intake following both trials.

Intervention Type
Behavioural

Primary outcome measure
1. Gastric emptying rate of a semi-solid meal will be measured using the 13C breath test . Breath samples will be collected at baseline and every 15min for a two-hour period.
2. Circulating levels of key gut hormones and metabolic markers. Blood samples will be collected at baseline, pre-milkshake, 1h-post milkshake, 2h-post milkshake, pre-semi-solid meal ingestion, 1-h post meal ingestion and 2h post meal ingestion
3. Substrate oxidation will be measured using a breath-by breath gas analyser at rest, during exercise sessions and every 30 min post food ingestion for 2h
4. Visual analogue scales will be used to measure subjective sensations of appetite at rest, pre-meal ingestion and every 30min post food ingestion for 2h.
5. 24h post trial energy intake using weighed food intake dietary record

Secondary outcome measures
1. Ratings of perceived exertion using the Borg scale and heart rate will be recorded pre exercise and every 15min during exercise

Overall study start date
26/07/2018

Completion date
30/08/2019

Eligibility

Key inclusion criteria
1. Healthy males
2. Age between 18-40 years
3. Body mass index = <29.9 kg/m2
4. Non-smokers
5. No history of GI symptoms
6. Not consuming prescription medication, or no other relevant medical conditions assessed by a medical screening questionnaire.
7. Subsequently be physically active, in order to complete the trials.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Male

Target number of participants
14 participants

Total final enrolment
16

Key exclusion criteria
1. Lactose Intolerant
2. Vegan

Date of first enrolment
17/12/2018

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Metropolitan University
John Dalton Building
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/02hstj355

Funder(s)

Funder type
University/education

Funder Name
Manchester Metropolitan University

Alternative Name(s)
MMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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

30/08/2020

Individual participant data (IPD) sharing plan

Participant level data is not expected to be available as this complies with the conditions of the ethical approval grated for this study.

IPD sharing plan summary

Not expected to be made available