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The effect of age and timing of protein consumption on energy intake and appetite.

Submission date
05/06/2019

Recruitment status
No longer recruiting

Registration date
16/07/2019

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Musculoskeletal health issues are becoming more frequent as the population ages. With ageing, decrements are observed in muscle strength due to the loss of skeletal muscle; this is termed sarcopenia. A reduction in muscle mass can lead to an abundance of negative outcomes, including an increase in falls and fracture risk. Overall, as a consequence of muscle loss, quality of life is greatly impacted in the elderly and this can come with distressing implications such as an increase in hospital visits/stays. If interventions can be identified to prevent age-related losses in muscle mass, this can provide substantial benefits for the individual as they will be able to maintain their independence for longer. Dietary protein is known to be important for the maintenance of muscle mass and function. However, a substantial proportion of the older adult population does not achieve the recommended daily intake of 0.8g per kg body of protein, with protein intake being particularly low at breakfast. A further consequence of ageing is a reduction in appetite. This can result in reduced energy intake, and it has been suggested that 1 in 10 adults over the age of 65 are malnourished in the UK.

In the older adult population, an increase in protein intake without a reduction in total energy and nutrient intake is preferred. This study aims to investigate the impact of timing of a protein supplement on energy intake and appetite over the course of the day. The results of the study will inform the design of future research investigating the impact of protein supplementation on muscle function in older adults.

Who can participate?
To take part in this study, participants can be any gender but must be aged between 50-75 years old. Volunteers who have issues relating to their kidney function, have diabetes or have with a body mass index (BMI) less than 18 or more than 30, or who regularly consume nutritional supplements will be ineligible to take part in this study

What does the study involve? (what interventions will be compared, will all participants receive the same treatment?)
The study is in 3 phases. In the first phase, participants will be asked to record everything they eat over a 3 day period (Monday, Wednesday and Friday). The researcher will provide all volunteers with detailed information and instructions about how to complete this food diary

before the trial commences. Participants will also be asked to complete a Visual Analogue Scale (VAS) for the assessment of hunger and appetite on the same days as they complete their food diaries. This questionnaire should be completed 3 hours after breakfast has been consumed. In the second phase, participants will be asked to consume a protein supplement in the form of a gel, containing 20g of whey protein, for 4 consecutive days. Instructions on when to consume the protein will be provided to the participant – this will either be in the morning, 30-60 minutes after they have consumed their regular breakfast or in the evening, 30-60 minutes just before bed. Food diaries and VAS questionnaires will also be required to be completed during phase 2 of the trial, on the Monday, Wednesday and Friday, as before. Following the second phase, there will be a week in which participants will not be required to do anything other than consume their habitual diet. The final phase will be similar to phase 2, the only difference will be the time in which participants consume the protein supplement – this will be the opposite time point to the one they previously undertook during phase 2. Following the completion of the supplementation phases of the trial, participants will be invited to meet with the research for a follow-up discussion. During this time, their feedback about their experience of taking part in the research will be invited.

What are the possible benefits and risks of participating?
In the short term, this study is unlikely to lead to any health benefits for the participants. However, the knowledge and information gained from this study could help develop the framework for interventions which can help prevent diseases associated with muscle loss and thus reduce the negative implications of these conditions. There are no known risks of taking part in this study. The protein provided in this study are food supplements and are safe to consume.

Where is the study run from?
The study will be run from the Department of Oncology and Metabolism, The University of Sheffield, UK.

When is the study starting and how long is it expected to run for?
The study is starting on 29th March 2019 and is expected to run until August 2019. Volunteers will be enrolled in the study for approximately 5 weeks from visit 1 to visit 2.

Who is funding the study?
The study is being conducted by the University of Sheffield, in collaboration with the Centre for Integrated research into Musculoskeletal Ageing (CIMA.) It is being funded by the Medical Research Council and Arthritis UK.

Who is the main contact?
Dr Liz Williams
e.a.williams@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Williams

ORCID ID

https://orcid.org/0000-0002-1431-7549

Contact details
Department of Oncology & Metabolism
The University of Sheffield.
Beech Hill Road
SHEFFIELD
United Kingdom
s10 2RX
0114 215 9065
e.a.williams@sheffield.ac.uk

Type(s)
Public

Contact name
Ms Esme Tuttiett

Contact details
Department of Oncology & Metabolism
The University of Sheffield.
Beech Hill Road
Sheffield
United Kingdom
S10 2RX
NA
ertuttiett1@sheffield.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
024856

Study information

Scientific Title
A randomised cross over trial to investigate the effect of a 20g protein gel consumed in the morning or evening on energy intake and appetite in UK older adults

Acronym
N/A

Study objectives
Null Hypothesis: Protein supplementation with a whey gel has no impact on appetite and energy intake.
Alternative hypothesis: protein supplementation will impact on appetite and will lead to a subsequent reduction in energy intake

Linked hypothesis: Consuming protein in the evening will have less impact on appetite and energy intake, in comparison to protein supplementation in the morning.
Linked hypothesis: Elderly adults (65-75 years old) will be more satiated following protein supplementation in comparison to middle aged adults (50-64 years old.)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2019, The University of Sheffield Research Ethics committee (Dr Penny Ottewell (Principal Ethics Contact) Medical School, Beech Hill Road, Sheffield, S10 2RX; 0114 215 9058; medschoolethics@sheffield.ac.uk), ref: 024856.

Study design
Single-centre, randomised cross-over design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy ageing, nutrition, appetite, energy intake

Interventions
A Whey based protein gel (containing 20g protein) is used in the intervention. Volunteers will be asked to consume the protein gel in the morning (for 4 days) and the evening (for 4 days). This is a crossover design trial so all participants will undergo both morning and evening interventions. Total duration of trial = 5 weeks, with a 1 week wash-out between intervention phases. The order of protein supplementation (morning or evening) will be be determined using a randomisation schedule.

The order of randomisation was determined using an on online randomisation generator: www.randomization.com using block sizes of 4 and stratified by age (50-64 years or 65-75 years). This randomisation list was held by the researcher and used to determine the sequence of intervention (morning - evening or evening - morning).

Intervention Type
Other

Primary outcome(s)
Mean daily energy intake (kJ) measured using a 3d food diary at baseline prior to intervention and during morning and evening protein consumption.

Key secondary outcome(s))
1. Mean daily macronutrient and micronutrient intake is measured using 3 d food diary prior to intervention and during morning and evening protein consumption.
2. Self-reported hunger and appetite using a Visual Analogue Scale measured prior to intervention and during morning and evening protein consumption.

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Age range: 50-75 years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Previous diagnosis of renal problems
2. Previous diagnosis of type 1 or type 2 diabetes
3. Self-reported regular users of nutritional supplements
4. BMI <18 or >30

Date of first enrolment
29/04/2019

Date of final enrolment
14/06/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Sheffield
Department of Oncology & Metabolism
Sheffield
United Kingdom
s10 2RX

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research council

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Liz Williams, e.a.williams@sheffield.ac.uk. The data will be made available in SPSS format and will be fully anonymised. The data will include sex, age and BMI of participants and averaged self reported feelings of hunger and appetite and average nutrient intakes before the intervention and during each phase of the intervention. Data will become available after publication of the research and will be available for 3 years (beyond that time, it is unknown whether investigators would have the resources/capacity to make data available to others).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/05/2021	15/06/2021	Yes	No
Protocol file			17/08/2022	No	No