

# Comparison of omega-3 fatty acid supplement formulations.

<b>Submission date</b> 05/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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 which 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

166337

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised cross over trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

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

## 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 measure**

Change in erythrocyte membrane percentage content of EPA and DHA at eight weeks compared with baseline

## **Secondary outcome measures**

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

## **Overall study start date**

01/10/2014

## **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

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

20

## **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**

England

United Kingdom

**Study participating centre**

**Human Appetite Research Unit, University of Leeds**

Institute of Psychological Sciences

University of Leeds

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## **Sponsor information**

**Organisation**

University of Leeds (UK)

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/024mrxd33>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Smartfish

## Results and Publications

**Publication and dissemination plan**

Peer-reviewed scientific journal and conferences (late 2016-early 2017).

**Intention to publish date**

31/03/2017

**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?
<a href="#">Results article</a>	results	01/11/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No