

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	<input type="checkbox"/> Prospectively registered
Registration date 26/05/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/12/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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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

Kapittelweg 33

Nijmegen

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Sponsor information

Organisation

HAN University of Applied Sciences

Sponsor details

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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