

# Physical activity as treatment for adolescents with ADHD

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2020	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/06/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Physical activity is important for overall health, both physical and mental health. Young people with good health find schoolwork easier according to a growing number of studies. Sufficient daily physical activity improves memory and concentration. One problem today is that many young people do not reach the recommendations for daily activity to maintain good health. The aim of this project is to investigate whether structured and regular physical activity can have a positive effect on adolescents with ADHD and other mental and physical symptoms connected with ADHD.

### Who can participate?

Patients aged 13-17 with an ADHD diagnosis in Child- and adolescent psychiatric (CAP) clinics in Västerås and Gävle.

### What does the study involve?

All participants will be randomly allocated to one of two treatment options over a 14 week period. Training group: Continuing regular treatment at CAP, adding an exercise program in groups of 10-12 participants 1h/3 times per week. The exercise program will be led by a personal trainer (PT) who provides personalized support. Control group: Regular treatment at CAP.

Measures: at baseline, after 14 weeks, and after 1 year

Symptoms of ADHD, anxiety, depression, quality of life and level of functioning will be assessed through questionnaires to parents and child. Physical parameters will be measured through clinical examination, blood-samples and by wearing accelerometer. Nutrition and dietary habits will be self-registered.

An interview with a sample of participants will be performed after the intervention. This will also include drop-outs from the study.

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

The results of this study will contribute to an enhanced knowledge of complimentary treatment options for adolescents with ADHD. Increased physical activity may also be of great value for participating adolescents. The possible risks could be that some participants may find the

physical exercise and the blood-sampling uncomfortable. Another possible risk is that a participant who chooses to drop out of the study may conceive this as a personal failure. By using a PT who can provide individualized support, we hope to minimize this risk.

Where is the study run from?

Child- and adolescent psychiatry clinics in Västerås and Gävle, Sweden.

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

October 2019 to June 2023

Who is funding the study?

The county of Västmanland, Sweden.

Who is the main contact?

MD PhD Eva Norén Selinus

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

# Study information

## Scientific Title

The effect of physical activity as treatment on ADHD symptoms in adolescents with ADHD

## Acronym

PA-ADHD

## Study objectives

Increased level of physical activity could be protective concerning physical and mental health, and psychosocial outcomes, for adolescents with ADHD.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 24/02/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 75002 Uppsala, Sweden; +46-10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2019-04827

## Study design

Randomized controlled multicenter trial

## Primary study design

Interventional

## Secondary study design

Qualitative content analysis

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied

Attention Deficit Hyperactivity Disorder (ADHD)

## Interventions

Structured physical activity in groups led by a personal trainer (PT) consisting of indoor aerobic exercise combined with weight training.

60 minutes, three times a week, 14 weeks.

Randomized according to sex and age by sealed envelope.

## Intervention Type

Behavioural

**Primary outcome measure**

Symptoms of ADHD, self- and parent-rated and by Swanson, Nolan and Pelham Questionnaire (SNAP-IV) at baseline, after 14-weeks of intervention, and after 1 year

**Secondary outcome measures**

At baseline, after 14-week intervention, and after 1 year:

1. Self-ratings of depression (Montgomery Åsberg Depression Rating Scale Self report (MADRS-S))
2. Self-ratings of anxiety (Spence Ångestskala (Spence anxiety scale))
3. Cardiovascular risk factors measured by blood sampling
4. Measures of physical fitness: a submaximal cycle ergometer test (Ekblom-Bak test), Handgrip strength test (hand dynamometer), vertical jump
5. Registration of nutrition and dietary habits: Food registration online provided by The National Food Agency, Sweden.
6. Daily physical activity registered by accelerometer

**Overall study start date**

01/10/2019

**Completion date**

30/06/2023

**Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

**Eligibility****Key inclusion criteria**

1. Diagnosis of ADHD
2. Patient at child psychiatric section in Västerås or Gävle
3. Age: 13-17 years
4. Stable medication at study-start

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

116

**Key exclusion criteria**

1. Suicidality
2. Eating disorder
3. Substance abuse
4. Intellectual impairment

**Date of first enrolment**

01/09/2020

**Date of final enrolment**

01/03/2022

**Locations****Countries of recruitment**

Sweden

**Study participating centre****Child- and adolescent psychiatry in Västerås**

Västmanland county hospital

Västerås

Sweden

721 89

**Study participating centre****Child- and adolescent psychiatry in Gävle**

BUP Region Gävleborg

Box 804

Gävle

Sweden

801 30

**Sponsor information****Organisation**

Center for Clinical Research, Västerås

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.medfarm.uu.se/ckfvasteras>

**ROR**

<https://ror.org/01qh83x04>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Landstinget Västmanland

## **Results and Publications**

**Publication and dissemination plan**

1. Publication describing the protocol of the RCT: Fall 2020
2. Publication of results from the feasibility study: Spring 2021
3. Publication of results from the RCT: Fall 2023
4. Qualitative study of interviews with participants from RCT: Fall 2022

**Intention to publish date**

31/12/2024

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date