Effects of daily protein supplementation on brain function in older adults with overweight or obesity

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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON57373

Source
ToetsingOnline

Brief title
Protein supplementation and brain function

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Cognitive and attention disorders and disturbances

Synonym
Insulin-resistance syndroom, Metabolic syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Cosun Nutrition Center

Intervention

Keyword: Brain function, Protein supplementation

Outcome measures

Primary outcome

The primary endpoint is the difference at follow-up in the cerebral blood flow response before and after intranasal insulin administration between interventions.

Secondary outcome

Cognitive performance will be assessed with a neuropsychological test battery, while we will also focus on appetite-related brain reward activity.

Study description

Background summary

Protein-rich foods may improve brain insulin-sensitivity, which is important for cognitive and metabolic health, and may also translate into an improved food intake regulation It is therefore pertinent to delineate the effects of plant-derived proteins, which are a more sustainable alternative to animal-derived proteins, on brain insulin-sensitivity and related functional benefits. We now hypothesize that daily plant-derived or animal-derived protein supplementation improves brain vascular function and insulin-sensitivity, thereby improving cognitive performance and appetite control in overweight or obese older men and women.

Study objective

The primary objective is to investigate in overweight or obese older adults the effect of daily protein supplementation for two weeks with either a plant-derived protein or an animal-derived protein on vascular function and insulin-sensitivity in the brain, while we will also focus on changes in cognitive performance and appetite-related brain reward activity (secondary study objectives). Cerebral blood flow responses before (brain vascular function) and after the administration of intranasal insulin spray (brain insulin-sensitivity) will be quantified by the gold standard magnetic resonance

imaging (MRI)-perfusion method Arterial Spin Labeling (ASL).

Study design

This intervention study will have a single-blind, randomized, controlled cross-over design. The total study duration will be 18 weeks, including three two-week intervention periods, separated by wash-out periods of at least six weeks.

Intervention

Study participants will consume, in random order, twice daily (2 x 20 g) a plant protein (fava bean protein isolate), animal protein (milk protein isolate) or no extra protein (control) for two weeks, separated by six-week wash-out periods.

Study burden and risks

Subjects will be screened to determine eligibility during one visit of 30 minutes. During these screening visits, anthropometric measurements will be performed and blood pressure will be determined. In addition, a fasting blood sample (5.5 mL) will be drawn. Participants will consume, in random order, twice daily (2 x 20 g) a plant protein, animal protein or no extra protein (control). Off note, protein supplementation regimens have already been provided in previous trials and were well-tolerated. There are no expected side effects related to daily protein supplementation. During the trial on different occasions, tests will be performed and blood will be sampled (a total of 245.5 mL during the whole trial). During these tests, study subjects have to stay at the university and are not allowed to eat. Some subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possibly a hematoma or bruise. Some participants may also report pain during the insertion of the cannula. Arterial Spin Labeling perfusion MRI non-invasively records cerebral blood flow without any significant risks. MRI measurements will be performed on a Siemens 3.0 Tesla Magnetom Prisma Fit scanner. No contrast medication or radioactive tracer substance will be administered to the participants. Brain insulin-sensitivity will be assessed by quantifying acute effects of insulin as nasal spray on cerebral blood flow, which is safe and has already been used in several studies from our research group before. Other measurements are routine and are not expected to lead to physical side effects. Participants that not fully adhere to the study protocol will be excluded from the statistical analyses, because a per protocol analysis will be performed. The total time investment is 14 hours (840 minutes), excluding travel time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Men and women, aged between 60-75 years
- BMI between 25-35 kg/m2 (overweight or obese)
- Fasting plasma glucose < 7.0 mmol/L
- Fasting serum total cholesterol < 8.0 mmol/L
- Fasting serum triacylglycerol < 4.5 mmol/L
- Systolic blood pressure < 160 mmHg and diastolic blood pressure < 100 mmHg
- Stable body weight (weight gain or loss < 3 kg in the past three months)
- Willingness to give up being a blood donor from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
- No difficult venipuncture as evidenced during the screening visit

Exclusion criteria

- Intolerant to milk products or fava bean allergy
- Vegetarians
- Left-handedness
- Current smoker, or smoking cessation < 12 months
- Diabetic patients
- Familial hypercholesterolemia
- Abuse of drugs
- More than 3 alcoholic consumptions per day
- Use of food products or dietary supplements known to interfere with the main outcomes as judged by the principal investigators
- Use medication to treat blood pressure, lipid, or glucose metabolism
- Use of an investigational product within another biomedical intervention trial within the previous 1-month
- Severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases, and rheumatoid arthritis
- Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
- Contra-indications for MRI imaging (e.g., pacemaker, surgical clips/material in body, metal splinter in eye, claustrophobia)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	50

Type:	Anticipated

Ethics review

Approved WMO Date:	28-03-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	ClinicalTrials.gov registratie zal plaatsvinden na goedkeuring door de METC
CCMO	NL88040.068.24