

The Influence of n-3 Fatty acid Supplementation on Vascular and Cognitive Function in Healthy Young Adults; a Randomized Controlled Trial

Submission date 27/01/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/05/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/07/2013	Condition category Circulatory System	☐ 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

Protocol serial number

N3RCT07

Study information

Scientific Title

Acronym

N3RCT

Study objectives

Primary:

Cardiovascular:

n-3 PUFA supplementation improves vascular function (flow-mediated endothelial dependent dilation) in healthy young adults.

Cognitive:

n-3 PUFA supplementation improves cognitive function in healthy young adults.

Secondary:

Cardiovascular:

n-3 PUFA supplementation improves other cardiovascular risk-factors in healthy young adults (vascular, biochemical and haematological).

Cognitive:

n-3 PUFA supplementation improves mood in healthy young adults.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Docosahexaenoic acid v Placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Cardiovascular:

Flow mediated endothelial dependent dilatation of the brachial artery, arterial distensibility and pulse wave velocity.

Cognitive:

CANTAB (CAmbridge Neuropsychological Test Automated Battery).

Key secondary outcome(s)**Cardiovascular:**

Plasma and red cell DHA and EPA levels and biochemical and haematological risk factors for CVD including such as fasting insulin, glucose, 32-33 split proinsulin, and leptin concentration and lipid profile including lipoprotein particle size will be determined. Hematological risk factors for CVD will include FBC, fibrinogen, factors VII and VIII, von Willebrand factor, soluble thrombomodulin and tissue plasminogen activator concentrations and inflammatory markers such as IL-6, IL-8 and CRP. Evidence of endothelial cell activation will be sought by the measurement of intra cellular adhesion molecule ζ 1 (ICAM-1), vascular cell adhesion molecule ζ 1 (VCAM-1), E-selectin, P-selectin IL-6 and other cell adhesion factors.

Cognitive:

Wechsler Abbreviated Scale of Intelligence (WASI; 29); inspection time, and a self-administered measure of mood (5 minutes) using visual analogue scales.

Completion date

31/05/2006

Eligibility**Key inclusion criteria**

Healthy volunteers

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2004

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Institute of Child Health

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Institute of Child Health (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Not defined

Funder Name

Part of MRC Programme Grant

Funder Name

Kellogg's Sales & Marketing plc

Funder Name

Martek Biosciences plc

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	01/07/2013		Yes	No