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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21796

Source
NTR

Brief title
Food2Learn

Health condition

Key words (English): omega-3 fatty acids, LCPUFA, krill oil, cognition, academic achievement, mental well-being, eye tracking

Key words (Dutch): omega-3 vetzuren, LCPUFA, krill olie, cognitie, schoolprestatie, mentale gezondheid, eye tracking

Sponsors and support

Primary sponsor: Open University in the Netherlands, Centre for Learning Sciences and Technologies
Source(s) of monetary or material Support: NWO (the Netherlands Organisation for Scientific Research)
Omegametrix
Aker BioMarine Antarctic AS
Olympic Seafood
Metrisquare B.V.

Intervention

Outcome measures

Primary outcome

Academic achievement: grade point average for Dutch, English, and Mathematics
Cognitive performance: neuropsychological tests covering several executive functions (LDST, D2, Digit Span Forward and Backward, CST,
Stroop test)
Behavior: absenteeism, motivation (MSLQ), Mood (CES-D), Self-esteem (RSE)

Secondary outcome

Two types of eye tracking parameters will be calculated, namely basic parameters and paragraph-related parameters. Basic parameters are number of blinks, number of fixations, total duration of fixations, average fixation duration, average dispersion of fixation positions, average saccadic amplitude, and average saccadic velocity. Moreover, we will calculate eye tracking measures per paragraph, namely time spent on each paragraph (number and duration of fixations), time elapsed until first looking at a paragraph, and amount of times going back to a paragraph (revisits). Sleep will be assessed in a subsample. Sleep quality and quantity as measured by activPAL and questionnaires (ASHS and ASWS) will be collected.

Study description

Background summary

The brain is primarily developed in the third trimester of pregnancy, but continues maturing through the late twenties, especially the prefrontal cortex. Omega-3 long-chain polyunsaturated fatty acids (LCPUFA) are important structural components of neural cell membranes, influence membrane fluidity and signal transduction, and thus learning, cognition and behaviour. Levels of omega-3 LCPUFA have been found to be low in individuals with limitations in these complex brain functions. Previous studies suggested that such functions could be improved by increasing LCPUFA. The adolescent brain, however, has been largely neglected.
This study investigates the effect of one-year daily omega-3 LCPUFA supplementation, in particular krill oil, in healthy 14-15 year old adolescents in lower general secondary education (MAVO/VMBO) on learning, cognition, and behaviour. The majority of the omega-3 PUFA in krill oil is incorporated into phospholipids, favouring tissue uptake of its omega-3 PUFA.
In a double blind, randomised controlled trial, 300 adolescents preselected from a population of 700 adolescents with low omega-3 index (<5%) will receive daily omega-3 LCPUFA supplementation or matching placebo. The omega-3 LCPUFA dose will be adjusted individually to reach a target level of 8-11%. The effects on learning (academic achievement,

objective cognitive performance), behaviour (mood, self-esteem, motivation, goal-orientation, absenteeism), and in a subsample cognitive processes, in particular perceptual processes measured by eye-tracking will be evaluated after 6, 12, and 24 months. This study will yield important insights in the effects of omega-3 LCPUFA supplementation, a safe intervention, on a large variety of complex brain functions.

Main changes (audit trail) 22-may-2016: Originally, the sample size calculation was based on a power of 0.8 and a medium effect size of 0.3 and ANOVA as analyses method. However, new insights led to the conclusion that not ANOVA but a mixed methods analyses would be more appropriate. The power analyses were, thus, redone for this. Also, the new power calculation took into account that there were multiple measurement moments and that drop out was possible. Multiple calculation in RMASS software with standardised input numbers such as an average effect size of d = 0.25 at 6 month follow-up and an equal or 10% higher effect size at 12 months follow up and a drop-out of 25% per measurement moment (and thus a total dropout rate of 43%), an error variation varying from 0.4 to 0.5 and a intercept variation of 0.3 to 0.5
with a slope variation of 0.0 (fixed effects), showed that between 183 and 285 participants at baseline should be sufficient to achieve a power of 0.8. The power calculation for the sleep sub study suggested that 42 students (21 in placebo and 21 in krill oil group) was sufficient. This number of students is based upon power calculation with a power of 0.8, $\alpha = 0.05$ and the ability to detect a 20 minute difference in sleep duration. For the eye-tracking study no power calculation was executed. As such a study had never been executed before, we did not believe that a reliable power calculation would be possible.

Study objective

Supplementation with omega-3 LCPUFA from krill oil in healthy adolescents will result in:

- improvement of the omega-3 index

- improved cognitive performance

- improved mental well-being

- better academic achievement

Study design

Baseline and follow up after 3 months, 6 months, and 12 months. Intervention of another 12 months (up to 24 months) is still under consideration.

Intervention

1 years supplementation with Krill oil provided by Aker BioMarine Antarctic AS equalling almost the daily recommended amount of 450 mg of
EPA/DHA intake per day.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy adolescents aged 14-15 years in lower general secondary education (MAVO/VMBO).

Exclusion criteria

Suffering from any medical disorders associated with learning deficits, such as ADHD, dyslexia, or autism.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	350
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-07-2013
Application type:	First submission

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
NTR-new	NL3912
NTR-old	NTR4082
Other	METC : 13-T-115

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A