The effect of rumenic acid rich conjugated linoleic acid supplementation on cognitive functioning

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The primary objective is to investigate the effect of 12 weeks of supplementation with 3.5g/day of rumenic acid on episodic memory in older men and women at risk of cognitive impairment. Secondary objectives include working memory, attention,...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48753

Source ToetsingOnline

Brief title Cognition and Rumenic Acid (CORA)

Condition

- Other condition
- Central nervous system infections and inflammations

Synonym cognitive decline, impaired brain functioning

Health condition

cognitieve stoornis

Research involving

Human

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Sponsors and support

Primary sponsor: Wageningen Universiteit **Source(s) of monetary or material Support:** Stepan Specialty Products B.V.

Intervention

Keyword: Ageing, Cognition, Conjugated linoleic acid, Rumenic acid

Outcome measures

Primary outcome

The primary study parameter is the performance on episodic memory.

Secondary outcome

Secondary parameters entail working memory, attention, executive functioning,

and psychomotor speed as measured with a battery of cognitive tests, the

evaluation of rumenic acid supplementation on anxiety, depressive symptoms,

quality of life (measured with questionnaires), and fatty acid status (measured

in blood).

Study description

Background summary

The ageing population is rapidly growing, leading to a steep increase in prevalence of cognitive decline. Cognitive decline is a major health threat and entails serious personal and economic consequences. Unfortunately, to date it is impossible to reverse the process of cognitive decline. This highlights the need for better understanding on how to prevent and slow down this process. As ageing and cognitive decline are associated with increased levels of inflammation, nutritional compounds that exhibit anti-inflammatory properties may propose a solution. Rumenic acid, a conjugated linoleic acid, has shown anti-inflammatory effects in several human intervention studies. Besides, a first intervention study investigating the effect of rumenic acid supplementation on cognitive performance has shown promising results. However, more research is needed to further investigate the potential beneficial effect of rumenic acid on cognition by means of well-designed intervention studies. The authors of the first intervention study specifically recommend future studies with a duration longer than 8 weeks and performed in elderly with impaired cognitive functioning.

Study objective

The primary objective is to investigate the effect of 12 weeks of supplementation with 3.5g/day of rumenic acid on episodic memory in older men and women at risk of cognitive impairment. Secondary objectives include working memory, attention, executive functioning, and psychomotor speed, the assessment of the effect of rumenic acid supplementation on mental well-being, handgrip strength, hand joint discomfort, and fatty acid blood levels.

Study design

Randomized, parallel, double-blind, placebo-controlled trial.

Intervention

Subjects will receive a daily dose of 3.5g rumenic acid divided over six capsules (intervention) or six placebo capsules (control).

Study burden and risks

Burdens that research subjects may experience include time investment (approximately 0.5 hour for the screening and 2 hours on each of the 2 measurement days) and daily consumption of the rumenic acid supplement or placebo. Both supplements are safe for human use. During each test session, a 1-hour cognitive test battery will be performed which may be experienced as tiresome. In addition, a total of 40 mL of blood will be sampled via venepuncture. This may lead to minor discomfort and can cause small hematomas to appear. Furthermore, research subjects have to come in fasting state which may give some discomfort. However, breakfast will be offered afterwards.

Contacts

Public Wageningen Universiteit

Museumlaan 16 Koog aan de Zaan 1541LP NL **Scientific** Wageningen Universiteit

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Museumlaan 16 Koog aan de Zaan 1541LP NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged 65 years or older
- At risk of cognitive impairment/ memory complaints
- Able to understand and perform the study procedures

Exclusion criteria

- Body Mass Index (BMI) >35 kg/m2
- Current use of medication belonging to the *sartans* or *glitazones*
- Current use of >500 mg/day of acetylsalicylic acid
- Current use of medication that affects inflammation (anti-inflammatory medication)
- Fish consumption of more than 1 serving per week
- Current or recent (<1 month) use of fish oil supplements
- Current or recent (<1 month) use of anti-inflammatory dietary supplements such as quercetin, curcumin, resveratrol, and/or other flavonoids
- Diabetes mellitus
- Having a disease which interferes with the effect of the RAR-CLA supplement and/or with the outcome measure (cognitive functioning) as judged by medical doctor
- Swallowing problems
- Current participation in other scientific research with the exception of EetMeetWeet!

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	52
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	13-05-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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.

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In other registers

Register

CCMO Other **ID** NL66867.081.18 NL7598