Food2Learn: Effect of omega-3 LCPUFA intervention on learning, cognition, behaviour and visual processing

Published: 01-11-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38932

Source
ToetsingOnline

Brief title
Food2Learn

Condition

- Other condition

Synonym
brain functioning, Cognitive performance

Health condition

Geen; het onderzoek heeft geen betrekking op een aandoening. Het betreft gezonde deelnemers. Uiteindelijk wordt wel gekeken naar de verandering in cognitieve prestatie en mentaal welbevinden

Research involving

Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: NWO,Aker Biomarine Antarctic AS,Metrisquare B.V.,Olympic Seafood,Omegametrix

Intervention

Keyword: academic achievement, cognition, krill oil, omega-3 LCPUFA

Outcome measures

Primary outcome

1. Academic achievement (grade point average for Dutch, English, and

mathematics)

2. Cognitive performance

Speed of information processing(Symbol Digit Modalities Test, Trail Making

Test)

Attention (D2 Test of Attention)

Working memory (N-back Taak)

3. Behavior

Absenteeism (schools will provide a list)

Motivation (MSLQ)

Goal orientation (Achievement Goal Questionnaire)

Mood (CES-D)

Self-esteem (Rosenberg Self-esteem Scale)

Secondary outcome

Perceptual processing measured with eye tracking (in sub-sample only)

Study description

Background summary

Previous research in (unborn) babies, children with a disorder, and elderly suggest that fish fatty acids / omega-3 fatty acids play a role in brain functioning. The period of adolescence was, until recently, for the most part neglected though it has been shown that the brain of adolescents, and especially the prefrontal cortex, continues to mature until their late twenties. Because of the continuing brain development during adolescence, it is important to take into account the role of the omega-3 fatty acids, also because the omega-3 fatty acids DHA and EPA are important structural components of the neural cell membranes and influence in this respect membrane fluidity and signal transduction and finally learning, cognition, and behaviour.
Therefore in the current study the effect of one year supplementation with omega-3 fatty acids from krill oil will be investigated in healthy 14-15 years old adolescents from lower vocational training on learning, cognitive performance, and behaviour.
This study answers the question whether omega-3 fatty acid supplementation from krill oil is useful to improve school performance.

Study objective

Primary objective of this study is to evaluate the short term (6 months) and long term (12 months and maybe 24 months) effects of a krill oil based omega-3 supplement on learning, cognitive performance and behavior.
Secundary goal of this study is to investigate the effect of above-mentioned supplement on visual processing measured by eye tracking.
We expect that in the intervention group the omega-3 status will increase significantly and will result in increments in learning, cognitive performance, and behavior.

Study design

A double-blind randomized controlled dietary intervention trial will be set up. 350 participants with low omega-3 index will be ad random allocated to an intervention or placebo group. After 6, 12, and (maybe) 24 months the effects on cognitive performance (performance on several neurocognitive tests) behavior (absenteeism, motivation, goal orientation, mood, and self-esteem) and in a sub-group visual processing by means of eye tracking will be determined.
At baseline, after 3 months and 12 months blood by finger prick is collected to determine fatty acid status. In case necessary dose adjustments will be made.
In addition at baseline a saliva sample will be collected. Recent studies indicate that the reaction on a fatty acid supplement may be dependent from the ApoE status. In case of a null finding ApoE status in saliva will be

determined.

Intervention

Participants will be randomly allocated to a placebo or an intervention group.
Participants in the intervention group will consume 2 g of krill oil a day.
This will result in the intake of the recommended daily amount of 450 mg of EPA/DHA per day.
The placebo has a fatty acid composition resembling the average European diet

Study burden and risks

Participation in the study will bring minimal or no risks. Participants are asked to take a daily Krill oil supplement together with the main course. In addition they are asked to complete several neuropsychological tests and questionnaires. This takes place in the class room in regular school time (4 times 1 lesson (50 min) per calendar year). In addition a subgroup of 60 students is asked to invest three times 25 minutes to participate in the sub-study regarding eye tracking.
All participants are asked to provide one saliva sample and four times blood from a finger prick.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Healthy adolescents
14-15 years old
Mother tongue is Dutch
Participating in lower general secondary education (it represents a group with a lower socio economic status and in this way it is assumed that we preselect a group with a low omega-3 index which might benefit most from a supplement like ours).
Only the first 350 students with an omega-3 index < 5% at baseline will be allocated to participate in the intervention study.

Exclusion criteria

Medical disorders associated with learning deficits such as ADHD, dyslexia, or autism.
Fish consumption higher than twice a week.
Use of fish oil supplements
Seafood allergy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2014
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2013
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL45803.096.13
Other	NTR15155, maar dit is enkele dagen geleden gebeurd en het officiele nummer moet nog worden toegekend