ISRCTN95281775 https://doi.org/10.1186/ISRCTN95281775

# The effect of whey protein on postprandial glycaemia in lean and obese males

**Submission date**
01/08/2019

**Recruitment status**
No longer recruiting

**Registration date**
02/08/2019

**Overall study status**
Completed

**Last Edited**
15/08/2024

**Condition category**
Nutritional, Metabolic, Endocrine

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

## Plain English summary of protocol

Background and study aims
Fat distribution is an important factor for insulin sensitivity, particularly when fat is stored around the stomach (central adiposity). It has been highlighted that individuals who store excess body fat in central areas may display normal fasting blood sugar levels, but show elevated blood sugar concentrations after eating, which is associated with an increased risk of cardiovascular disease. Given that most of the day is spent in the fed state, strategies to improve obese individual's blood sugar responses following eating are essential in halting the progression of cardiovascular disease. Previously, consumption large doses of whey protein (about 55 g; 250 kcals) 30 minutes before meals has improved blood sugar responses by influencing gut hormones, slowing the rate of digestion and increasing insulin secretion in both lean and type 2 diabetic populations. However, its effect on individuals with central obesity is not fully understood. Given the importance of weight management, whether the benefits of whey protein consumption are demonstrated in smaller amounts that are more energy-friendly, that are consumed closer to meal times is not known. Therefore, this study aims to understand if small amounts of whey protein consumed soon before a common breakfast meal affects the rate of food digestion and the appearance of blood sugar over a 4h period in both centrally obese and lean adult males. This study also wants to investigate whether body fatness affects the responses to whey protein consumption.

Who can participate?
Non-diabetic adults (18 - 65 years old) who have a BMI of 18.9 – 24.9 or more than 30 kg.m2 (waist circumference of more than 102cm/40"), are non-smokers and have no known dietary intolerances.

What does the study involve?
Participants are randomly allocated to consume one of two 100 ml beverages 10 minutes before a mixed-meal tolerance test consisting of a standardised breakfast meal. Seven days later, participants consume the different beverage and repeat the mixed-meal tolerance test. Participants attend the NU Food facility of Newcastle University (Newcastle upon Tyne, UK) a total of 4 times over a 3-week period. On the first and third visits, participants are provided with a wrist-worn activity monitor to wear to monitor physical activity in the preceding 24h to each mixed-meal tolerance test, and a standardised evening meal to consume the evening prior to

each experimental visit. During trial days (visits 2 and 4), participants report to NU Food in a fasted state via a pre-arranged taxi to perform the mixed-meal tolerance tests. Once settled, a small cannula is introduced for repeated-blood sampling and a fasting sample is collected. Participants consume a small whey protein beverage or water 10 minutes before a breakfast meal of cereal and milk. Paracetamol (1.5 g) is consumed alongside the breakfast meal for the measurement of gastric emptying. Blood samples and subjective appetite measurements are collected periodically for a 4h period. Dietary records are collected before each mixed-meal tolerance test.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in this study. However, participation may help develop larger trials for individuals with type 2 diabetes, obesity and the metabolic syndrome, which may help influence future treatments and nutritional advice for such populations. Blood samples will be collected from a small cannula where it is possible there might be some slight discomfort when it is being inserted and/or bruising when it is being taken out. However, all blood sampling will be performed by trained phlebotomists reducing the risk of this occurring. To assess the rate of gastric emptying, 1.5 g of paracetamol will be issued alongside breakfast. This is a very common method for assessing gastric emptying with previous studies using similar doses of paracetamol in healthy individuals and those with type 2 diabetes with no adverse events reported. The dose administered (1.5g ) falls in line with the National Institute for Health and Care Excellence's (NICE) guidelines for oral paracetamol consumption in adults over 50 kg of bodyweight of '1 g every 4-6 hours … maximum 4 g per day'.

Where is the study run from?
Newcastle University (UK)

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

Who is funding the study?
Arla Foods Ingredients Group P/S (Viby J, Denmark) from a grant awarded to Newcastle University

Who is the main contact?
Dr Daniel J West
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# Contact information

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Public

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
WP/GE

## Study information

### Scientific Title
The influence of a novel, ready-to-drink whey protein beverage on appetite, postprandial glycaemia and gastric emptying in lean and centrally obese adults

### Study objectives
Consuming a novel whey protein beverage compared to the control will attenuate postprandial glucose excursions and delay the rate of gastric emptying in both cohorts.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 01/06/2018, Faculty of Medical Science Ethics Committee (Research & Innovation office, Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, NE2 4HH; Tel: +44 (0)191 208 5301; Email: fmsethics@ncl.ac.uk), ref: 1512/4830/2018

## Study design
Single-centre randomised control counterbalanced crossover design

## Primary study design
Interventional

## Secondary study design
Randomised cross over trial

## Study setting(s)
Other

## Study type(s)
Treatment

## 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
Central obesity and lean

## Interventions
Participants will randomly consume either a small dose (15g) of whey protein (Arla Foods Ingredients Group P/S., [AFI], Denmark) or a null-comparator (water) 10 minutes before a carbohydrate-rich breakfast. Trial sequences will be determined prior to participant enrolment using a computerised online random generator (www.randomization.com), randomly assigning participants in a balanced permutation, into two treatment groups.

Adult males with a BMI of 18.9 – 24.9 kg.m2 and those who with central adiposity (as measured by waist girth of > 102cm, or a BMI of > 30 kg.m2) will be recruited into a nutritional intervention examining the influence of a novel small whey protein beverage on postprandial blood glucose regulation and rate of gastric emptying. Participants will attend the NU Food facilities of Newcastle University (Newcastle upon Tyne, UK) a total of 4 times over a 2-week period that includes two pre-trial appointments [visits 1 and 3] and two mixed-meal tolerance tests [visits 2 and 4]. On participants first and third visit, a wrist worn activity monitor (GENEActiv, Activinsights LTd., USA) will be issued to monitor free-living physical activity for the preceding 24h prior to each mixed-meal tolerance test. To standardise dietary intake prior to experimental visits, participants will be required to complete a food diary for the day preceding the first mixed meal tolerance test [visit 2] and will be asked to replicate this intake at the subsequent visit [visit 4]. A standardised evening meal (~900 kcal) will also be provided to be consumed the evening before each mixed meal tolerance test to ensure standardisation between appetite and gut hormone parameters.

Following an overnight fast, patients will enter NU Food to perform a mixed meal tolerance test to assess the acute effects of pre-meal whey protein consumption on the rate of gastric

emptying, and plasma glucose and subjective appetite responses [visits 2 and 4]. In a randomised, counterbalanced manner, patients will consume a protein-rich whey shot [WP; 15g protein] or volume-matched water [CON; 0g protein] immediately prior to a mixed-nutrient breakfast meal. For the assessment of gastric emptying, 1.5g of paracetamol will be issued alongside breakfast. Blood samples and subjective appetite parameters will be measured periodically over a 4-hour postprandial period.

### Intervention Type
Supplement

### Primary outcome measure
Postprandial glycaemic responses (incremental area under the curve [iAUC]) to a mixed-nutrient breakfast following prior consumption of the protein-rich supplement and control beverage (i.e. “pre-load”). Glycaemic responses will be measured from venous whole blood samples over a 4-hour postprandial period. Postprandial glycaemic responses will be calculated using the trapezoidal rule and broken down into epochs depicting different stages of the postprandial period – i.e. 0-60 min (early), 120-240 min (late) and 0-240 min (total). Glucose concentrations will be determined using a commercially available assay.

### Secondary outcome measures
1. Rate of gastric emptying (iAUC) following prior consumption of the whey protein beverage compared to the control drink will be determined by pharmacokinetics of plasma acetaminophen concentrations [visits 2 and 4]. Postprandial acetaminophen responses will be calculated using the trapezoidal rule and broken down into epochs depicting different stages of the postprandial period – i.e. 0-60min (early), 120-240min (late) and 0-240min (total). Acetaminophen concentrations will be determined using a commercially available assay.
2. Time-course changes in subjective appetite sensations measured using a 100 mm paper-based linear visual analogue scale during the mixed meal tolerance tests [visits 2, and 4] – i.e. baseline, pre-meal, and 0, 15, 30, 45, 60, 90, 120, 150, 180, 210 and 240 min post-meal.
3. Time-course responses in blood glucose, acetaminophen and gut hormones following a standardised mixed-nutrient breakfast meal – i.e. baseline, pre-meal, and 0, 15, 30, 45, 60, 90, 120, 150, 180, 210 and 240 min post-meal [visits 2 and 4]. All markers will be analysed by routinely available assays.
4. The influence of adiposity on the efficacy of whey protein. A regression analysis will be performed on pooled data [visits 2 and 4] from both cohorts (lean and centrally obese) to determine if there are any markers of adiposity (weight, BMI, waist circumference and waist-to-hip ratio) that predict the glucose-lowering properties of whey protein (i.e. magnitude of change in plasma glucose concentrations from fasting levels).

### Overall study start date
01/04/2018

### Completion date
01/10/2019

## Eligibility

### Key inclusion criteria
Lean:
1. Aged between 18 – 65 years
2. BMI of 18 - 25 kg.m2

3. Weight stable for > 2 months (± 1kg) preceding the commencement of the intervention
4. Physically active as assessed by the International Physical Activity Questionnaire
5. Adhere to a normal wake/sleep cycle (i.e. non-shift workers)
6. Regularly consume breakfast

Centrally obese:
1. Aged between 18 – 65 years
2. BMI > 30 kg.m2 or waist circumference of > 102 cm
3. Weight stable for > 2 months (± 1kg) preceding the commencement of the intervention
4. Physical inactive as assessed by the International Physical Activity Questionnaire
5. Adhere to a normal wake/sleep cycle (i.e. non-shift workers)
6. Regularly consume breakfast

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
30 (accounting for potential dropout: 15 lean/15 obese)

### Total final enrolment
25

### Key exclusion criteria
1. History of metabolic or cardiovascular diseases
2. Taking medicines that may influence gut function or satiety
3. Smokers
4. Gastrointestinal issues
5. Known food intolerance's or allergies
6. Substance abuse

### Date of first enrolment
01/08/2018

### Date of final enrolment
01/05/2019

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Faculty of Medical Sciences**
Medical School,
Newcastle University,
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# Sponsor information

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Newcastle University

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**Sponsor type**
University/education

**ROR**
https://ror.org/01kj2bm70

# Funder(s)

**Funder type**
University/education

**Funder Name**
Newcastle University

**Alternative Name(s)**

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
Planned publication in high-impact peer-reviewed journals. No additional documents are to be made available.

### Intention to publish date
01/03/2021

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other publications | K. Smith., Taylor. G.S., Okwose, N., Allerton, D.M., Brunsgaard, L.H., Stevenson, E.J. & West, D.W. (). 2276-PUB: A Palatable, Novel Whey Protein Shot Attenuates Postprandial Glycemia in Lean and Centrally Obese Adult Males, Diabetes. 68 (supplement 1). | 01/06/2019 | | Yes | No |
| Results article | | 18/06/2021 | 06/07/2021 | Yes | No |
| Other publications | secondary analysis | 13/08/2024 | 15/08/2024 | Yes | No |