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

Submission date	Recruitment status	[X] Prospectively registered
30/11/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2023	Other	

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?
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Contact information

Type(s)
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
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Sponsor information

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

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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.

IPD sharing plan summary
Available on request

Study outputs

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