# A randomised placebo-controlled trial of polyunsaturated omega-3 fatty acid (PFA), in the treatment of dementia: a pilot study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
02/02/2018	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Janet Carter

#### Contact details

North East London Mental Health Trust Mascalls Park Mascalls Lane Brentwood United Kingdom CM14 5HQ

#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0577150953

# Study information

#### Scientific Title

A randomised placebo-controlled trial of polyunsaturated omega-3 fatty acid (PFA), in the treatment of dementia: a pilot study

#### **Study objectives**

A pilot study to evaluate the conjunctive, functional and behavioural effects of dietary supplementation of omega-3 PFA in elderly patients with dementia.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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

Dementia

#### **Interventions**

Randomised double-blind placebo-controlled trial

#### Intervention Type

Supplement

#### Primary outcome measure

Improvements in mood, cognition, quality of life on the functioning measures MMSE, QOL-AD, GHQ-12, CIBIC and neuropsychological battery subjects.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/09/2004

#### Completion date

31/03/2005

# Eligibility

#### Key inclusion criteria

50 outpatient attendees at a Memory Clinic with a diagnosis of dementia (MMSE score 17-24)

#### Participant type(s)

**Patient** 

#### Age group

Senior

#### Sex

Both

#### Target number of participants

50

#### Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

01/09/2004

#### Date of final enrolment

31/03/2005

## **Locations**

#### Countries of recruitment

England

United Kingdom

# Study participating centre North East London Mental Health Trust

Brentwood United Kingdom CM14 5HQ

# Sponsor information

#### Organisation

Department of Health

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

North East London Mental Health NHS Trust (NELMHT), Research & Development Department (UK)

### **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