

# The effect of exercise and nutrition on structural and functional systems in the elderly brain

<b>Submission date</b> 30/11/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/01/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Elderly people may benefit from increased physical and cognitive (mental) fitness through the combination of video-game based physical fitness with omega-3 fatty acids. The aim of this study is to evaluate the effect of physical exercise combined with omega-3 fatty acid supplementation in elderly people.

### Who can participate?

People aged over 65, healthy, and living independently or in a community residence.

### What does the study involve?

Participants are randomly allocated to one of the two groups. One group receives omega-3 supplements, while the second group receives olive oil supplements. Participants take nutritional supplements for 26 weeks. After 16 weeks, they start with physical exercise three times per week for 30 minutes. Participants undergo brain scans before and after the intervention. Blood samples are taken before the intervention, after 16 weeks, and at the end of the intervention.

### What are the possible benefits and risks of participating?

Participants possibly benefit from increased physical and cognitive (mental) fitness through the combination of video-game based physical fitness with omega-3 fatty acids. The risk of falls is not greater than in the normal life of the elderly participants. Special attention is given to minimize the risk of falls while training. The risks of omega-3 fatty acid supplementation are minimal with the given dosage. No other risks or side effects are expected.

### Where is the study run from?

Swiss Federal Institute of Technology (Switzerland)

### When is the study starting and how long is expected to run for?

November 2015 to December 2016.

Who is funding the study?  
Swiss Federal Institute of Technology (Switzerland)

Who is the main contact?  
Alexandra Schättin  
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## Contact information

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Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

The combinatory effect of physical exercise and omega-3 fatty acid supplementation on the neuronal system in the elderly brain: randomized placebo-controlled trial using structural and functional neuronal test methods

## Acronym

ENEB

## Study objectives

1. The combination of physical exercise with omega-3 fatty acid nutritional supplementation is more effective than single physical exercise in contributing to structural level (synaptic plasticity) changes in the elderly brain
2. The combination of physical exercise with omega-3 fatty acid nutritional supplementation is more effective than single physical exercise in contributing to functional level (neuronal activity, neuronal drive, and cognitive functioning) changes in the elderly brain

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Canton of Zurich Ethics Committee (Switzerland), 20/10/2015, ref: KEK-ZH-Nr. 2015-0190
2. Swissmedic (Bern, Switzerland), 17/11/2015, ref: 2015DR2173

## Study design

Single-centre two-groups pre-test, mid-test (blood sample after 16 weeks), post-test (26 weeks) randomized controlled clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## 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

People over 65 years, healthy (self-report), and living independently or in a community residence

## **Interventions**

Participants are randomized into two groups with different nutritional supplementation:

1. Intervention group: This group will take 13.5 ml of omega-3 fatty acid supplementation daily for 26 weeks at home
2. Control group: This group will take 13.5 ml of olive oil supplementation daily for 26 weeks at home

After 16 weeks, all participants follow 10 weeks of guided video-game-based physical exercise. Training sessions take place three times per week for 30 minutes. For the video-game training, the participant follows the step instructions presented on a computer screen. Participants are standing on a pressure-sensitive platform, which records right and wrong movements. Participants are accustomed slowly to the exercise and are continuously monitored by the instructors.

## **Intervention Type**

Mixed

## **Primary outcome measure**

Current primary outcome measures as of 24/02/2016:

1. Structural level:
    - 1.1. Transcranial magnetic stimulation: Motor evoked potential in M.tibialis anterior
  2. Functional level:
    - 2.1. Electroencephalography: Event related potential and frequency band distribution
    - 2.2. Cognitive test: Test for Attentional Performance (TAP)
- All measures are assessed pre-intervention and after intervention.

Previous primary outcome measures:

1. Structural level:
    - 1.1. Transcranial magnetic stimulation: Motor evoked potential in M.tibialis anterior
  2. Functional level:
    - 2.1. Electroencephalography: Event related potential and frequency band distribution
    - 2.2. Cognitive tests: Test for Attentional Performance (TAP) and Attention Network Test (ANT)
- All measures are assessed pre-intervention and after intervention.

## **Secondary outcome measures**

1. Gait parameters:
  - 1.1. Temporal and spatial gait parameters are assessed with the Physilog®
2. Prevention of falls:
  - 2.1. Icon Falls Efficacy Scale International (Icon-FES-I) questionnaire is used as a measure of 'concern' about falling, to determine the transfer effects of training to activities of daily living
3. Mental state and depression:
  - 3.1. Mini Mental State Examination (MMSE)
  - 3.2. Geriatric Depression Scale (GDS): symptoms of depression are recorded. The German version of the GDS has a good validity and reliability
4. Blood samples measuring fatty acid

All measures are assessed pre-intervention and after intervention. In addition, blood samples are measured after 16 weeks.

## **Overall study start date**

20/11/2015

**Completion date**

31/12/2016

## **Eligibility**

**Key inclusion criteria**

1. Age above 65 years
2. Live independently or in a residency dwelling
3. Non-smoker
4. Healthy (self-reported)

**Participant type(s)**

Healthy volunteer

**Age group**

Senior

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Mobility or cognitive impairments
2. Orthopaedic or neurological diseases preventing training participation
3. Rapidly progressive or terminal illness, acute or chronic illness
4. History of stroke, epilepsy, or seizure
5. Medication that interacts with nutritional supplementation
6. Medication that acts on a neuronal level
7. Mini Mental Status < 22 points
8. Signs of upcoming depression (GDS)
9. Electronic or metallic head implants

**Date of first enrolment**

01/12/2015

**Date of final enrolment**

30/06/2016

## **Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**

**ETH Zurich, Institute of Human Movement Sciences and Sport**  
Switzerland  
8093

## **Sponsor information**

### **Organisation**

Swiss Federal Institute of Technology Zurich (ETH) (Switzerland)

### **Sponsor details**

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CH- 8093

### **Sponsor type**

University/education

### **ROR**

<https://ror.org/05a28rw58>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Eidgenössische Technische Hochschule Zürich (ETH Research Grant ET-17 13-2)

### **Alternative Name(s)**

ETH Zurich, ETH Zürich, Federal Institute of Technology Zurich, ETH Zürich (Eidgenössische Technische Hochschule Zürich), Eidgenössische Technische Hochschule Zürich (Switzerland), Eidgenössische Technische Hochschule Zürich (ETH), ethzurich, ETH

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

Switzerland

## Results and Publications

### Publication and dissemination plan

We plan to publish the article in a high-impact peer reviewed journal.

### Intention to publish date

30/04/2018

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Alexandra Schättin, [schaetta@ethz.ch](mailto:schaetta@ethz.ch).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>	results	13/12/2017	22/01/2018	No	No
<a href="#">Results article</a>		13/03/2019	26/03/2019	Yes	No
<a href="#">Protocol article</a>		29/11/2016	10/01/2023	Yes	No