SmartMoves - a pilot study

Submission date 10/06/2014	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 07/08/2014	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 05/01/2016	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aims

Physical activity (exercise) isnt just good for a child's health. Research has shown that physical education (PE) and physical activity can also improve academic performance. However, to date, there have been few studies looking into the effects of physical activity on the cognitive functioning (for example thinking, remembering, judging, and problem-solving) in children. Furthermore, the effects of prolonged sitting on the cognitive functioning of children has never been properly investigated, or indeed how physical activity (or prolonged sitting) affects children s cardiometabolic health (i.e. their risk of developing heart disease or diabetes). Here, we are going to look into how feasible it is to set up a study to measure the effect of physical activity on the cognitive functioning of children when at school.

Who can participate?

Dutch speaking, healthy children between the ages of 10 and 13.

What does the study involve?

All participating children eat the same breakfast in the morning. They are then randomly allocated into one of three groups. Those in group A sit for a prolonged period in their classroom at school (all morning). Those in group B also sit in their classroom, but with an active break (where the children do a physical activity) halfway through the morning. Those in group C start the day with a physical activity, then sit down in their classroom with an active break halfway through the morning. Blood samples are taken from all the children just before they eat their breakfast and then at the end of the morning. They all take part in cognitive functioning tests at various times throughout the morning.

What are the possible benefits and risks of participating? There is very little risk to taking part in this study. Blood samples are collected using a fingerprick method, a commonly used technique with few risks.

Where is the study run from?

Department of Public and Occupational Health, VU University Medical Centre, Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for? June 2013 to June 2014 Who is funding the study? EMGO Institute for Health and Care Research (Netherlands)

Who is the main contact? Dr Amika Singh a.singh@vumc.nl

Contact information

Type(s) Scientific

Contact name Dr Amika Singh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers NL43909.029.13

Study information

Scientific Title Physical activity, sitting and cognition a pilot study

Study objectives

We hypothesized that both one as well as two bouts of moderate-intensity physical activity would enhance childrens selective attention, with larger effects for repeated bouts, when compared to sitting the whole morning.

Ethics approval required Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the VU University Medical Center, Amsterdam (The Netherlands), 17/12/2013

Study design Randomised pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Other

Study type(s) Quality of life

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

Physical activity, cognitive functioning

Interventions

Group A - prolonged sitting Group B - sitting with an active break halfway the morning Group C - day start with physical activity, then sitting with an active break halfway the morning

Intervention Type

Behavioural

Primary outcome measure

Selective attention according to the TEA-CH test, measured at baseline, after 20, 110, 130 and 220 minutes

Secondary outcome measures

Fasting blood levels of C-peptide, triglycerides and cholesterol, measured at baseline, after 20, 110, 130 and 220 minutes

Overall study start date 01/06/2013

Completion date 01/06/2014

Eligibility

Key inclusion criteria

Aged between 10-13 years
 Apparently healthy
 Dutch speaking

Children were requested to refrain from any moderate-to-vigorous physical activity (MVPA) for at least 3 days prior to the experiment.

Participant type(s) Healthy volunteer

Age group Child

Lower age limit 10 Years

Upper age limit 13 Years

Sex Both

Target number of participants 60

Key exclusion criteria

Known physical activity contraindications
 Major illness/injury (acute or chronic)
 Physical problems that may limit the ability to perform the experiment

Participants will be screened by a health check questionnaire.

Date of first enrolment 01/06/2013

Date of final enrolment 01/06/2014

Locations

Countries of recruitment Netherlands

Study participating centre van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

Sponsor information

Organisation EMGO Institute for Health and Care Research (Netherlands)

Sponsor details

VU University Medical Center Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

Sponsor type University/education

ROR https://ror.org/0258apj61

Funder(s)

Funder type University/education

Funder Name EMGO Institute for Health and Care Research, VU University Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Results article Details Date created results 01/10/2016

Date added

Peer reviewed? Yes Patient-facing?

No