Longer-term effects of wild blueberry consumption on brain function in older men and women

Published: 01-10-2024
Last updated: 22-12-2024

The primary objectives are to investigate in older adults the effect of 16-week wild blueberry consumption on (regional) vascular function and insulin-sensitivity in the brain, while we will also focus on changes in cognitive performance as assessed...

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

Summary

ID

NL-OMON57048

Source
ToetsingOnline

Brief title
Wild blueberries 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: Wild Blueberry Association of North America

(WBANA)

Intervention

Keyword: Brain Function, Wild blueberries

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 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 associated with cognitive decline. Evidence from epidemiological studies has already suggested beneficial effects of wild blueberry consumption on cognitive performance. However, underlying mechanisms have not yet been established, while well-controlled trials on longer-term effects of wild blueberries on cognitive performance are highly needed. We hypothesize that longer-term wild blueberry intake 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 adults the effect of 16-week wild blueberry consumption on (regional) vascular function and insulin-sensitivity in the brain, while we will also focus on changes in cognitive performance as assessed with a neuropsychological test battery (i.e., secondary objective). Cerebral blood flow responses before (brain vascular function) and after the administration of intranasal insulin spray (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 double-blind, randomized, controlled cross-over design. The total study duration will be 40 weeks, including two 16-week interventions, separated by a wash-out period of at least 8 weeks.

Intervention

Study participants will receive, in a random order, daily 26 g of freeze-dried wild blueberry powder (wild blueberry intervention) or a matched placebo (control intervention) for sixteen weeks, separated by a wash-out period of minimal eight 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 wild blueberry intervention, adults will receive daily 26 g of freeze-dried wild blueberry powder for sixteen weeks. These regimens were well-tolerated in previous trials and are safe, and there are no expected side effects related to wild blueberry consumption. During the trial at different occasions, tests will be performed and blood will be sampled (a total of 425.5 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 possibly 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 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 23 hours (1380 minutes), excluding travel time.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

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

- Allergy or intolerance to berries
- 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:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	36

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	01-10-2024
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 METC
CCMO	NL87039.068.24