Longer-term effects of peanut consumption on brain function in older men and women.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56398

Source
ToetsingOnline

Brief title
Peanuts and brain function

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

Health condition

cognitieve stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: The Peanut Institute Foundation (TPIF)

Intervention

Keyword: Brain function, Peanuts

Outcome measures

Primary outcome

At baseline, first anthropometric measurements will be performed and blood pressure will be determined. In addition, a fasting blood sample will be drawn. Another fasting blood sample will be drawn at eight weeks, while participants have to attend the research facilities to perform follow-up measurements after sixteen weeks. 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 that will be assessed with a neuropsychological test battery is the secondary endpoint.

Study description

Background summary

Impaired brain vascular function precedes the development of reduced cognitive performance, while brain insulin-resistance is also associated with cognitive decline. Peanut consumption has already been shown to beneficially affect cognitive performance. However, underlying mechanisms have not yet been established, while well-controlled trials on longer-term effects of peanuts on cognitive performance are highly needed. We hypothesize that longer-term peanut consumption improves (regional) brain vascular function and

insulin-sensitivity, thereby improving cognitive performance in older men and women.

Study objective

The primary objectives are to investigate in older men and women the effect of 16-week peanut consumption on brain vascular function and brain insulin-sensitivity in cognitive-control brain areas, while we will also focus on changes in cognitive performance as assessed with a neuropsychological test battery (secondary objective). Cerebral blood flow responses before (brain vascular function) and after the administration of intranasal insulin (brain insulin sensitivity) will be non-invasively quantified by the non-invasive gold standard magnetic resonance imaging (MRI)-perfusion method Arterial Spin Labeling (ASL).

Study design

This intervention study will have a randomized, controlled, cross-over design. The total study duration will be 40 weeks, including two 16-week interventions, separated by a washout period of at least 8 weeks.

Intervention

Study participants will receive in random order daily 60 g of skin roasted peanuts (peanut intervention) or no peanuts for a total of 16 weeks (control intervention), separated by a wash-out period of at least 8 weeks.

Study burden and risks

Subjects will be screened to determine eligibility during one visit of 20 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. During the peanut intervention, adults will receive daily 60 g of peanuts for sixteen weeks. These regimens were well-tolerated in previous trials and are safe, and there are no expected side effects related to the nut consumption. 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, subjects have to stay at the university and are not allowed to eat. Some study subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possible a hematoma or bruise. Some adults 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 is used in a study from our research group already (METC 19-058). This is also being used by experts at the University of Tübingen (Germany) and Leiden University Medical Centre (protocol code numbers P13.164 and NL45043.058.13). 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 12 hours (720 minutes), excluding travel time. The study will provide insight into the potential beneficial effect of peanuts on brain function in older men and women.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged between 60-75 years
- BMI between 20-35 kg/m2
- 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

- Allergy or intolerance to nuts
- 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 nuts 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:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-02-2023
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	16-11-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-06-2023
Application type:	Amendment
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
CCMO	NL82095.068.22