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# The effect of whole-food dairy products on blood sugar regulation, bone health and feelings of hunger

**Submission date**
13/05/2022

**Recruitment status**
No longer recruiting

**Registration date**
26/05/2022

**Overall study status**
Completed

**Last Edited**
18/12/2023

**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
Dietary protein has several important health effects on muscle and bone tissue and is associated with several health outcomes such as reduced heart disease risk. In general, people have a skewed distribution of protein intake, with protein intakes at breakfast below the recommendations for optimal muscle health. Besides contributing to muscle and bone health, increasing protein intake with breakfast can aid in weight management, as increased protein intakes are associated with increased fullness following food intake. Also, consuming protein with carbohydrates is associated with a more favorable blood sugar response. Dairy protein may be a favourable protein source as it contains other nutrients that can substantially improve the quality of breakfast, such as vitamin B2 and B12, potassium, calcium and phosphorus. The benefits of (high doses of) isolated milk-derived nutrients for muscle health, blood sugar control, fullness, and bone metabolism have been well established. However, much of the evidence cannot be directly translated to daily life, as people consume mixed diets rather than isolated nutrients.
The main aim of this study is to assess metabolic responses when graded amounts of whole-food dairy products are incorporated into a common breakfast. The researchers also aim to explore the potential of jumping exercise to enhance the benefits of dairy on bone metabolism.

Who can participate?
Healthy volunteers aged 20 - 40 years

What does the study involve?
Within this study there are four experimental conditions (four test days). Participants undergo all these conditions in a random order. This order is determined by the computer.
Condition 1: Consuming a carbohydrate-rich breakfast with bread, margarine, jam and tea with sugar.
Condition 2: Consuming a breakfast with bread, margarine, jam and milk.
Condition 3: Consuming a breakfast with bread, margarine, cheese and milk.
Condition 4: Consuming a breakfast with bread, margarine, cheese and milk. After this breakfast, participants will perform a short jump exercise session.

What are the possible benefits and risks of participating?
Participants may experience some discomfort from some soreness in the legs after the jump training. Participants may experience some discomfort from the blood draw.

Where is the study run from?
HAN University of Applied Sciences (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to October 2022

Who is funding the study?
1. FrieslandCampina (Netherlands)
2. Nederlandse Zuivel Organisatie (Netherlands)

Who is the main contact?
Luuk Hilkens
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
NL80607.096.22

# Study information

### Scientific Title

The postprandial metabolic response with graded amounts of whole-food dairy products as part of breakfast

## Acronym
DAYBREAK

## Study objectives
The main objective of the current project is to assess postprandial metabolic responses when graded amounts of whole-food dairy products are incorporated into a common breakfast. Furthermore, the researchers aim to explore the potential of jumping exercise to enhance the benefits of dairy on bone metabolism.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 21/04/2022, Medical Ethical Review Commission METC Zuyderland (Postbus 5500, 6130 MB, Sittard, The Netherlands, +31 (0)88 4590129, metc@zuyderland.nl), ref: METCZ20220015

## Study design
Open-label randomized cross over trial

## 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 the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Nutritional study in healthy individuals

## Interventions
Randomisation is carried out using a Williams Design Latin Square with four trial sequence possibilities. These four sequences are randomized in 2 blocks of 8 and 1 of 4, using an online randomization tool.

Participants will be exposed to the following conditions in a randomized order:
1. Common high-carbohydrate breakfast: bread, tea with sugar, half-fat margarine and marmalade (LOW*)
2. Breakfast with milk: bread, milk, half-fat margarine and marmalade (MOD*)

3. Breakfast with milk and cheese: bread, milk, half-fat margarine, cheese (HIGH*)
4. Breakfast with milk and cheese: bread, milk, half-fat margarine, cheese. Followed by a ~5-min bout of jumping exercise to stimulate bone formation (HIGH+JUMP*).
*LOW = low dairy intake (~10 g protein); SUB = moderate dairy intake (~16 g protein); HIGH = high dairy intake (~26 g protein); HIGH+JUMP = high dairy intake (~26 g protein) + ~5 min jumping exercise.

The duration of the intervention per subject is 4 weeks (i.e. 4 test days separated by 1 week).

### Intervention Type
Behavioural

### Primary outcome measure
Postprandial kinetics and bioavailability of amino acids measured using blood samples at baseline, 15, 30, 45, 60, 90, 120, 180, 240, and 300 minutes

### Secondary outcome measures
1. Glycaemic response measured using blood samples (glucose, insulin, GLP-1) at baseline, 15, 30, 45, 60, 90, 120, 180, 240, and 300 minutes
2. Bone metabolism measured using blood samples (calcium, PTH, CTX, P1NP) at baseline, 15, 30, 45, 60, 90, 120, 180, 240, 300 minutes, and 24 hours
3. Feelings of hunger and satiety measured using the visual analogue score (VAS) baseline, 60, 120, 180, 240, and 300 minutes

### Overall study start date
01/01/2022

### Completion date
19/10/2022

## Eligibility

### Key inclusion criteria
1. Males and females
2. Age ≥20 and ≤40 years.
3. BMI ≥18.5 and ≤27.5 kg/m²

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
20 Years

### Upper age limit
40 Years

### Sex

Both

### Target number of participants
20

### Total final enrolment
23

### Key exclusion criteria
1. Blood donation during the study period
2. Currently smoking
3. Consumption of >21 alcoholic beverages per week
4. Use of illicit drugs
5. Regular use of protein or calcium supplements
6. A self-reported reported lactose intolerance, allergy or sensitivity to dairy ingredients
7. Reported slimming or medically prescribed diet
8. Use of antibiotics in the past month
9. Medical condition that can interfere with the study outcome (i.e. cardiovascular disease, pulmonary disease, rheumatoid arthritis, orthopaedic disorders, renal disease, liver disease, diabetes mellitus, inflammatory disease, cognitive impairment, and thyroid or parathyroid disease)
10. Use of medications known to interfere with selected outcome measures (i.e. corticosteroids)
11. (Chronic) injuries of the locomotor system that can interfere with the intervention
12. Current participation in another biomedical research study
13. Trained individuals (i.e. performing sport activities for more than 6 hours per week)
14. Structural or competitively participating in exercise/sports with a substantial high-impact component, such as soccer, volleyball, running, and lower body resistance training

### Date of first enrolment
16/05/2022

### Date of final enrolment
13/09/2022

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**HAN University of Applied Sciences**
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## Sponsor information

**Organisation**
HAN University of Applied Sciences

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**Sponsor type**
University/education

**Website**
https://www.hanuniversity.com/en/

**ROR**
https://ror.org/0500gea42

# Funder(s)

**Funder type**
Industry

**Funder Name**
FrieslandCampina

**Alternative Name(s)**
FrieslandCampina Nederland, FrieslandCampina N.V.

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
Netherlands

**Funder Name**
Nederlandse Zuivel Organisatie

### Alternative Name(s)
Dutch Dairy Association, NZO

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
Netherlands

## Results and Publications

### Publication and dissemination plan
Planned publication(s) in high-impact peer-reviewed journal(s) by the end of 2023.

### Intention to publish date
31/12/2023

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Upon reasonable request by other researchers, raw data (Excel file) will be made available after the publication of the scientific reports. Data can be used for scientific peer-review or meta-analytic procedures. Data will be fully anonymised. Access to the datasets via JanWillem.vanDijk@han.nl.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/12/2023 | 18/12/2023 | Yes | No |