

Physical activity, sitting and cognition - a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38817

Source

ToetsingOnline

Brief title

Physical activity, sitting and cognition

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Personality disorders and disturbances in behaviour

Synonym

Attention, concentration

Health condition

Cognitie

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute effects, Attention Deficit Hyperactivity Disorder, Cognitive functioning, Physical activity

Outcome measures

Primary outcome

The primary outcome of the experiment is cognition, and the primary outcome of the observations is classroom behaviour (for example on-task and off-task behaviour). In general, no fixed primary outcomes for qualitative research are used.

Secondary outcome

Secondary outcome measures of the pilot experiment include glucose level, C-peptides, triglycerides, and cholesterol (total, HDL and LDL).

For the observational research, behaviour of the children during the break is the secondary outcome measure.

For the qualitative research, no secondary outcomes are defined.

Study description

Background summary

Besides the positive effects on physical health, a recent systematic literature review found that there is also a positive relation between physical activity and academic performance. However, few experimental studies examined the acute effects of physical activity on cognitive functioning in youth. The acute effects of prolonged sitting on cognitive functioning in children have never been assessed using an experimental design. Additionally, the acute effects of

physical activity and sitting on cardiometabolic health have not been studied in youth using an experimental design. Up to now no applied research exploring the possibilities to implement physical activity in the class setting in order to improve children's learning performance has been conducted.

Study objective

We will examine the feasibility of an experimental condition- in which either a passive or active school morning is simulated- to test the effect of physical activity on cognition and cardiovascular health in children. In addition, we will gather qualitative data in order to investigate the possibilities of implementing physical activity in the classroom setting to improve the cognitive functioning of children. Special attention will be paid to children with attention- and concentration problems (or Attention-Deficit-Hyperactivity Disorder; ADHD).

Study design

The current study exists of two different parts: 1) a randomised pilot study (experiment) and 2) qualitative research (interviews) and class room observations.

Intervention

EXPERIMENT

Children are randomised in one of the following four conditions: group A) prolonged sitting, group B) day start with physical activity and prolonged sitting afterwards, group C) day start with physical activity, then sitting with an active break halfway the morning. Participants come to school having fasted for at least 8 hours. Before consuming a standardized breakfast, and at the end of the morning, they will donate a couple of blood drops by means of a finger prick. At different time points during the experiment, participants will perform cognition tests.

QUALITATIVE

Interviews with health care professionals, teachers and children with ADHD are conducted using a question route.

OBSERVATIONAL

The in-classroom behaviour of children (with and without ADHD) will be scored by two researchers during one school morning.

Study burden and risks

EXPERIMENT

Participants will visit the laboratory, having fasted for at least 8 hours.

Anthropometrics (weight, height and waist circumference) and cognition will be measured at baseline. Capillary blood will be collected at baseline and after the experiment using a finger prick (capillary samples using a validated collection kit developed for ambulatory purposes [Demecal, Haarlem]). Depending on the experimental condition, participants will either sit the whole morning or combine sitting with one or two times of being physically active (20 minutes of activity at moderate intensity, supervised by experienced researchers). In this experiment, no new research methods will be tested. The finger prick procedure is similar to the procedure used in the ABCD study and ENERGY-metabolic functioning study. The finger prick will be conducted by qualified and experienced researcher. We hypothesize that prolonged sitting (maximal four hours in group A) has detrimental effects on both cognition and health, and that breaking up sitting prevents those effects. Because in this pilot study participants will exhibit prolonged sitting on one morning only, no lasting negative effects on health or cognition are expected. There is a minimal chance that participants will be injured or hurt during the experiment. There is no risk associated with participants in this pilot experiment.

QUALITATIVE/OBSERVATIONS

There is no risk associated with participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

EXPERIMENT

Children who participate in the experiment:

- 1) are (apparently) healthy;
- 2) are between the age of 10 and 12 years;
- 3) understand and speak the Dutch language;
- 4) can hand in a consent form which is signed by their parent(s) before the start of the research.;

QUALITATIVE RESEARCH - INTERVIEWS

Teachers and healthcare professionals who participate in the qualitative research:

- 1) have at least 5 years of teaching/working experience
- 2) work actively with adolescents to improve their school performance;
- 3) have affinity with the subject of attention-deficit hyperactivity disorders (ADHD);
- 4) understand and speak the Dutch language.;

Children with Attention-Deficit-Hyperactivity Disorder (ADHD) who participate in the qualitative research:

- 1) struggle with attention and concentration problems, problems with impulsivity and/or problems with hyperactivity;
- 2) perform worse on subjects like reading and math than their peers;
- 3) understand and speak the Dutch language;
- 4) can hand in a consent form which is signed by their parent(s) before the start of the research.;

OBSERVATIONAL RESEARCH

For children that participate in the classroom observations the inclusion criteria as described above apply. Children that serve as a control during the classroom observations should also hand in a consent form which is signed by their parent(s) before the start of the research.

Besides they should:

- 1) not struggle with attention and concentration problems, problems with impulsivity and/or problems with hyperactivity;
- 2) perform moderately at school.

Exclusion criteria

EXPERIMENT

Exclusion criteria are known physical activity contraindications, major illness/injury (acute or chronic) or physical problems that may limit the ability to perform the experiment.

Participants will be screened by a health check questionnaire.;

QUALITATIVE AND OBSERVATIONAL RESEARCH

No exclusion criteria apply.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO	
Date:	04-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43909.029.13