MEMO study: Mental health in Elderly Maintained with Omega-3.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25512

Source
NTR

Brief title
MEMO

Health condition

Cognitive decline

Depression

Sponsors and support

Primary sponsor: Wageningen University (Division of Human Nutrition):
Ir. O. van de Rest
Dr. Ir. L.C.P.G.M. de Groot
Dr. J.M. Geleijnse
Prof. Dr. Ir. F.J. Kok
Prof. W.A. van Staveren

University Medical Centre / Radboud University Nijmegen (Geriatrics):
Prof. Dr. W.H.L. Hoefnagels

Free University Amsterdam (Psychiatrics):
Prof. Dr. A.T.F. Beekman
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Cognitive function and mental well-being.

Secondary outcome

Quality of life.

Study description

Background summary

The efficacy of EPA-DHA supplementation will be assessed in a randomized placebo-controlled trial with cognitive decline and early signs of depression as primary outcome measures. In this study 300 elderly people will be randomly allocated to one of three treatments. Two groups will receive fish oil capsules with different doses EPA/DHA (a normal dose or a high dose) and the third group will receive placebo capsules. At the start and at the end of the intervention period cognitive function, the occurrence of depression, quality of life, anthropometric values and biochemical indicators will be measured.

After completion of the trial a workshop will be organized in which the outcomes of the proposed study will be presented to representatives of several key areas concerning mental health of elderly people.

Study objective

Counteract the process of mental deterioration in elderly people through enhancement of their EPA-DHA status.

Study design

N/A

Intervention

1. 400 mg EPA-DHA in capsules;

2. 1.8 g EPA-DHA in capsules;

3. Placebo oil in capsules.

Contacts

Public
Wageningen University, Division of Human Nutrition
P.O. Box 8129
Ondine Rest, van de
Wageningen 6700 EV
The Netherlands
+31 (0)317 485867
Scientific
Wageningen University, Division of Human Nutrition
P.O. Box 8129
Ondine Rest, van de
Wageningen 6700 EV
The Netherlands
+31 (0)317 485867

Eligibility criteria

Inclusion criteria

1. Men and women;

2. Aged 65 years and over;

3. Informed consent signed.

Exclusion criteria

1. A score of > 16 on the CES-D (Centre for Epidemiological Studies-Depression Scale;

2. A score of < 21 points on MMSE (Mini-Mental State Examination);

3. Current or recent (<4 weeks) use of fish oil supplements or intake of more than 4 times fish/ week; 24.35 g of EPA-DHA from fish per month (800 mg/day) as judged by a fish consumption questionnaire;

4. Current use of pharmacological antidepressants;

5. Current use of dementia (Alzheimer) medication;

6. Serious liver disease;

7. Use of more than 4 glasses of alcohol per day;

8. Unable to participate as judged by the responsible medical physician;

9. Allergy to fish(oil);

10. Swallowing problems;

11. Participation in another clinical trial less than 2 months before the start of the trial or at the same time.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2005
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2005
Application type:	First submission

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
NTR-new	NL65
NTR-old	NTR97
Other	METC-WU : 2005_05/08
ISRCTN	ISRCTN46249783

Study results

Summary results
N/A