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# Neural effects of exercise, diet and sleep

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 10/11/2015 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 16/11/2015 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 30/12/2022 | Mental and Behavioural Disorders | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
The brain of a child and that of an adult are organised very differently. In adolescence the brain undergoes extensive remodelling, maturing and building connections. It is during this time that the cerebral cortex (the folded, outer part of the brain) undergoes extensive changes, marking the development of complex thinking processes, increasing a persons' capacity for learning. There are many known benefits of taking part in regular physical activity for the body, but there is a good deal of evidence that it is also valuable for healthy cerebral development. Despite this, teenagers are becoming increasingly inactive, many becoming overweight or obese. Many studies have shown that cognitive function (mental abilities such as thinking, reasoning, memory and attention) is improved after taking part in exercise in children, boosting academic performance. The aim of this study is to find out whether taking part in high-intensity exercise will help to improve cognitive function and learning in adolescents.

Who can participate?
Healthy adolescents aged between 15 and 19 who attend a participating high school or vocational school.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in three 20 minute exercise sessions every week during school hours. In these sessions, participants complete a warm up (low intensity), and then high intensity interval running exercise such as running or circuit training, followed by a short low intensity cool down. Those in the second group continue with their usual exercise regime and have no extra training sessions. At the start of the study and then again after one months, participants in both groups have a scan to test their brain activity, as well as completing a number of tests to find out if there has been any change to their cognitive function. A subgroup of the study population also have a scan to test their brain activity before and after a single high intensity interval exercise to study the effects of acute exercise on brain functioning.

What are the possible benefits and risks of participating?
Participants will benefit from taking part in the study are they will be able to receive detailed information about their health and fitness levels, as well as feedback about any changes they could make to improve. There is a small risk of injury during the exercise training, although measures will be taken to prevent this.

Where is the study run from?
University of Jyväskylä (Finland)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
Jenny and Antti Wihuri Foundation (Finland)

Who is the main contact?
Dr Eero Haapala

# Contact information

### Type(s)
Scientific

### Contact name
Dr Eero Haapala

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
High-intensity exercise training intervention study to improve cognitive functions and learnining in adolescents

### Acronym

NEEDS

## Study objectives
High-intensity and low-volume exercise intervention will improve cognitive function and learning in the study group compared to the control group during the three month intervention period.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics committee of University of Jyväskylä, 25/08/2015

## Study design
Current study design:
Single-centre single-blind parallel controlled cross-over study

Previous study design:
Single-centre single-blind cluster-randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
School

## Study type(s)
Other

## 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
Cognition, learning, brain function

## Interventions
Current Interventions as of 17/03/2017:
Participants are allocated to the intervention group or the control group.

Intervention group: Participants take part in high-intensity and low volume exercise training during school days. The aim of the exercise intervention is to provide three short (approximately 20 minute) exercise sessions weekly and to improve cardio-respiratory fitness, totaling in all 12 sessions over the 1-month intervention period. As a training mode high intensity running will be adopted. The protocol includes 3 minute warm-up at light to moderate intensity and eight to twelve repeated bouts of 0.5 to 1 minute at 90% to 100% of the capacity of the participants interspersed by 75–90 second recovery at light intensity, followed by 3 minute recovery period at light to moderate intensity.

In the sub-study, the participants participate in three brain scans. First scan is performed two weeks before second visit to the laboratory. During the second visit, the participants perform a brain scan before and after the acute high intensity interval exercise. The exercise is performed using mechanically braked cycle ergometer. The exercise protocol include eight 30-second maximal intensity exercise bouts interspersed by 90-second active recovery.

Control Group: Participants will continue their usual physical activity behavior without supervised exercise by the study.

There is no follow-up planned.

Previous Interventions:
Participants are randomly allocated to the intervention group or the control group.

Intervention group: Participants will take part in high-intensity and low volume exercise training during school days. The aim of the exercise intervention is to provide three short (approximately 20 minute) exercise sessions weekly and to improve cardio-respiratory fitness and motor performance, totaling in all 24 sessions over the 2-month intervention period. As a training mode high intensity running and circuit training will be adopted. The protocol includes 3 minute warm-up at light to moderate intensity and eight to twelve repeated bouts of 1 minute at 90% to 100% of the capacity of the participants interspersed by 75–90 second recovery at light intensity, followed by 3 minute recovery period at light to moderate intensity.

Control Group: Participants will continue their usual physical activity behavior without supervised exercise by the study.

After the intervention period, the participants will be followed-up until the end of vocational and high school for approximately for two years (from baseline) but no intervention is provided during follow-up.

## Intervention Type
Behavioural

## Primary outcome measure
Current primary outcome measures as of 17/03/2017:
1. Attention, working memory, associative learning, processing speed and executive function is measured using the computerized CogState battery at the baseline and at the 3 months
2. Brain functions by magnetoencephalography (MEG) in a subsample of participants taking part in sub study investigating the effects of acute high intensity interval training on cognition and brain functioning.

Previous primary outcome measures:
1. Attention, working memory, associative learning, processing speed and executive function is measured using the computerized CogState battery at the baseline and at the 3 months
2. Reading and arithmetic skills are measured using pseudo word reading and KTLT tests, respectively, at the baseline and at the 3 months
3. Brain functions by magnetoencephalography (MEG) at baseline and 3 months

## Secondary outcome measures
Current secondary outcome measures as of 17/03/2017:
1. Cardiorespiratory fitness is measured using maximal cycle ergometer test with respiratory gas analyses at baseline and 3 months

2. Physical activity is measured using PA-3D accelerometer, the Youth Physical Activity Questionnaire and the Youth Sedentary Behaviour questionnaire at baseline and 3-months
3. Sleep length and quality is measured using the Epworth sleepiness scale and Basic Nordic Sleep Questionnaire at baseline and 3 months
4. Arterial stiffness is measured using an Arteriograph at baseline and 3 months
5. Motivation is measured using a questionnaire developed by Professor Niemivirta in the 2002 study "Motivation and performance in context: The influence of goal orientations and instructional setting on situational appraisal and task performance" at baseline and 3 months
6. Self-efficacy is measured using a questionnaire developed by Professor Niemivirta in the 2002 study "Motivation and performance in context: The influence of goal orientations and instructional setting on situational appraisal and task performance" at baseline and 3 months
7. Depression is measured using the 21 item Beck Depression Scale at baseline and 3 months

Previous secondary outcome measures:
1. Cardiorespiratory fitness is measured using maximal cycle ergometer test with respiratory gas analyses at baseline and 3 months
2. Physical activity is measured using PA-3D accelerometer, the Youth Physical Activity Questionnaire and the Youth Sedentary Behaviour questionnaire at baseline and 3-months
3. Sleep length and quality is measured using the Epworth sleepiness scale and Basic Nordic Sleep Questionnaire at baseline and 3 months
4. Arterial stiffness is measured using an Arteriograph at baseline and 3 months
5. Adiposity is measured using dual-energy x-ray absorbtiomerty at baseline and using bio-impedance device at baseline and 3 months
6. Motivation is measured using a questionnaire developed by Professor Niemivirta in the 2002 study "Motivation and performance in context: The influence of goal orientations and instructional setting on situational appraisal and task performance" at baseline and 3 months
7. Self-efficacy is measured using a questionnaire developed by Professor Niemivirta in the 2002 study "Motivation and performance in context: The influence of goal orientations and instructional setting on situational appraisal and task performance" at baseline and 3 months
8. Depression is measured using the 21 item Beck Depression Scale at baseline and 3 months

### Overall study start date
11/01/2015

### Completion date
30/12/2018

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 17/03/2017:
1. Aged 15-19 years of age
2. Attending high school and vocational schools

Previous inclusion criteria:
1. Aged 15-17 years of age
2. Attending high school and vocational schools

### Participant type(s)
Healthy volunteer

**Age group**
Child

**Lower age limit**
15 Years

**Upper age limit**
19 Years

**Sex**
Both

**Target number of participants**
30-40

**Key exclusion criteria**
1. Heart disease
2. Untreated or poorly controlled type 1 diabetes
3. Musculoskeletal disease or trauma
4. Severe depression or anxiety

**Date of first enrolment**
01/12/2015

**Date of final enrolment**
30/03/2017

# Locations

**Countries of recruitment**
Finland

**Study participating centre**
**University of Jyväskylä**
Department of Biology of Physical Activity
Jyväskylä
Finland
FI-40014

# Sponsor information

**Organisation**
University of Jyväskylä

**Sponsor details**

Department of Biology of Physical Activity
PL 35
Jyväskylä
Finland
40014

**Sponsor type**
University/education

**ROR**
https://ror.org/05n3dz165

# Funder(s)

**Funder type**
Charity

**Funder Name**
Jenny ja Antti Wihurin Rahasto

**Alternative Name(s)**
Jenny JA Antti Wihurin Rahasto sr, Jenny and Antti Wihuri Foundation

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Finland

**Funder Name**
Päivikki and Sakari Sohlberg Foundation

# Results and Publications

**Publication and dissemination plan**
Planned publication to a peer reviewed journal in the form of a preliminary results paper and a main results paper.

**Intention to publish date**
30/06/2018

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other publications | | 01/09/2020 | 30/12/2022 | Yes | No |