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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51598

Source
ToetsingOnline

Brief title
DAYBREAK

Condition

- Other condition

Synonym
N/A

Health condition

Glucose- en botmetabolisme bij gezonde mensen

Research involving
Human

Sponsors and support

Primary sponsor: HAN University of Applied Sciences
Source(s) of monetary or material Support: PPS Call Landbouw;Water;Voedsel,TKI Agri and food

Intervention

Keyword: bone metabolism, breakfast, dairy, glucose metabolism

Outcome measures

Primary outcome

Post-prandial metabolic response as assessed by amino acids concentrations, and

the bone formation marker procollagen type I N propeptide

Secondary outcome

Post-prandial metabolic response as assessed by glucose metabolism (glucose,

insulin, GLP-1) and bone metabolism (calcium, PTH, CTX). Hunger and satiety

will be assessed by means of a VAS scale.

Study description

Background summary

Dietary protein has several important health effects on muscle and bone tissue , and is associated with several health outcomes such as improved cardiovascular risk. In general, people have a skewed distribution of protein intake, with protein intakes at breakfast below 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 satiety following food intake. Also, the co-ingestion of protein with carbohydrates is associated with a more favorable glycemic response. Dairy protein may be a favorable 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, postprandial glycemic control, satiety, 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.

Study objective

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

Study design

Open-label randomized crossover trial.

Intervention

In a randomized order, all participants will consume a carbohydrate-rich breakfast with graded amounts of dairy protein with or without postprandial jumping exercise.

Participants will beexposed to the following conditions in a randomized order:
1. Common high-carbohydrate breakfast: bread, tea with sugar, half-fat margarin and marmalade (LOW*)
2. Breakfast with milk: bread, milk, half-fat margarin and marmalade (MOD*)
3. Breakfast with milk and cheese: bread, milk, half-fat margarin, cheese (HIGH*)
4. Breakfast with milk and cheese: bread, milk, half-fat margarin, 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.

Study burden and risks

• Participants will visit our lab 7 times (1 x ~30 min, i.e. screening; 4 x ~5.5 h, i.e. test day; 2 x 10 min, i.e. test day).
• Overall, 10 blood samples (~8-12 mL/sample) per test day will be drawn via an intravenous canula. After 2 test days participants will return to our lab 24h post breakfast for a single blood sample by vena puncture. The discomfort associated with inserting an intravenous canula is transient and is comparable to having an injection by a needle, or donating blood.
• The ~5 min jumping exercise intervention consists of non-exhaustive rope skipping-type exercise.
• The consumed breakfast will contain regular food products purchased in a supermarket.
• BMD and body composition will be assessed once by DXA. The measurement is

painless, non-invasive and involves only low radiation exposure (<10 µSv). Altogether, it can be concluded that the burden and risks associated with this study are limited.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age >=20 and <=40 years.
• BMI >=18.5 and <=27.5 kg/m2
• Willing to give blood samples

Exclusion criteria

• Blood donation during the study period
• Currently smoking
• Consumption of >21 alcoholic beverages per week
• Use of illicit drugs
• Regular use of protein supplements.
• A self-reported reported lactose intolerance, allergy or sensitivity to dairy ingredients
• Reported slimming or medically prescribed diet
• Use of antibiotics in the past month
• 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)
• Use of medications known to interfere with selected outcome measures (i.e. corticosteroids)
• (Chronic) injuries of the locomotor system that can interfere with the intervention.
• Current participation in another biomedical research study.
• Trained individuals (i.e. performing sport activities for more than 6 hours per week).
• Structural or competitively participating in exercise/ sports with a substantial high-impact component, such as soccer, volleyball, running, and lower body resistance training.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80607.096.22