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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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Open-label randomized cross over trial

Study type(s)
Other

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(s)
Postprandial kinetics and bioavailability of amino acids measured using blood samples at baseline, 15, 30, 45, 60, 90, 120, 180, 240, and 300 minutes

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
All

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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6525 EN

Sponsor information

Organisation
HAN University of Applied Sciences

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

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