# To examine the effect of dietary supplementation with fish oils and complex lipids on mitochondrial, physical, and cognitive function, in elderly humans.

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The main objective of this study is to determine whether supplementation with FO combined with complex phospholipids can alter skeletal muscle mitochondrial function more effectively than FO alone. Additional exploratory objectives are;...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

# Summary

### ID

NL-OMON48470

**Source** ToetsingOnline

Brief title Membrane Lipid Study

### Condition

• Other condition

**Synonym** Ageing, Metabolism

#### Health condition

veroudering, energiemetabolisme

# Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Universiteit Maastricht **Source(s) of monetary or material Support:** Top Institute Food and Nutrition

#### Intervention

Keyword: Elderly, Membrane lipid, Mitochondria, Skeletal muscle

### **Outcome measures**

#### **Primary outcome**

The main outcome parameters relate to the anticipated differences in

mitochondrial function and include ex vivo mitochondrial respiratory capacity

as the main study endpoint.

#### Secondary outcome

Resting energy metabolism, body composition, and physical and cognitive

function. Furthermore, markers of mitochondrial metabolism and mitochondrial

respiratory capacity in skeletal muscle tissue will be determined.

# **Study description**

#### **Background summary**

Reduced mitochondrial membrane phospholipid content and unsaturation is associated with aging, resulting in reduced mitochondrial function that underlies age associated decrements in physical and cognitive function. Since membrane phospholipids are diet modifiable, supplementation with omega-3 fish oils (FO) and a phospholipid enriched dairy fat fraction (Cream serum powder; CSP) may represent an effective, novel therapeutic strategy for enhancing mitochondrial, physical, and cognitive function in aging.

#### **Study objective**

The main objective of this study is to determine whether supplementation with FO combined with complex phospholipids can alter skeletal muscle mitochondrial function more effectively than FO alone. Additional exploratory objectives are; determination of 1) Skeletal muscle and physical function 2) body composition, 3) cognitive function, and 4) molecular pathways and gene transcription responsible for improved mitochondrial health and function.

#### Study design

A multicentre, double-blind, randomised, controlled, parallel trial, where FO plus CSP will be compared to FO with a calorie matched, phospholipid free lipid mixture.

#### Intervention

FO (3g Total, 2.1g EPA & DHA) combined with 13g of either a CSP or with a skimmed milk (75%) and palm oil powder (25%) (SMPO) mixture.

### Study burden and risks

This study will lead to novel insights with respect to the ability of food constituents to improve mitochondrial function and health in the elderly. The major burden to the subjects is a time investment. Subjects will be asked to attend the university on ~5 occasions for measurement procedures. Additionally, subjects will consume FO capsules in combination with either CSP or SMPO daily for 12 weeks. The experimental procedures present minimal risk, Local hematoma or bruising can occur from IV insertion and muscle biopsy procedures. The risk of infection or prolonged bleeding is low due to state-of-the-art techniques, screening procedures, and sterility measures. In the event of coincidental medical findings subjects will be informed and may be advised to contact a doctor about this.

# Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- Males and females;
- Caucasian;
- Age \* 65 years;
- BMI \* 20 kg/m2 \* 30 kg/m2;

- Normal physical activity levels: maximum of 1 hour per week engagement in moderate or high intensity structured exercise

- Subject should be in sufficient health to participate in the experiments, to be judged by the site-specific responsible physician, based on the subject's medical history.

# **Exclusion criteria**

- Not meeting all inclusion criteria;
- Habitual smoker within the past 5 years;
- Excessive alcohol use (greater than 20g per day) and/or drug abuse;
- Subjects with diagnosed diabetes mellitus type 2;
- Significant food allergies or intolerances concerning the study products,
- e.g. cow\*s milk protein allergy
- Participation in another biomedical study within 1 month before the first study visit, possibly interfering with the study results;
- Medication use known to hamper subject\*s safety during the study procedures;
- Subjects habitually taking fish oil supplements within 3-months of the initial study visit or habitually taking lipid supplements that are likely to affect the main study outcomes;

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- Subjects who do not want to be informed about unexpected medical findings;

- Subjects who do not want their treating physician to be informed about unexpected medical findings;

- Inability to participate and/or complete the required measurements.

# Study design

### Design

Interventional
Parallel
Randomized controlled trial
Double blinded (masking used)
Placebo
Treatment

### Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2019
Enrollment:	108
Type:	Actual

# **Ethics review**

Approved WMO	
Date:	19-06-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	02-10-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register

CCMO Other **ID** NL68966.068.19 volgt z.s.m.