ISRCTN18662143 https://doi.org/10.1186/ISRCTN18662143

Comparison of omega-3 fatty acid supplement formulations.

Submission date
05/06/2015

Recruitment status
No longer recruiting

Registration date
22/06/2015

Overall study status
Completed

Last Edited
06/11/2018

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Oily fish such as mackerel and sardines contain natural omega-3 fatty acids (O3FAs) such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). O3FAs are commonly used as nutritional supplements, with scientific evidence suggesting numerous health benefits including improved cognitive performance, maintenance of a healthy heart and even possible anticancer effects. These supplements are traditionally taken as capsules, although recently developed fruit flavoured drink cartons are now available e.g. Smartfish® Nutrifriend Cachexia (NFCax). There is however a lack of scientific data available related to the O3FA juice supplements and therefore we wish to compare taking two Smartfish® NFCax drinks per day with the equivalent dose (4 g total EPA/DHA) as eight O3FA capsules per day. The primary comparison between the capsules and cartons is the level of O3FAs within the blood after 8 weeks. Other areas under investigation include the acceptability and tolerability of both types of O3FA supplement, the effects on cognitive performance (memory and reaction time) and the effect of O3FA supplementation on the bacteria found within the gut.

Who can participate?
Healthy volunteers aged 50 or over.

What does the study involve?
Participants will be asked to take the O3FA-containing capsules and Smartfish NFCax drinks separately during two separate 8 week intervention periods. There will be a 12 week 'washout' period at the end of each intervention period during participants will not take any supplements. Participants will be asked to attend the Human Appetite Research Unit (HARU) at the University of Leeds on five separate occasions at which they will provide blood and urine samples and will also be asked to complete computerised cognitive tests. Prior to each visit participants will be asked to submit a stool sample for analysis.

What are the possible benefits and risks of participating?
Although participants are unlikely to directly benefit from taking part in the study, scientific evidence suggests O3FAs are associated with improved cognitive performance, maintenance of

a healthy heart and even possible anti-cancer effects.
Omega-3 fatty acids are ‘over the counter’ nutritional supplements with few side-effects and therefore there is minimal risk associated with taking part in the study.

Where is the study run from?
Human Appetite Research Unit (HARU) at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2014 to March 2016

Who is funding the study?
Smartfish (UK)

Who is the main contact?
Professor Mark Hull
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
166337

Protocol serial number
2.0 - IRAS project ID: 166337

Study information

Scientific Title

A randomised cross-over trial to compare erythrocyte membrane incorporation, acceptability and tolerability of omega-3 fatty acids in a drink carton formulation with an equivalent dose of omega-3 fatty acids in soft gelatin capsule form.

Study objectives
Omega-3 fatty acid (O3FA) supplementation with two Smartfish® NFCax drinks daily for eight weeks produces an equivalent increase in erythrocyte membrane eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) levels compared with the administration of an equivalent daily dose of O3FAs in soft-gel capsule form.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - South Yorkshire, 29/04/2015, REC reference: 15/YH /0142

Study design
Single-centre open-label randomised cross-over trial design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
This is a healthy volunteer study.

Interventions
An open label, randomised, cross-over trial in healthy volunteers aged >50 years randomised to omega-3 fatty acid (O3FA) supplementation for a period of eight weeks with either:
1. Two Smartfish® Nutrifriend Cachexia (NFCax) drinks per day (total 2000 mg EPA and 2000 mg DHA)
2. Four O3FA capsules twice daily (250 mg EPA and 250 mg DHA per capsule)

There will be a minimum 12 week ‘washout’ period after both intervention periods.

Intervention Type
Supplement

Primary outcome(s)
Change in erythrocyte membrane percentage content of EPA and DHA at eight weeks compared with baseline

Key secondary outcome(s))
1. Percentage erythrocyte membrane EPA and DHA content at 8 weeks.
2. Difference in erythrocyte membrane percentage content of arachidonic acid (AA) at 8 weeks compared with baseline.
3. Acceptability of and compliance with each O3FA preparation
4. Tolerability and adverse events related to each O3FA preparation

5. Change in intestinal microbiome after O3FA supplementation for eight weeks
6. Urinary prostaglandin metabolite levels following O3FA supplementation
7. Change in memory and learning functions after 8 weeks of O3FA supplementation

Completion date
29/07/2016

Eligibility

Key inclusion criteria
1. Healthy male and female subjects >50 years
2. Signed informed consent
3. Be able to understand and comply with the requirements of the study, as judged by the Investigator

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Ongoing or planned use of other O3FA or cod-liver oil supplements
2. Seafood allergy
3. Unable to provide written informed consent
4. Unable to commit to study timetable
5. Concomitant use of non-steroidal anti-inflammatory medications including aspirin
6. Current treatment for any chronic inflammatory condition or malignancy
7. Previous colonic or small bowel resection
8. Current smoker (minimum of 6 months smoking cessation)
9. Pregnancy
10. Any other condition which according to the Investigator would interfere with the study or safety of the patient in the planning and conduct of the study
11. Administration of any unlicensed or study product within 4 weeks of entry to the study or during the study

Date of first enrolment
01/06/2015

Date of final enrolment
16/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Human Appetite Research Unit, University of Leeds
Institute of Psychological Sciences
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Smartfish

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018		Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes