# An egg-protein hydrolysate (NWT-03) to boost brain function - mind your blood vessels

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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-OMON50991

**Source**
ToetsingOnline

**Brief title**
An egg-protein hydrolysate and brain function

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Newtricious R&D ,Stichting Life Sciences Health - TKI (trade name Health Holland)

## Intervention

**Keyword:** Brain function, Egg-protein hydrolysate

## Outcome measures

### Primary outcome

The primary endpoints are the difference in brain vascular function and

cognitive performance between interventions.

### Secondary outcome

Secondary endpoints are effects on insulin-sensitivity and peripheral vascular

function.

# Study description

### Background summary

Age-related chronic diseases including dementia, type II diabetes mellitus (T2DM) and cardiovascular disease (CVD) become more prevalent and of increasing societal concern. Common denominators of these co-morbidities are insulin-resistance and impaired vascular function. Animal and short-term human studies now suggest that NWT-03 - an egg-protein hydrolysate - improves insulin-sensitivity and peripheral vascular function, which are risk markers for the development of T2DM and CVD. Insulin-resistance is also associated with cognitive decline, while impaired brain vascular function is an important event preceding the development of impaired cognitive performance. We have already shown in a shorter-term trial (12 weeks) beneficial effects of a daily dose of 5.0 g of NWT-03 on cognitive performance. However, underlying mechanisms have not yet been addressed, while the long-term effects remain unknown. Thus, we now hypothesize that NWT-03 beneficially affects brain vascular function and cognitive performance following long-term daily intake.

### Study objective

The primary objectives of this trial are to evaluate in overweight or obese adults (aged 60-75) with subjective cognitive decline (SCD) the effects of a 36-weeks NWT-03 intervention on (1) cognitive performance using a neurophysiological test battery, and (2) cerebral blood flow, as quantified by the current non-invasive gold standard magnetic resonance imaging (MRI)

perfusion method Arterial Spin Labeling (ASL). Secondary study objectives are to examine effects on insulin-sensitivity and peripheral vascular function.

### Study design

This intervention study will have a randomized, controlled, parallel design. The total study duration will be 36 weeks.

### Intervention

During the study, subjects will receive daily (in the morning) 5.7 g NWT*03 or placebo powders for 36 weeks.

### Study burden and risks

Subjects will be screened to determine eligibility during one visit of 20 minutes. During the screening visit, anthropometric measurements will be performed and blood pressure will be determined. In addition, a fasting blood sample (5.5 mL) will be drawn. After inclusion, subjects will be randomized. Half of the subjects will receive daily NWT*03 and the other half placebo powders. NWT-03 has already been provided in a similar dose and format during previous trials and was well-tolerated. There were also no side effects related to the intervention. The total study duration will be 36 weeks. During the study, tests will be performed on different occasions, and blood will be sampled (225.5 mL during the whole trial). During these tests, 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 adults may also report pain during the insertion of the cannula. ASL 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 will be administered. Other measurements are also not expected to lead to physical side effects. The total time investment is 18 hours (1080 minutes), excluding travel time. The study will provide insight into the effects of NWT-03 on brain vascular function and cognitive performance in older adults with subjective cognitive decline.

## Contacts

**Public**
Universiteit Maastricht

Universiteitsingel 50
Maastricht 6229ER

NL
**Scientific**
Universiteit 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

- Men and women, aged between 60-75 years
- Subjective cognitive decline (SCD)
- BMI between 25-35 kg/m2
- Fasting plasma glucose < 7.0 mmol/L
- Fasting serum total cholesterol < 8.0 mmol/L (further testing will be performed for excessive hyperlipidemia [serum total cholesterol * 8.0 mmol/L] according to the Standard for cardiovascular risk management of NHG)
- 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

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

- Familial hypercholesterolemia
- Abuse of drugs
- More than 3 alcoholic units per day
- Use of products or dietary supplements known to interfere with the main outcomes as judged by the principal investigators within the previous 1-month
- Use of medication to treat blood pressure, lipid or glucose metabolism
- Use of an investigational product within another 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

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-05-2021 |
| Enrollment: | 44 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 19-01-2021 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 09-09-2021 |
| 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 | NL75618.068.20 |