Effects of exercise on brain and vascular functions in adolescents

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/08/2023		☐ Protocol		
Registration date 08/08/2023	Overall study status Completed Condition category Other	Statistical analysis plan		
		Results		
Last Edited		[] Individual participant data		
08/08/2023		Record updated in last year		

Plain English summary of protocol

Background and study aims

There is increasing evidence of the inverse associations of sedentary behaviour and positive associations of physical activity with brain, cognitive, and vascular health in youth. A limitation of the current evidence base is a lack of understanding of how brain and vascular functions are influenced by sedentary behaviour and food intake in youth. This is a pertinent research question given that youth spend at least half of their waking hours sedentary, and 2/3 of the day may be spent in the postprandial state. This study investigates whether accumulating small volumes of exercise at moderate or high intensity across the day preserves brain and vascular functions during prolonged sitting and unhealthy meals.

Who can participate?

Healthy adolescents aged 12-14 years old without cardiovascular, metabolic, or neuromuscular conditions affecting the ability to exercise.

What does the study involve?

In this study, participants will come to the laboratory four times over a 4- to 6-week period. The first visit is a preparation session, where information about the participants' fitness level and body composition is collected. During the first visit, participants are also familiarised with the cognitive task they will be doing during the experimental visits. This is to make sure that they are familiar with it and won't be influenced by the learning process during the actual experiments. The other three visits are the actual experiment visits.

In the experimental sessions, three different conditions are tested. The first one is prolonged sitting for 7 hours, which includes activities like playing with a mobile phone. The second condition is a moderate-intensity interval exercise, where the participants will do short bouts of moderate-intensity exercise followed by a short rest. The third condition is a high-intensity interval exercise, which is more intense than the moderate one. The high-intensity exercise includes three 3-minute bouts of near-maximal intensity exercise. The number of bouts in the moderate-intensity condition matches the total work performed during high-intensity interval exercise.

During these visits, participants' cognitive functions are assessed using a computer-based task, brain function using brain scanning technology, and vascular functions using non-invasive methods.

What are the possible benefits and risks of participating?

It is possible that there are no direct benefits from participating in the study. Participants receive feedback on their cardiorespiratory fitness and physical activity levels. The risk of the study may include possible uncomfortable bodily feelings during the exercise, such as increased heart rate and exhaustion, as well as some numbness of fingers during the vascular assessments.

Where is the study run from? Faculty of Sport and Health Sciences, University of Jyväskylä (Finland)

When the study is starting and how long is it expected to run for? June 2021 to December 2023

Who is funding the study?
The Juho Vainio Foundation (Finland)
The Finnish Foundation for Cardiovascular Research (Finland)

Who is the main contact?

Dr Eero Haapala, eero.a.haapala@jyu.fi (Finland)

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

202200238

Study information

Scientific Title

Vascular and brain health, ExeRcise, and Nutrition in Adolescents

Acronym

VERNA

Study objectives

Interrupting prolonged sitting with a small amount of interval exercise, especially at high intensity, preserves or improves cognitive, brain, and vascular outcomes.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 17/03/2022, Ethics Committee of the Central Finland Hospital District (Keski-Suomen sairaanhoitoitopiirin tutkimuseettinen toimikunta) (Sairaala Nova, Hoitajantie 3, Jyväskylä, 40620, Finland; +358 14 269 5134; paivi.lampinen@ksshp.fi), ref: 5U/2021

Study design

Randomised three-arm crossover intervention study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Laboratory

Study type(s)

Prevention, Efficacy

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied

Prevention of prolonged sitting-induced deterioration in brain and vascular functions with exercise in apparently healthy adolescents.

Interventions

Each participant will make four visits to the laboratory over a 4 to 6-week period, with at least two days separating each visit. While flexible, 2 to 3 days between the sessions are aimed to allow for sufficient recovery and standardisation of the menstrual cycle in girls. To minimise the effect of the first visit, it will include the assessment of background characteristics such as cardiorespiratory fitness and body composition, and the other three visits will be experimental. During the first visit, the participants will be familiarised with the cognitive task to minimise the learning effect.

Experimental conditions include:

- 1. Prolonged sitting (7 h, including the participant preparation) with normal sedentary behaviour such as playing with a mobile phone
- 2. Moderate intensity interval exercise (MIIE), consisting of the number of 1 min bouts at a 90% gas exchange threshold. The number of bouts will match the total work performed during high-intensity interval exercise. During MIIE, each bout will be separated with 75s of recovery cycling at 20W
- 3. High-intensity interval exercise (HIIE), consisting of a total of 9x1-minute bouts at 90% peak power with 75s of recovery cycling at 20W between each bout. The MIIE and HIIE protocols will be delivered on an electronically braked cycle ergometer.

The participants perform the experimental conditions in random order. The conditions are randomised with the web-based list randomiser available at www.random.org. After the exercise bouts, the participants will consume a meal challenge consisting of ice cream, added cream, croissant, Nutella, chocolate, and cardamon bread, providing ~1.5g/kg of fat following earlier work and the typical diet composition in youth. A high-fat and sucrose diet has been found to impair brain outcomes in experimental animals and a high-fat meal has been found to impair peripheral endothelial function in adolescents and adults for hours, with an implication for possible impairment in cognitive and brain outcomes.

Intervention Type

Behavioural

Primary outcome measure

- 1. Executive inhibition as a measure of cognitive function is assessed by the flanker task at baseline and 1h, 2h, and 4 h after the baseline
- 2. Brain activity is measured by combined magnetoencephalography (MEG)–EEG with a 306-channel whole-head neuromagnetometer (Elekta Neuromag TRIUX, Elekta ltd., Stockholm, Sweden) during quiet sitting. First, resting state data as a measure of functional connectivity will be acquired for 10 minutes while the participant sits relaxed in a neuromagnetometer with eyes open. Second, the changes in the magnetic fields and electric potentials in the neural networks in response to the flanker task are assessed.

Secondary outcome measures

- 1. Arterial stiffness measured by oscillometric tonometry (Arteriograph) and arterial tonometry (PulsePen) is measured in visit 1 and during visits 2-3 at baseline and 2h, and 4h after the baseline
- 2. Microvascular function, i.e., transient increase in microvascular blood flow after five-minute occlusion, is measured by the laser Doppler methodology (Moor Intruments Ltd) from the left forearm in visit 1 and during visits 2-3 at baseline and 2h, and 4h after the baseline
- 3. Physical activity and sedentary time are monitored for 72-h prior to the experimental visits using a thigh-worn movement and posture sensor (ActivPALmicro, PALTechonologies). Physical activity and sedentary behaviours are also measured using the PANIC Physical Activity Questionnaire, filled in during visit 1
- 4. Dietary factors are assessed using one-day dietary records. The participants will note down all food and drink consumed during the previous day prior to the experimental visits. The data will be analysed using the FINELI dietary analysis software (https://fineli.fi/fineli/en/ruokapaivakirja?)
- 5. Maximal oxygen uptake will be measured during a ramp incremental exercise test with a supramaximal verification phase on a cycle ergometer at visit 1
- 6. Body composition is estimated using bioelectrical impedance device (InBody 770, Biospace) in visit 1

Overall study start date 01/06/2021

Completion date 31/12/2023

Eligibility

Key inclusion criteria

- 1. Adolescents aged 12-14 years
- 2. Apparently healthy (no known cardiovascular or metabolic diseases, musculoskeletal injury, serious food allergies)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

12 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

- 1. Metal objects in the body
- 2. Musculoskeletal injury preventing exercise
- 3. Cardiovascular or metabolic disease
- 4. Participating in another study at the same time

Date of first enrolment

30/08/2022

Date of final enrolment

30/09/2023

Locations

Countries of recruitment

Finland

Study participating centre

Faculty of Sport and Health Sciences, University of Jyväskylä

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Sponsor type

University/education

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ROR

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Funder(s)

Funder type

Research organisation

Funder Name

Juho Vainion Säätiö

Alternative Name(s)

Juho Vainio Foundation, Reppy Institute

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Finland

Funder Name

Sydäntutkimussäätiö

Alternative Name(s)

Finnish Foundation for Cardiovascular Research

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Finland

Results and Publications

Publication and dissemination plan

Publications created with the project are either published in peer-reviewed scientific journals favouring open-access publishing and/or parallel publication in the university repository JYX (https://jyx.jyu.fi/). The results will also be presented at international scientific conferences and meetings.

Intention to publish date

30/08/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr. Eero Haapala (eero.a.haapala@jyu.fi). The research material will be carefully maintained, documented, and stored in the servers of the Information Management Center of the university. The metadata will be made publicly available.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			08/08/2023	No	Yes
Participant information sheet			08/08/2023	No	Yes