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Long chain monounsaturated fatty acids from fish and their effect on metabolic health (MonoFish)

Submission date	Recruitment status	[X] Prospectively registered
10/08/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/08/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/08/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Heart and blood vessel diseases are a major cause of illness and death worldwide. High cholesterol, high blood pressure and excess body weight can increase the risk of developing these conditions. Some types of fats found in fish may help to improve heart health. While the benefits of omega-3 fatty acids are already well known, researchers are also interested in a group of fats called long-chain monounsaturated fatty acids (LCMUFAs), which are found in some fish oils.
The aim of this study is to find out whether taking a fish oil supplement rich in LCMUFAs for 12 weeks can improve cholesterol levels and other measures linked to heart and metabolic health. The study will also compare the effects of this supplement with a standard omega-3 supplement and a placebo.

Who can participate?
Adults aged 18 to 65 years can take part if they:
• Have moderately raised LDL ("bad") cholesterol levels between 115 and 159 mg/dL
• Have a body mass index (BMI) between 18 and 30 kg/m²
• Do not smoke or use e-cigarettes
• Are not currently taking fish oil or omega-3 supplements
• Do not have a fish oil allergy
• Do not have a chronic condition such as type 2 diabetes or an autoimmune disease
• Are not taking supplements or medicines that could affect cholesterol levels or other study measurements

What does the study involve?
People who are interested in taking part will first complete a screening questionnaire and attend a screening visit. At this visit, a small finger-prick blood sample will be taken to measure cholesterol levels and check eligibility.

A total of 174 participants will take part in the study. Those who are eligible and agree to participate will be randomly assigned to one of three groups:

• An omega-3 supplement group
• An omega 3-9-11 supplement group containing high levels of LCMUFAs
• A placebo group

Participants will not know which supplement they receive. They will be asked to take two capsules each day for 12 weeks, preferably with a meal.

Participants will attend two study visits, one before starting the supplements and one after 12 weeks. Each visit will last about 1 hour. Before each visit, participants will need to fast from 10 pm the night before.

During the visits, researchers will:
• Measure height, weight, waist circumference and body composition
• Measure blood pressure
• Take a blood sample
• Ask participants to complete questionnaires about their health, lifestyle and physical activity

Participants will be asked to maintain their usual diet and lifestyle throughout the study and avoid taking other omega-3 supplements.

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct health benefit from taking part. However, the information collected may help researchers better understand whether these fish-derived fats can improve heart and metabolic health. This knowledge could support future research and the development of new nutritional approaches for improving health.
The study procedures involve minor risks. Some people may experience temporary discomfort, bruising or light-headedness when blood samples are taken. It is also possible that the supplements may cause mild side effects in some individuals. If any unexpected health results are identified during the study, participants will be informed and can discuss them with their GP if they wish.

Where is the study run from?
The study is being run from the Human Intervention Studies Unit at Ulster University, Coleraine, Northern Ireland, UK.

When is the study starting and how long is it expected to run for?
August 2026 to September 2027.

Who is funding the study?
The study is funded by Epax Norway AS and the Co-Centre for Sustainable Food Systems.

Who is the main contact?
Professor Emeir McSorley, em.mcsorley@ulster.ac.uk

Contact information

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Integrated Research Application System (IRAS)
366082

Study information

Scientific Title
Exploring the effects of marine derived long chain monounsaturated fatty acids (LCMUFA) on metabolic risk factors: a randomised controlled trial

Acronym
MonoFish

Study objectives
1. The primary aim of this study is to determine the effect of 12week supplementation with a marinederived oil rich in longchain monounsaturated fatty acids (LCMUFAs) on low-density lipoprotein (LDL) cholesterol, compared with placebo

Secondary aims are to:
1. Evaluate the effect of omega3 (EPA+DHA) supplementation on plasma lipid profiles compared with placebo
2.Compare the effects of omega3 supplementation with those of LCMUFA supplementation on plasma lipid profiles
3. Determine the effects of omega3 and LCMUFA supplementation on other cardiometabolic

risk markers, including blood pressure, inflammatory markers, and body composition, compared with placebo and with each other

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2026, Northern Ireland Health and Social Care Research Ethics Committee B (Office for Research Ethics Committees Northern Ireland (ORECNI), Business Services Organisation (BSO), Belfast, BT2 8DQ, United Kingdom; no telephone number provided; RECB@hscni.net), ref: 26/NI/0065

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Basic science, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Elevated cholesterol

Interventions
Adults aged 18–65 years with moderately elevated low-density lipoprotein (LDL) cholesterol concentrations (115–159 mg/dL) will be recruited to participate in this 12-week, randomised, double-blind, placebo-controlled, parallel-group intervention study. Participants will be recruited through local general practitioners (GP's) and community-based recruitment strategies. Eligibility will be confirmed through screening questionnaires, assessment of medical history, and measurement of LDL cholesterol using a finger-prick blood sample. Participants recruited from the community will additionally undergo cardiovascular risk assessment using the QRISK3 calculator, a validated algorithm that estimates an individual's 10-year risk of developing cardiovascular disease
A total of 174 participants will be recruited. Sample size calculations were based on a fixed-effects one-way ANOVA assuming a 5–6% reduction in LDL cholesterol, a within-cell standard deviation of 15, 80% statistical power, and a two-sided significance level of 0.05. To account for an anticipated 10% attrition rate, 58 participants will be recruited into each intervention arm. Following completion of baseline assessments, participants will be randomly assigned in equal numbers to one of three intervention groups:

Arm 1 – Omega-3 supplement taken twice daily with ~20mg LCMUFA per day)
Arm 2 – Omega 3-9-11 supplement taken twice daily with 956mg LCMUFAs per day)
Arm 3 – Placebo supplement taken twice daily (2g/day corn oil)
Randomisation will be conducted by an independent researcher and stratified by sex and body mass index (BMI; 18–24.9 kg/m² and 25–30 kg/m²).
Participants will attend study visits at baseline and following completion of the 12-week intervention. At each visit, anthropometric measurements will be obtained using standardised procedures, including body weight, body composition, waist circumference, and blood pressure. Height will be measured at baseline only for the calculation of BMI. Body composition measures will include fat mass, fat-free mass, and lean body mass assessed using TANITA scales. Blood pressure will be measured following a period of seated rest using an automated blood pressure monitor, with duplicate measurements obtained and averaged.
Fasting venous blood samples will be collected at baseline and post-intervention
Secondary outcomes will include changes in red blood cell fatty acid composition and omega-3 index, lipid profiles, blood pressure, body composition, markers of inflammation, oxidative stress, endothelial function, and clinical chemistry. Inflammatory biomarkers will include adiponectin, leptin, C-reactive protein (CRP), tumour necrosis factor-alpha (TNF-α), interferon-gamma (IFN-γ), interleukins (IL-1β, IL-2, IL-4, IL-6, and IL-10), intracellular adhesion molecule-1 (ICAM-1), vascular cell adhesion molecule-1 (VCAM-1)
Untargeted and targeted lipidomic analyses will be performed using mass spectrometry to investigate the effects of supplementation on plasma lipid mediators, including oxylipins and other specialised pro-resolving mediators. Routine clinical chemistry measures, including liver and kidney function markers and full blood count parameters, will be assessed to evaluate safety and tolerability of the interventions.
Participants will complete a health and lifestyle questionnaire at baseline and a validated physical activity questionnaire at both baseline and post-intervention. A four-day food diary will be completed at baseline to assess habitual dietary intake. Compliance and tolerability will be assessed through capsule counts and participant follow-up at week six and at study completion.
Statistical analyses will be performed using SPSS version 28. Data will be assessed for normality and transformed where appropriate. Baseline differences between groups will be evaluated using one-way analysis of variance (ANOVA) or Kruskal-Wallis tests. Intervention effects will be assessed using analysis of covariance (ANCOVA) with adjustment for age, sex, BMI, and relevant baseline values. Tukey post-hoc comparisons will be used where appropriate. A secondary per-protocol analysis will also be performed, with compliance determined objectively based on changes in the Omega-3 Index over the intervention period. Both intention-to-treat and sensitivity analyses will be performed, and statistical significance will be accepted at $p < 0.05$.

Intervention Type
Supplement

Primary outcome(s)
1. Low density lipoprotein (LDL) cholesterol measured using RX Daytona+ Analyser at baseline and 12 weeks

Key secondary outcome(s)
1. Red blood cell polyunsaturated fatty acid status (linoleic acid [LA], arachidonic acid [AA], alpha-linolenic acid [ALA], eicosapentaenoic acid [EPA], docosahexaenoic acid [DHA], Omega-3 index (% EPA and DHA in red blood cell membranes); % weight) measured using gas chromatography–mass spectrometry (GC/MS) at baseline and 12 weeks

2. Inflammatory cytokine concentrations (e.g., C-reactive protein (CRP) interleukin-5 [IL-5], interferon-gamma [IFN-γ], interleukin-10 [IL-10], interleukin-1β [IL-1β], interleukin-4 [IL-4], interleukin-6 [IL-6], tumour necrosis factor-alpha [TNF-α]; pg/mL) measured using validated immunoassays at baseline and 12 weeks

3. Cardiovascular inflammatory markers (intercellular adhesion molecule-1 [ICAM-1], vascular cell adhesion molecule-1 [VCAM-1]) measured using validated immunoassays at baseline and 12 weeks

4. Adipokine concentrations (adiponectin and leptin; ng/mL or µg/mL) measured using validated immunoassays at baseline and 12 weeks

5. Blood pressure (systolic and diastolic) measured using standard clinical sphygmomanometry at baseline and 12 weeks

6. Lipidomic profile (sphingolipids, phospholipids, oxylipins) measured using mass spectrometry at baseline and 12 weeks

7. Clinical chemistry markers (full blood profile; liver enzymes [ALT, AST, GGT, ALP] and kidney function markers) measured using Sysmex and RX Daytona+ clinical chemistry analyser. at baseline and 12 weeks

8. Body composition (weight (kg), fat mass (kg), fat free mass (kg), waist circumference (cm)) measured using TANITA scales at baseline and 12 weeks

9. Blood lipids (Total cholesterol, High Density Lipoprotein, Triglycerides: mmol/L) measured using RX Daytona+ Analyser at baseline and 12 weeks

10. Apolipoprotein B concentrations (mg/dL) measured using RX Daytona+ Analyser at baseline and 12 weeks

Completion date
20/09/2027

Eligibility

Key inclusion criteria
1. Aged 18-65 years
2. BMI 18-30 kg/m²
3. LDL cholesterol 115-159 mg/dL
4. Able to fast from 22:00 the night before the appointment
5. Non-smoker and non-e-cigarette user
6. Not currently using fish oil or omega-3 supplements
7. No allergies to fish oil products
8. No known diagnosis of a chronic condition, for example type 2 diabetes or autoimmune disease
9. Not regularly taking food supplements that influence cholesterol levels, for example plant sterols or stanols

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
174

Key exclusion criteria
1. Aged under 18 years or over 65 years
2. BMI below 18 kg/m² or above 30 kg/m²
3. LDL cholesterol below 115 mg/dL or above 159 mg/dL
4. Current smoker or e-cigarette user
5. Pregnant or lactating female, or planning to become pregnant during the study period
6. Current user of fish oil or omega-3 supplements
7. Known allergy or sensitivity to fish oil products
8. Diagnosis of a chronic condition, for example type 2 diabetes or an autoimmune disease
9. Regular use of food supplements known to influence cholesterol levels, for example plant sterols or stanols
10. Regular use of medications that may influence study outcomes or affect the ability to participate in the study, including proton pump inhibitors, statins or other cholesterol-lowering medications, blood pressure medications, anti-inflammatory medications, and glucose-lowering medications

Date of first enrolment
17/08/2026

Date of final enrolment
21/06/2027

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Nutrition Innovation Centre for Food and Health (NICHE)
School of Biomedical Sciences, Biomedical Sciences Research, Coleraine Campus, Ulster University

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Sponsor information

Organisation
University of Ulster

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type

Funder Name
Epax Norway AS

Funder Name
Co-Centre for Sustainable Food Systems

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available