

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

Submission date 07/12/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 11/12/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/02/2021	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☐ 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?
Mr Lewis Mattin
lewis.mattin@stu.mmu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gethin Evans

Contact details
School of Healthcare Science
Manchester Metropolitan University
Chester Street
Manchester
United Kingdom
M1 5GD
+44 (0)1612471208
gethin.evans@mmu.ac.uk

Type(s)
Public

Contact name
Mr Lewis Mattin

Contact details
School of Healthcare Science
Manchester Metropolitan University
Chester Street
Manchester
United Kingdom
M1 5GD
+44 (0)1612471215
lewis.mattin@stu.mmu.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Interventional, repeated measures with randomised crossover

Study type(s)

Other

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(s)

1. Gastric emptying rate of a semi-solid meal will be measured using the ^{13}C 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

Key secondary outcome(s)

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

Completion date

30/08/2019

Eligibility

Key inclusion criteria

1. Healthy males

2. Age between 18-40 years

3. Body mass index = $<29.9 \text{ kg/m}^2$

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Male

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

United Kingdom

England

Study participating centre**Manchester Metropolitan University**

John Dalton Building

School of Healthcare Science

Chester Street

Manchester

United Kingdom

M1 5GD

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

Results and Publications

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 granted for this study.

IPD sharing plan summary

Not expected to be made available