

# The effect of short-term Aronia melanocarpa extract supplementation on cognitive function in healthy young adults

Published: 06-02-2019

Last updated: 12-04-2024

With this research we look at the short-term effects of an aronia melanocarpa extract on cognitive functioning in healthy young adults compared to placebo.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Approved WMO        |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | Other condition     |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON49838

### Source

ToetsingOnline

### Brief title

The effect of aronia extract on cognitive function

### Condition

- Other condition

### Synonym

cognition

### Health condition

Cognitief functioneren

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** BioActor BV, voedingsindustrie

## Intervention

**Keyword:** Aronia melanocarpa, cognition, polyphenols

## Outcome measures

### Primary outcome

The short term (7 days) effect of supplementation on cognitive functioning

### Secondary outcome

The short term (7 days) effect of supplementation on blood and saliva biomarkers

The short term (7 days) effect of supplementation on mood

The short term (7 days) effect of supplementation on vascular function.

The short term (7 days) effect of supplementation on microvasculature of the eye

The short term (7 days) effect of supplementation on subjective cognition

## Study description

### Background summary

There is a great interest in improving cognitive performance, including memory and attention. Improved attention is desirable for a large group of people because it is linked to improved performance (Vast, Young & Thomas, 2010). Students and professionals can benefit from improved attention and thus performance in academic and other work environments. In addition, cognitive functioning also plays an important role in sports. Various cognitive skills, including attention, reaction time and motor function, have shown that they can influence sport performance (Baker, Nuccio & Jeukendrup, 2014). A completely natural supplement with aronia melanocarpa extract could be a promising way to naturally improve cognitive performance.

The product in this study is aronia melanocarpa extract, which contains polyphenols. A limited number of clinical studies have already been carried out to see the effect of this products and simular products on cognitive

functioning. However, these studies have often been done in older study populations, over a longer period of time.

In this study, in healthy adolescents (ages between the 18-35 and with a BMI between 18.5 and 30), we want to test the short term (7 days) effect of aronia melanocarpa extract on cognitive functioning. We will also test the effect of supplementation on the participant's mood, subjective cognition, vascular function, microvasculature of the eye, biomarker level in the blood and saliva, as well as the blood pressure.

The study product is aronia malanocarpa (with an anthocyanin content of 24%). Studies with aronia malanocarpa have shown positive indications with regard to cognitive functioning, but this has not been tested in healthy young adults.

### **Study objective**

With this research we look at the short-term effects of an aronia malanocarpa extract on cognitive functioning in healthy young adults compared to placebo.

### **Study design**

Randomized, double-blind, placebo-controlled cross-over study

### **Intervention**

Subjects are randomly assigned to receive the intervention conditions in random order. All subjects are randomly assigned to start one of the two conditions (placebo, aronia melanocarpa). Each condition consists of taking supplements for 7 days (30 minutes before breakfast) after which a wash-out period of 2 weeks follows and the remaining condition, which again consists of 7 days supplementation, is started.

### **Study burden and risks**

Participation in the study is a time investment in which some food products have to be avoided, also a food diary must be filled out 4 times and a logbook to specify the times of the intake of the capsules also needs to be filled out for 7 days at a time during the two experimental conditions.

The dosage of aronia melanocarpa used in this study has no known side effects based on previous human research.

Also for the intake of the placebo product, cellulose, no side effects are known from previous human research.

For the intake of the Aronia extract no side effects are know from previous human research,

Blood collection: risk of local hematoma, bruise and / or pain.

saliva collection: no risks

Cognitive test battery: no risks

Filling out the questionnaires, logbook and food diary: no risks

Vascular function assessment: no risks

fundus photography: no risks

## Contacts

### Public

Universiteit Maastricht

Gaetano martinolaan 85

Maastricht 6229 GS

NL

### Scientific

Universiteit Maastricht

Gaetano martinolaan 85

Maastricht 6229 GS

NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Healthy young adults: ages between 18 and 35, BMI between 18.5-30 kg/m<sup>2</sup>

### Exclusion criteria

Medicine usage that could influence the endpoint of the study  
Pregnancy or lactating  
Known allergies for berries  
High blood pressure (>140 systolic and/or >90 diastolic mmHg)  
Usage of more than 20 alcoholic consumptions a week  
Drug usage  
Supplement usage  
Participation in a scientific intervention study which may interfere with this study in the 180 days prior to this study

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Crossover                   |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Placebo                     |
| Primary purpose:    | Other                       |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 09-10-2020          |
| Enrollment:               | 39                  |
| Type:                     | Actual              |

## Ethics review

|                    |   |
|--------------------|---|
| Approved WMO       |   |
| Date:              | 06-02-2019  |
| Application type:  | First submission  |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO       |   |

|                    |   |
|--------------------|---|
| Date:              | 11-12-2019  |
| Application type:  | Amendment   |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO       |   |
| Date:              | 27-05-2020  |
| Application type:  | Amendment   |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO       |   |
| Date:              | 14-09-2020  |
| 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             |
|--------------------|----------------|
| ClinicalTrials.gov | NCT03793777    |
| CCMO               | NL67045.068.18 |