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Physical activity as treatment for adolescents with ADHD

Submission date
04/03/2020

Recruitment status
Stopped

Registration date
27/04/2020

Overall study status
Stopped

Last Edited
19/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
eva.noren.selinus@regionvastmanland.se

Contact information

Type(s)
Scientific

Contact name
Dr Eva Norén Selinus

ORCID ID
https://orcid.org/0000-0002-6104-7836

Contact details
BUP mottagningen
Västmanlands sjukhus
ingång 24
Västerås
Sweden
721 89
+46 (0)21-173000
eva.noren.selinus@regionvastmanland.se

Additional identifiers

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 acitivity 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), ref: 2019-04827

Primary study design
Interventional

Study design
Randomized controlled multicenter trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
17 Years

Sex
All

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

ROR
https://ror.org/01qh83x04

Funder(s)

Funder type
Government

Funder Name
Landstinget Västmanland

Results and Publications

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