

'The effects of Omega-3 Fatty Acids Dietary Supplements (Fish Oil) on Impulsivity in Patients with a Personality Disorder'

Published: 14-09-2007

Last updated: 08-05-2024

The primary research question of this study is: *What is the effect of omega-3 fatty acids dietary supplementation compared to placebo in the treatment of impulsivity in patients with a personality disorder? *The secondary research question of this...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30834

Source

ToetsingOnline

Brief title

Omega-3 Fatty Acids and Impulsivity

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym

impulscontrol problem, impulsivity

Health condition

impulsiviteit

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fish Oil, Impulsivity, Omega-3 Fatty Acids, Personality disorders

Outcome measures

Primary outcome

The primary study parameter is impulsivity, which will be measured by self-report questionnaires and computerized cognitive tasks.

Secondary outcome

The secondary study parameters are several psychological symptoms, among which depression. These complaints will be measured by a self-report questionnaire and a semi-standardized interview-observation scale.

Study description

Background summary

Omega-3 fatty acids (DHA and EPA), generally known as fish oil, has proven to be important for physical health. Since years, researchers study the contribution of fish oil to mental health and the treatment of several psychological symptoms or psychiatric disorders. Research findings show that fish oil can be of therapeutic value for several psychological complaints. The aim of this study is to examine the effect of omega-3 fatty acids on impulsivity in patients with a personality disorder. Impulsivity is a common problem within this group of patients and the opportunities for treatment are still limited.

Some research findings show positive effects in reducing impulsivity by omega-3 fatty acids. In this study, it will be examined if these results can be replied in a Dutch group of people with personality disorders, being in outpatient

treatment.

If omega-3 fatty acids prove to have a positive effect in the reduction of impulsivity, it would implicate an extra treatment opportunity for people with impulsivity problems.

The hypothesis is that omega-3 fatty acids dietary supplementation compared to placebo has a significant beneficial effect on impulsivity in patients with a personality disorder.

Study objective

The primary research question of this study is:

What is the effect of omega-3 fatty acids dietary supplementation compared to placebo in the treatment of impulsivity in patients with a personality disorder?

The secondary research question of this study is:

What is the effect of omega-3 fatty acids dietary supplementation compared to placebo on other psychological complaints, like depression, anxiety and hostility?

Study design

A double-blind, randomized, placebo-controlled trial.

Intervention

Subjects are prescribed to take in fish oil - or placebo capsules (randomly assigned and double blind) for 8 weeks on a daily basis.

Impulsivity (and other psychological symptoms) will be measured at intake, after 1 week and then again after 7 weeks.

Before and after the 8 weeks of study a blood sample will be taken to control for compliance and for a possible increased fish or fish oil consumption in the placebo group.

Study burden and risks

The burden for subjects can be described as follows. Blood samples will be taken 2 times, daily intake of 4g fish oil- or placebo capsules, administration of an interview, self-report questionnaires and computerized tasks. Total duration: 4-4,5 hours. The subject has to travel 3 times to the laboratory of PsyQ.

All the interventions are spread over 8 weeks, which diminishes the burden for the subjects. The clear and full explanation of the study before participation, the possibility to contact the independent physician and the possibility to stop participating in the study at any time, are factors which can diminish

the burden for the subjects.

The risks of participation in this study are minimal. The side effects of 4 gram of fish oil per day are rare and minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Dutch speaking men and women
- Presence of a cluster B personality disorder or a Personality disorder Not Otherwise Specified (according to the DSM-IV)
- Presence of impulsivity (according to the DSM-IV diagnostic criteria for impulsivity in the Axis II Personality disorders and according to the Barratt Impulsiveness Scale BIS-11)

Exclusion criteria

- Current substance abuse or dependence (DSM-IV criteria)
- Current use of medication, unless the intake is stable
- Current use of omega-3 fatty acids dietary supplements or eating more than 1 fatty fish per week
- Diagnosis of a psychotic disorder, bipolar disorder or a major depressive episode (DSM-IV criteria)
- Patients, participating in the module for Impulscontrol (CPP) during the 8 weeks of the study.

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:	Pending
Start date (anticipated):	25-06-2007
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO	
Date:	14-09-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL17466.097.07