# Effects of Fish Oil Supplementation on Healthy Older Men Undergoing Single Leg Immobilization

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28397

**Source**
NTR

**Brief title**
n-3 PUFA during immobilization

**Health condition**

Immobilization, aging

### Sponsors and support

**Primary sponsor:** McMaster University, Canada
**Source(s) of monetary or material Support:** Canadian Institutes of Health Research

### Intervention

### Outcome measures

**Primary outcome**

To determine the impact of n-3 PUFA supplementation on muscle disuse atrophy and recovery from 7 d of single leg immobilization

### Secondary outcome

1) To determine the effects of n-3 PUFA supplementation on muscle strength

2) To determine the effects of n-3 PUFA supplementation on muscle protein synthesis during immobilization and recovery

## Study description

### Background summary

Aging is accompanied by the loss of skeletal muscle mass and strength. This loss of muscle mass can limit older individuals in their ability to carry out activities of daily living. Moreover, muscle loss has negative health effects and increases the risk of falls and fractures. The loss of skeletal muscle mass is a gradual process that begins in the fifth decade of life. This process of muscle loss is accelerated by short periods of inactivity or muscle disuse that can occur during hospitalization, home-bound sickness, or orthopedic injuries. Older individuals often do not completely recover from these short periods of muscle disuse. Effective ways to slow the loss of muscle mass with disuse are currently lacking. Recent research however suggests that n-3 PUFA supplementation (as found in fish oil) enhances the capacity of the muscle to grow in response to infusion of amino acids. In this study we aim to investigate whether n-3 PUFA supplementation can elevate muscle protein synthesis during single leg immobilization and thereby attenuate the loss of muscle mass.

### Study objective

n-3 PUFA supplementation attenuates the loss of skeletal muscle mass during unilateral lower limb immobilization in healthy older men

### Study design

Before and after 1 week of immobilization and 2 weeks of recovery

### Intervention

The experimental trial is composed of 7 weeks of n-3 PUFA or placebo supplementation, including 4 weeks of pre-immobilization, 1 week of single leg immobilization, and 2 weeks of recovery. At t=-28 d, a blood sample and muscle biopsy will be obtained and muscle strength will be assessed before daily n-3 PUFA or placebo supplementation will be initiated. Participants will consume 20 mL fish oil per day providing 5 g of n-3 PUFA (containing 3.1 g EPA and 1.9 g DHA). Sunflower oil will be used as placebo, which has the same taste, texture, and appearance as the fish oil supplement. The fish oil and sunflower oil bottles are coded to ensure complete blinding to both researchers and participants. Additional blood samples will

be obtained throughout the experimental trial to check for compliance to the supplementation. Muscle strength will be assessed every week to familiarize the participants with the equipment.

Three days prior to immobilization (t=-3 d) a blood sample and saliva sample will be obtained before ingesting 150 mL of deuterium-labeled water (D2O). Daily saliva sampling will be continued until the end of the experimental trial to assess precursor pool enrichments. Dietary intake will be controlled for 10 days (including 3 d prior to immobilization and 7 d of immobilization) providing an energy balanced diet containing 1.0 g of protein per kg body weight per day equally distributed over breakfast, lunch, and dinner (15). Participants will be instructed to refrain from vigorous-intensity physical activity (running, fast cycling, competitive sports, carrying heavy loads, etc.) and refrain from alcohol consumption for 3 d prior to and during the 7 d of immobilization. Daily activity will be monitored with a SenseWear Armband, which subjects will be required to wear from t=-3 d until the end of the experimental trial. On t=0 d, a blood sample, saliva sample, and muscle biopsy will be obtained for the assessment of muscle protein synthesis rates. Moreover, muscle volume and muscle strength will be assessed using MRI scan and Biodex, respectively. Next, a knee brace will be placed to start the 7-d single leg immobilization phase. One week of immobilizing the leg of an elderly person is associated with unknown risk of DVT. The choice of leg for immobilization will be randomized and balanced for dominance according to maximal isometric strength. A 50 mL maintenance dose of D2O will be consumed on t=0, 7, and 14 d. At the end of the immobilization phase (t=7 d), a blood sample will be obtained, muscle biopsies will be collected from both the immobilized and non-immobilized leg, and muscle volume and strength will be assessed.
Following the 7-d immobilization phase and upon removal of the knee brace, subjects will begin a 14-d recovery phase. During the recovery phase, subjects will continue to receive n-3 PUFA supplementation or placebo. On day 14 (7 d after the immobilization phase), muscle strength will be assessed. Two weeks after immobilization (t=21 d), a blood sample and muscle biopsies from both the immobilized and non-immobilized leg will be obtained. Moreover, muscle volume and muscle strength will be assessed.

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# Eligibility criteria

## Inclusion criteria

1) Generally healthy, non-smoking, as assessed by questionnaire

2) Willing and able to provide informed consent

3) Men age 55-75 years

4) BMI between 22 and 33 kg/m2

5) Mini-Mental State Exam (MMSE) score > 20

## Exclusion criteria

1) Any concurrent medical, orthopedic, or psychiatric condition that, in the opinion of the Investigators, would compromise the ability to comply with the study requirements

2) History of cancer within the last 5 years, except basal cell carcinoma, non-squamous skin carcinoma, prostate cancer, or carcinoma in situ with no significant progression over the past 2 years

3) Significant orthopedic, cardiovascular, pulmonary, renal, liver, infectious disease, immune disorder, or metabolic/endocrine disorders or other disease that would preclude oral n-3 PUFA supplement ingestion and/or assessment of safety and study objectives

4) Current illnesses which could interfere with the study (e.g. prolonged severe diarrhea, regurgitation, difficulty swallowing)

5) Participation in a study of an investigational product less than 60 days or 5 half-lives of the investigational product, whichever is longer, before enrollment in this study

6) Hypersensitivity to the test product

7) Excessive alcohol consumption (>21 units/week)

8) Prior gastrointestinal bypass surgery

9) History of bleeding diathesis, platelet or coagulation disorders, or antiplatelet/anticoagulation therapy

10) Personal or family history of clotting disorder or deep vein thrombosis

11) Concomitant use of corticosteroids, testosterone replacement therapy (ingestion, injection, or transdermal), or any anabolic steroid

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2016 |
| Enrollment: | 24 |
| Type: | Anticipated |

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# 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 | ID |
|---|---|
| NTR-new | NL5841 |
| NTR-old | NTR5996 |
| Other | N/A : 2016-1932-GRA |

# Study results