The effects of a healthy lifestyle on brain vascular function in elderly people

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

Summary

ID

NL-OMON48037

Source
ToetsingOnline

Brief title
Lifestyle and Brain Vascular Function

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Lifestyle, Vascular function

Outcome measures

Primary outcome

At baseline and follow-up, participants have to attend the research facilities

for one day to perform measurements. The primary endpoint is the effect of a

16-week healthy lifestyle intervention on cerebral blood flow, as assessed by

Arterial Spin Labeling.

Secondary outcome

Cognitive performance and HOMA-ir

Study description

Background summary

Cognitive performance is negatively related to an impaired glucose metabolism, possibly due to impairments in brain vascular function. Supported by the statement from the American Heart and Stroke Association that healthy lifestyle is one of the most effective strategies to protect against cognitive decline, we now hypothesize that healthy lifestyle induced changes in glucose metabolism cause beneficial effects on brain vascular function thereby improving cognitive performance.

Study objective

The primary objective of this intervention study is to evaluate in sedentary elderly men and women the effect of a 16-week healthy lifestyle intervention on cerebral blood flow, as quantified by the non-invasive gold standard magnetic resonance imaging (MRI) perfusion method Arterial Spin Labeling (ASL). Cerebral blood flow is a robust and sensitive physiological marker of brain vascular function. Secondary objectives are to examine effects on peripheral glucose metabolism using the homeostatic model assessment for insulin resistance (HOMA-ir) and cognitive performance as assessed with a neuropsychological test battery.

Study design

The proposed study will have a randomized, controlled, parallel design. The total study duration will be sixteen weeks.

Intervention

The intervention group will follow a 16-week healthy lifestyle intervention, which includes physical activity according to the dutch guidelines and dietary advice adhering to the guidelines described in the *wheel of five*. Participants will receive thorough instructions about the guidelines at the baseline and intermediate visit at the university and will be monitored every two weeks via e-mail or telephone.

Study burden and risks

Participants will be screened to determine eligibility during one visit of 30 minutes. During these screening visits, we will measure antropometrics and blood pressure will be determined. Additionally, a resting 12-lead ECG will also be recorded and a venous blood sample (9.0 mL) will be drawn. During the healthy lifestyle intervention, participants will receive instructions to comply to the Dutch nutrition and movement guidelines, which will be monitored every two weeks. The healthy lifestyle intervention is safe and there are no expected side effects related to the intervention. During the trial measurements will be performed and blood will be sampled (a total of 210 mL during the whole trial) at baseline, intermediate and at follow-up visit. During these tests, participants have to visit the university and are not allowed to eat. Some study participants may report pain during venipuncture. Arterial Spin Labeling perfusion MRI non-invasively records cerebral blood flow without any significant risks. 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. Other measurements are routine in our metabolic research unit (MRUM) 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, excluding travelling time, is approximately 14 hours.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Universiteitsingel 50

Maastricht 6229ER
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Universiteitsingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged between 55-70 years
- BMI between 25-35 kg/m2 (overweight and slightly obese)
- Sedentary (assessed as low physically active using the International Physical Activity Questionnaire)
- Rights handedness and footedness
- 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

- Current smoker, or smoking cessation < 12 months
- Diabetic patients

- Familial hypercholesterolemia
- Abuse of drugs
- Consumption of more than 21 alcoholic units/week (men), or more than 14 alcoholic units/week (women)
- Use of dietary supplements known to interfere with the main study 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2019
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
CCMO	NL71184.068.19

Study results

Date completed: 22-09-2020

Actual enrolment: 20

Summary results
Trial ended prematurely