Omega-3 fatty acid supplementation and the recovery from anorexia nervosa and comorbid depressive and anxiety problems: a pilot study

Published: 20-01-2020
Last updated: 15-05-2024

To draw definite conclusions about the effectiveness of omega-3 PUFA supplementation in anorexia nervosa patients a double-blinded, placebo-controlled randomized controlled trial (RCT) with a substantial sample size should be conducted. Prior to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eating disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON48430

Source
ToetsingOnline

Brief title
Omega-3 supplementation and recovery from anorexia nervosa: a pilot study

Condition

- Eating disorders and disturbances

Synonym
anorexia nervosa (anorexia)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting LvE

Intervention

Keyword: anorexia nervosa, omega-3 fatty acids

Outcome measures

Primary outcome

Primary parameters are inclusion rate, treatment adherence, and dropout rate.

Secondary outcome

A complete overview of the assessments is provided in Table 1 of the C1 research protocol. In addition to assessments that are completed as part of care as usual, we will monitor side effects at two time points. Furthermore, participants and one of their parents or legal guardians will be asked to complete two internationally validated assessment instruments at two time points (baseline and 8 weeks), namely:

* the Dutch version of the Children*s Depression Inventory 2nd edition (CDI-2) (61), to assess depressive symptoms. The CDI-2 has adequate psychometric properties and has been validated in 8-21-year-old children and adolescents.

* and the Dutch version of the Screen for Child Anxiety Related Emotional Disorders (SCARED-NL) (62), to assess anxiety symptoms. The SCARED-NL has adequate psychometric properties and has been validated in 7-19-year-old children and adolescents.

Study description

Background summary

Anorexia nervosa (AN) is an eating disorder characterized by a morbid fear of weight gain, which results in chronic dietary restriction and weight loss behaviors. AN is associated with severe medical morbidity, decreased quality of life, defects in cognitive and emotional functioning, and significant mortality. Furthermore, most patients with AN have at least one comorbid psychiatric diagnosis. Depressive and anxiety disorders are the most common co-occurring disorders. Such comorbidity has repeatedly been associated with adverse outcomes and is known to complicate treatment. Though sufficient caloric intake reduces depressive and anxiety problems in patients with AN, it does not sufficiently eliminate symptoms. Apart from a deficiency of nutrients and caloric intake, patients with AN have significant deficiencies in dietary intake of omega-3 polyunsaturated fatty acids (PUFAs) such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Omega-3 PUFAs are essential fatty acids and are found in foods which are strictly avoided by patients with AN, also when caloric intake is restored. The deficiency of omega-3 PUFAs in AN may be involved in the etiology of the comorbid depressive and anxiety problems and deficits in cognitive functioning. Multiple meta-analyses have demonstrated positive effects of omega-3 PUFA supplementation on several psychiatric disorders, including depressive and anxiety disorders. Moreover, omega-3 PUFAs positively affect brain development. Considering the above, we hypothesize that the supplementation of omega-3 PUFAs will improve comorbid depression, anxiety, and cognitive functioning in patients with AN, subsequently improving treatment outcomes. Studies examining this hypothesis are very scarce and have methodological limitations.

Study objective

To draw definite conclusions about the effectiveness of omega-3 PUFA supplementation in anorexia nervosa patients a double-blinded, placebo-controlled randomized controlled trial (RCT) with a substantial sample size should be conducted. Prior to conducting such an RCT, it is important to examine the feasibility of the study, which is the aim of the current pilot study. More specifically, through this study we will (1) examine how many patients with AN are willing and able to use omega-3 PUFA supplements and to complete participation, (2) assess side effects experienced by participants, and (3) test the assessment instruments that will be used in a future RCT.

Study design

The current study is a one group pilot/feasibility study.

Intervention

All participants will receive 3 capsules of 764 mg EPA and 236 mg DHA daily for a period of 8 weeks.

Study burden and risks

The main benefit of participation in this feasibility study is that supplementation of omega-3 PUFAs increases AN patients* omega-3 PUFA intake. Omega-3 PUFAs are essential fatty acids and should be included in a healthy diet, but foods rich in omega-3 PUFAs are generally strictly avoided by AN patients. Omega-3 PUFA intake may also have a positive effect on symptoms of depression and anxiety.

The risks associated with the current study are negligible and the burden is minimal. Participants may experience mild side effects. Participants and their parents will be asked to complete 2 questionnaires at 2 time points (baseline and end of study). It will take approximately 10 minutes to complete each questionnaire (i.e., in total 2x20=40 minutes per person). Participants will also be asked to complete a side effects questionnaire at 2 time points, which will take 5 minutes per assessment moment (i.e., in total 2x5=10 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* 10- to 19-years old (inclusive);
* diagnosed with anorexia nervosa;
* currently receiving inpatient or day treatment at De Bascule.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* mental incapacity;
* intellectual impairment as estimated or determined by a mental health professional (intelligence quotient of <80);
* chronic psychosis or schizophrenia;
* insufficient mastery of the Dutch language by the adolescent and/or parents;
* substance dependence requiring detoxification;
* inability to take pills;
* current use of omega-3 supplements;
* known allergy of omega-3 supplement ingredients.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2020
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23442
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71760.018.19
OMON	NL-OMON23442