

# Treating Depression with Omega-3

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/11/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Double-blind, placebo-controlled, randomised trial of eicosapentaenoic acid (EPA) for major depression

## Acronym

Omega-3-D

## Study objectives

1. To determine whether 1050 mg per day of eicosapentaenoic acid (EPA) is more effective than placebo (sunflower oil) in reducing depressive symptoms over 8 weeks
2. To report data on the tolerability and the safety of EPA in comparison to placebo

Please note that as of 14/01/2009 this record was updated to include the actual start and end dates of the trial. The initial anticipated trial dates were as follows:

Initial anticipated start date: 21/09/2005

Initial anticipated end date: 21/09/2007

Please also note that the target sample size at the end of recruitment was 432 participants; the initial target number of participants was 508. This target sample size change was approved by the Data and Safety Monitoring Committee in June 2008.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Centre Hospitalier de l'Université de Montréal Research Ethics Board gave approval on the 30th March 2005 (ref: SL-05.036)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Patient information material can be found on [http://www.omega3d.com/3\\_etude/en\\_etude\\_01.html](http://www.omega3d.com/3_etude/en_etude_01.html)

## Health condition(s) or problem(s) studied

Major depression

### **Interventions**

Participants are randomly assigned to take three capsules per day of 500 mg of omega-3 fish oil supplement or a matched sunflower oil placebo (low in omega-3 and omega-6) for 8 weeks. The fish oil supplement consist of the OM3 formula marketed by Isodis Natura containing 70% EPA-5% DHA fish oil ethyl-ester, which provides the equivalent of 1050 mg of eicosapentaenoic acid (EPA) and 150 mg of docosahexaenoic acid (DHA) per day.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Eicosapentaenoic acid (EPA)

### **Primary outcome measure**

The 30-item Inventory of Depressive Symptomatology, self-report (IDS-SR), administered at baseline, 1, 2, 4 and 8 weeks.

### **Secondary outcome measures**

1. The Montgomery-Asberg Depression Rating Scale (MADRS) will be completed at baseline, 1, 2, 4 and 8 weeks to allow comparison with standard pharmaceutical trials
2. Rate, type and severity of non-serious adverse events
3. Rate and type of serious adverse events

### **Overall study start date**

17/10/2005

### **Completion date**

05/12/2008

## **Eligibility**

### **Key inclusion criteria**

1. Greater than 18 years of age, either sex
2. Current diagnosis of major depressive episode based on the Mini-International Neuropsychiatric Interview (MINI version 5.0.0)
3. Inventory of Depressive Symptomatology (IDS-SR) score greater or equal to 27
4. Presence of significant depressive symptoms for at least 4 weeks, as judged by the clinician
5. If on antidepressants, has been at maximum recommended tolerable dosage for greater than 4 weeks
6. If not on antidepressants, has been either intolerant to at least two previous trials of antidepressants or refuses to take an antidepressant despite medical advice
7. Provision of signed informed consent for participation

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

432

**Key exclusion criteria**

1. Known allergy to fish or sunflower oil
2. Known intolerance of fish oil supplements
3. Has taken greater than 28 capsules of fish oil supplements during the last 4 weeks
4. Current alcohol or drug abuse or dependency based on the MINI
5. Bipolar disorder based on the MINI
6. Significant suicidal risk based on clinical judgement
7. Pregnant women (all non-menopausal women will need to have a negative pregnancy test before randomisation) and those planning to become pregnant over the course of the trial, or women of child bearing potential not using an accepted method of contraception
8. With coagulation diseases and/or subjects regularly taking any drugs or herbs that thin the blood such as aspirin, heparin, clopidogrel, warfarin, dalteparin, dipyrdamole, enoxaparin, ticlopedine, and ginkgo
9. History of myocardial infarction
10. Pancreatic insufficiency
11. Investigator's judgement that the patient is unable/unwilling to comply with study regimen

**Date of first enrolment**

17/10/2005

**Date of final enrolment**

05/12/2008

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Department of Psychiatry

Montreal

Canada

H2L 4M1

**Sponsor information**

## Organisation

University Hospital of Montreal (CHUM) Research Centre (Canada)

## Sponsor details

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Montreal  
Canada  
H2W 1T7  
+1 514 890 8110  
jacques.turgeon.chum@ssss.gouv.qc.ca

## Sponsor type

Hospital/treatment centre

## Website

<http://www.chumontreal.qc.ca>

## ROR

<https://ror.org/0410a8y51>

## Funder(s)

### Funder type

Industry

### Funder Name

Isodis Natura (Canada)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

01/08/2011

Yes

No