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# Double-blind, placebo-controlled, randomised, clinical trial of eicosapentaenoic acid in the treatment of mood disorders among middle-aged women

**Submission date**
20/12/2006

**Recruitment status**
No longer recruiting

**Registration date**
13/02/2007

**Overall study status**
Completed

**Last Edited**
06/01/2009

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

## Study information

**Scientific Title**

## Study objectives
To determine whether fish oil supplement rich in eicosapentaenoic acid (EPA) is more effective than placebo (sunflower oil) in reducing distress and depressive symptoms over eight weeks.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This project received ethics approval on March 25, 2004 from the Ethical Committee of the clinical research of the Saint-François d'Assise Hospital. On the 17th December 2004 we received, for this study, the agreement of the Bureau Product Review and Assessment (BPRA) of the Natural Health Products Directorate (NHPD) of Health (Canada).

## Primary study design
Interventional

## Study design
Double-blind, placebo-controlled, randomised, clinical trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Mild to moderate major depression, moderate to severe psychological distress

## Interventions
Women will be randomly assigned to a dietary supplement (OM3®) rich in omega-3 fatty acids (1.2 g/day) or a placebo (sunflower oil) for a period of eight weeks. Each capsule will be provided by Isodis Natura. Each 500 mg capsule of OM3® contains 350 mg of EPA and 50 mg of Docosahexaeonic Acid (DHA). Women will have to take one capsule three times a day (before each meal). The three omega-3 capsules will correspond to a daily intake of 1.05 g of EPA and 150 mg of DHA for a total of 1.2 g of omega-3 fatty acids per day.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Eicosapentaenoic acid (EPA), docosahexaeonic acid (DHA)

## Primary outcome(s)
Psychological distress based on General Well-Being Scale (GWB) administered at baseline, four and eight weeks.

## Key secondary outcome(s)

1. Hamilton-21 Depression (HAM-D) Rating Scale administered at baseline and eight weeks
2. Depression subscale of the Symptom Check-List-90-R (SCL-Dep) administered at baseline, four and eight weeks
3. Frequency and severity of menopause vasomotor symptoms administered at baseline, four and eight weeks
4. Quality of life (MENopause Specific Quality Of Life [MENQOL], Short Form health survey [SF36], fatigue, sexual activities, work limitations, sleep problems) administered at baseline and eight weeks
5. Clinical Global Impression of improvement evaluated by doctor (CGI) and by the patient (Patient Global Impression of Improvement [PGI-I]) administered at baseline and eight weeks

### Completion date
01/02/2007

## Eligibility

### Key inclusion criteria
1. Women between 40 and 55 years of age
2. Moderate to severe psychological distress based on General Well-Being Scale (GWB) (score less than 72)
3. Have a negative results on a pregnancy test and currently using an adequate method of contraception
4. Provision of signed informed consent for participation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Hamilton-21 score of 26 or more, or Patient Health Questionnaire (PHQ-9) score of 20 or more
2. Past or current history of schizophrenia or bipolar I disorders
3. Current or significant imminent risk of suicide or homicide
4. Post-menopausal for more than five years
5. Major medical disorders such as malabsorption disease, gastrectomy and acute pancreatitis
6. Inherited or acquired disease of the haemostatic or the coagulation
7. Medical conditions that interfere with the digestion and the absorption of medication
8. Taking antihypertensive medications or suffer from hypercholesterolaemia or diabetes type two
9. Endocrine diseases that could be linked to psychiatry
10. Others medical causes that could be linked to psychiatry
11. Have a current substance abuse disorders such as drugs (marijuana, cocaine, etc.) or alcohol (more than 40 g of alcohol by day)

12. Fish allergies
13. Have regularly consumed fish (more than three serving per week) in the last months
14. Have taken antidepressant medication or hormone replacement therapy (HRT) or St-Johns Wort (Hypericum Perforatum) in the last six months before enrolment
15. Current use of any drugs that thin blood such as aspirin, ibuprofen, heparin, clopidogel, warfarin, dalteparin, dipyrimadole, enoxaparin, ticlopidine, ginkgo or other anticoagulants

### Date of first enrolment
01/03/2005

### Date of final enrolment
01/02/2007

## Locations

### Countries of recruitment
Canada

### Study participating centre
**Foundation Lucie et André Chagnon**
Québec
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## Sponsor information

### Organisation
Foundation Lucie et André Chagnon (Canada)

### ROR
https://ror.org/05ret9323

## Funder(s)

### Funder type
Charity

### Funder Name
Foundation Lucie et André Chagnon, Laval University (Canada)

**Funder Name**
Isodis Natura (Canada)

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2009 | | Yes | No |