The effect of AlgaSense® on the stress response and mental wellbeing in young adults: The Stress Examination: Relief Effects with Nutritional AlgaSense® (SERENAL) study

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The aim of the present study is to investigate the effect of a microalgae (Hematoccocus pluvialis) on the stress response and mental wellbeing in jong adults.

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Other condition
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON56854

Source
ToetsingOnline

Brief title
SERENAL study

Condition

- Other condition

Synonym
mental wellbeing, tension

Research involving
Human

Sponsors and support

Primary sponsor: BioActor BV
Source(s) of monetary or material Support: BioActor BV

Intervention

- Food (substances)

Keyword: Mental wellbeing, Microalgae powder, Stress

Explanation

N.a.

Outcome measures

Primary outcome

The primary objective is to assess the effect of 8 weeks of supplementing daily
 270 mg microalgae powder on the stress response

Secondary outcome

The secondary objective are to study the effects on mental wellbeing with the
 aid of questionnaires and measuring physiological markers such as BDNF and
 GABA. An exploratory study objective ais to study the effect on the microalgae
 supplementation on cognition.

Study description

Background summary

On a global scale, individuals experience more worries and stress compared to the last couple of years. This is a major concern because increased stress levels can alter hormonal release, which could have negative impacts on health. The supplementation of a whole microalgae powder, rich in multiple bioactive compounds such as astaxanthin, can be an effective strategy to target stress and mental wellbeing, due to its potential to attenuate cortisol release, the stress hormone.

Study objective

The aim of the present study is to investigate the effect of a microalgae

(Hematoccocus pluvialis) on the stress response and mental wellbeing in jong adults.

Study design

A randomized, double-blind, placebo-controlled, parallel trial

Intervention

Participants will ingest daily with breakfast 270 mg microalgae powder or placebo capsules for 8 weeks

Study burden and risks

The total study duration will be 8 weeks. During the study, blood samples will be collected (<500 mL in total), which occasionally may cause a hematoma or bruise. Other measurements are not expected to cause side effects. Subjects will have a time investment of ± 13.5 hours (screening, three test days, preparation at home).

Contacts

Scientific
BioActor BV
BioActor BV BioActor BV
Gaetano Martinolaan 50 4th floor
Maastricht 6229 GS
Netherlands
043 711 4555
Public
BioActor BV
BioActor BV BioActor BV
Gaetano Martinolaan 50 4th floor
Maastricht 6229 GS
Netherlands
043 711 4555

Trial sites

Trial sites in the Netherlands

Universiteit Maastricht
Target size: 120

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18-35 years old
• BMI between 18 and 30 kg/m2
• Willing to abstain from nutritional supplements known to affect the study outcome (e.g., ashwagandha, omega-3 fatty acids, rhodiola, vitamin c, and magnesium)

Exclusion criteria

• Currently smoking or quitted smoking in the past year
• Allergy to an ingredient of the product
• Having donated blood within one month prior to the start of the study, or planning to donate blood during the study
• Use of medication known to affect the outcomes of the study
• Irregular menstrual cycle
• Adrenal gland diseases (such as Addison*s disease and Cushing*s syndrome)
• Prader-Willi syndrome
• Known pregnancy or lactation
• Shift workers
• Major psychiatric/mental health disorders (e.g., depression, anxiety, post-traumatic stress)
• Diabetes

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	18-09-2024
Enrollment:	120
Duration:	2 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
Registration:	No

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	28-06-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-03-2025

Application type:	Amendment
Review commission:	METC AZM/UM

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	NL86217.068.24
Research portal	NL-005743