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The effect of oily fish and fish oil supplementation on markers of cardiovascular health and exercise performance

Submission date
30/08/2024

Recruitment status
No longer recruiting

Registration date
10/09/2024

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Evidence from observational studies, prospective cohort studies and randomized clinical intervention studies indicate that moderate doses of long-chain n-3 polyunsaturated fatty acids (LC n-3 PUFA) significantly decrease the risk of fatal coronary heart disease (CHD). The exact mechanisms through which LC n-3 PUFA affects CHD are not well established but may include a decrease in fasting and postprandial triacylglycerol levels, a decrease in arrhythmias, modulation of platelet aggregation and decreased synthesis of pro-inflammatory agents and improved vascular function. In addition, there is a strong positive correlation between patients with cardiovascular disease and low mood/depression. Omega-3 highly unsaturated fatty acids (HUFAs) were recently reported in a meta-analytic review published by the British Journal of Psychiatry to have an effect size of .061 in reducing clinical symptoms of depression. The UK recommendation is that people eat at least two portions (with a portion being 140 g) of fish per week, one of which should be oily fish. Despite recommendations and sufficient availability, the majority of the UK population does not consume enough fish, particularly oily fish, and should be encouraged to increase consumption. However, it is unknown whether the benefits of eating fish come from the omega-3 fatty alone, or in combination with other macro and micronutrients within the fish. This research aims to investigate the health benefits of oily fish consumption, at a level achievable in the diet, compared to omega-3 supplementation on markers of cardiovascular health and exercise performance.

Who can participate?
Participants are required to be >40 years old, BMI >20 kg/m² and CVD scoring tool using the Framingham Risk Score

What does the study involve?
The study involves 2 testing sessions and 1 screening session where blood and urine samples are collected, and functional cognition measures and cardiovascular measures are carried out, as well as a submaximal exercise test.

Participants are assigned into one of three groups:
Group 1: placebo supplement + oily fish
Group 2: fish oil supplement + white fish
Group 3: placebo supplement + white fish
At the end of 12 weeks, participants returned to the University for a repeat session of testing.

Blood samples were used to assess:
Omega-3 index,– University of Southampton
Blood lipid profiles, number and procoagulant activity of extracellular vesicles – University of Reading

What are the possible benefits and risks of participating?
Participants will find out their blood lipid profile, and omega-3 index as well as their current fitness level.

Where is the study run from?
The School of Sport and Exercise Sciences, Liverpool John Moores University (UK)

When is the study starting and how long is it expected to run for?
July 2015 to March 2021

Who is funding the study?
British Broadcasting Corporation (UK)

Who is the main contact?
Prof Parveen Yaqoob, p.yaqoob@reading.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of fish oil supplements vs oily fish on the number, phenotype and procoagulant activity of extracellular vesicles

Study objectives
Fish oil is more effective than oily fish in reducing the number and of thrombogenic activity of extracellular vesicles

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/07/2015, LJMU's Research Ethics Committee (Research and Innovation Services 1st Floor, Exchange Station, Tithebarn St, Liverpool, L2 2QP, United Kingdom; +44 (0)151 904 6467; researchethics@ljmu.ac.uk), ref: S16SPS041

Study design
Randomized double-blind placebo-controlled parallel trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease in subjects who were at above average risk of developing CVD.

Interventions
This is a randomized, double-blind, placebo-controlled, parallel trial.

Volunteers will be asked to attend 2 testing and 1 screening session at the University where blood will be taken, urine samples collected, and functional cognition measures and cardiovascular measures carried out, as well as a submaximal exercise test.

Volunteers will then be asked to eat 2 portions of fish per week and take a supplement daily for 12 weeks. Participants will be randomized into one of three groups:
Group 1: placebo supplement + oily fish
Group 2: fish oil supplement + white fish
Group 3: placebo supplement + white fish

Fish oil capsules are provided as 2.2 g/d of n-3 PUFA ethyl esters. Two oily fish meals contain 1.44 g/d of n-3 PUFA (one meal containing salmon and the other mackerel).

At the end of 12 weeks, participants will return to the University for a repeat session of testing (blood, urine and functional measures).

Intervention Type
Behavioural

Primary outcome(s)
Circulating extracellular vesicles (EVs) numbers are measured using Nanoparticles Tracking Analysis at baseline and after the intervention

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline and after the intervention:
1. Numbers of EV subpopulations including phosphatidylserine-positive EVs, platelet-derived EVs and endothelial-derived EVs are measured using a flow cytometer
2. Fatty acid compositions of circulating EVs and red blood cells (RBCs) are measured using gas chromatography
3. Thrombogenicity of circulating EVs is measured using a thrombin generation assay
4. Clot-forming and fibrinolytic capacity of circulating EVs are measured using clot formation assay and plasmin generation assay
5. Plasma lipid profile including triglycerides, total cholesterol, low-density lipoprotein and high-density lipoprotein, and plasma glucose levels are measured using Daytona Plus clinical chemistry analyzer

Completion date
09/03/2021

Eligibility

Key inclusion criteria

1. >40 years old
2. BMI >20 kg/m²
3. CVD scoring tool using the Framingham Risk Score

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
73 years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Infection
2. Immune disorder including HIV, autoimmune disease, or fever of unknown origin
3. Unstable medical conditions requiring immediate intervention
4. Unstable or rapidly progressive neurological diseases
5. A history of haemorrhagic or ischemic stroke within the last 3 months
6. Consuming oily fish more than once per week on average
7. Allergy, hypersensitivity, or intolerance to fish, fish oils or omega-3 fats
8. Any known food allergies
9. Pregnant or breastfeeding

Date of first enrolment
15/08/2016

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool John Moores University
Rodney House 70
Mount Pleasant
Liverpool
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Sponsor information

Organisation
British Broadcasting Corporation (United Kingdom)

ROR
https://ror.org/01qepzr42

Funder(s)

Funder type
Other

Funder Name
British Broadcasting Corporation

Alternative Name(s)
BBC Worldwide, BBC Research and Development, BBC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository in the University of Reading data repository https://doi.org/10.17864/1947.001350

IPD sharing plan summary

Stored in publicly available repository