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

No registrations found.

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

Summary

ID

NL-OMON23442

Source
NTR

Brief title
TBA

Health condition

Anorexia nervosa; depressive & anxiety problems

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Department of Child and Adolescent Psychiatry
Source(s) of monetary or material Support: Stichting LvE

Intervention

Outcome measures

Primary outcome

To examine the feasibility of the study and the willingness of patients to participate, we will assess the inclusion percentage, treatment adherence, and dropout rate.

Secondary outcome

Assessment of side effects, eating disorder symptoms and parameters (height and weight), depressive symptoms and anxiety symptoms.

Study description

Background summary

Rationale: 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.
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 which will include 10 participants.
Study population: Ten- to 19-year-old (inclusive) patients diagnosed with AN who receive inpatient treatment or day treatment at De Bascule are eligible for participation. Exclusion criteria are decision making incompetence, intellectual disability 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, and known allergy of omega-3 supplement ingredients.
Intervention: All participants will receive 3 capsules of 635 mg EPA and 195 mg DHA daily for a period of 8 weeks.
Main study parameters/endpoints: Primary parameters are inclusion rate, treatment adherence, and dropout rate.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 gastrointestinal 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).

Study objective

We hypothesize that the supplementation of omega-3 polyunsaturated fatty acids will improve comorbid depression, anxiety, and cognitive functioning in patients with anorexia nervosa, subsequently improving treatment outcomes.

Study design

T1 = pre-supplementation
T2 = week 1
T3 = week 8 (end of supplementation)

Intervention

Supplementation of omega-3 polyunsaturated fatty acids (EPA & DHA) during 8 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

• 10- to 19-years old (inclusive);
• diagnosed with anorexia nervosa;
• currently receiving inpatient or day treatment at De Bascule.

Exclusion criteria

• decision making incompetence;
• 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2020

Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion
Date:	17-02-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48430
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8386
CCMO	NL71760.018.19
OMON	NL-OMON48430

Study results

Summary results

N/A