

# Effectiveness of asset-based physical activity promotion intervention program in pre-vocational adolescents to enhance intervention effectiveness through student participation: the SALVO parallel-group randomized trial

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<b>Registration date</b> 12/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/06/2021	<b>Condition category</b> Other	<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 declines during adolescence resulting in activity levels below recommended guidelines. Only about 28% of 12-17-year-old children in the Netherlands meet these recommendations. Therefore, promotion of physical activity within the (pre-vocational) school context is recommended. Although some school-based interventions are theoretically well-founded, data on effectiveness are missing. To stimulate pre-vocational students to become more physically active researchers invited the target group to participate in the co-creation and implementation of an intervention plan. The interventions arising from this process were aligned to the assets of the students and were aimed to promote physical activity and physical fitness.

### Who can participate?

Pre-vocational adolescents aged 13-16 years old, teachers, school project coordinators and school principals at pre-vocational schools in the Netherlands

### What does the study involve?

The prevocational schools are randomly allocated into an intervention group or a control group. The control schools conduct the regular school curriculum. The intervention schools receive an intervention mix tailored to their students and the school environment. These activities are additional to the regular physical education classes. Interventions vary in types of physical activities, duration, frequency and location per school. The effectiveness of the intervention is assessed using physical activity questionnaires and fitness tests during regular physical education classes at the start of the study and 1 and 2 years follow up.

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

Students are invited to participate in physical activities that meet their interests and are enjoyable. Intervention activities arising from the intervention plan are organized during the

school day always under the supervision of school staff. Students might benefit from increased physical activity and fitness level. There are no potential risks for participants.

Where is the study run from?

1. Amsterdam University of Applied Sciences Faculty of Sports and Nutrition (Netherlands)
2. University of Applied Sciences Arnhem/Nijmegen (Netherlands)

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

September 2013 to December 2017

Who is funding the study?

1. Netherlands Organisation for Scientific Research
2. Netherlands Organisation for Health Research and Development

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

50-54600-98-105

## Study information

## **Scientific Title**

Mixed methods evaluation of the school-based SALVO intervention on physical activity and fitness

## **Study objectives**

1. Over 2 years of follow-up, the intervention group has a higher degree of physical activity compared to the control group
2. Over 2 years of follow-up, the intervention group has a higher physical fitness level compared to the control group
3. Over 2 years of follow-up, the intervention group with a higher degree of student participation shows a greater intervention effect on the outcome measures compared to the intervention group with a lower degree of student participation

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The study does not fall under the jurisdiction of the Dutch Medical Research Involving Human Subjects Act (WMO) given that the researchers are not conducting scientific medical research in which the subjects need to complete actions or protocols covered under the Dutch Medical Research Involving Human Subjects Act. The study was approved on 16/05/2016 by the ethics committee of the HAN University of Applied Sciences (Postbus 6960, 6503 GL Nijmegen, The Netherlands; Tel: +31 (0)6 55 43 42 84; Email: adviescommissie-onderzoek.ggm@han.nl), ref: ACPO 34.05/16

## **Study design**

Two-group cluster randomized trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Physical activity behavior and physical performance level

## **Interventions**

A two-group cluster randomised trial (22 pre-vocational schools) was conducted with assessments at baseline (2015) and two yearly follow up (2016 & 2017). The prevocational schools were randomized into an intervention group or a control group after stratification according to their location. The implementation of the intervention followed three steps. Firstly, the asset-based analysis of behavioral determinants was performed on a subsample of the pre-vocational adolescents (1 class) of each intervention school by using Motivational Interviewing in the Structured Interview Matrix (SIM) and the Photovoice (PV) method. The SIM examines what students think of an active lifestyle and which ways they know how to follow up on this lifestyle. In the PV method, students use photos to make a presentation about the opportunities for an active lifestyle in the school environment and their own neighborhood. These photos are then presented to each other and to the researchers, with an oral explanation. During the second step, two focus group sessions were held between a subsample of 4 students, researchers, members of the teaching staff and school board. In this triangulation process, the drivers of

behavior (assets) were matched with an inventory of the best described and substantiated interventions for this target group and the opportunities for implementation of an intervention provided by the school. During focus group sessions, students were encouraged to advise and co-decide in the development of an intervention plan. In the third step, an intervention mix tailored to the assets of the adolescents and the school environment was designed and implemented per school. These activities were additional to the regular physical education classes. Extra focus group sessions were held if external stakeholders would play a role in conducting the intervention at the school. Interventions vary in types of physical activities, duration, frequency and location per school. The control schools conducted the regular school curriculum. An implementation process of at least 1 school year (max. 3) at schools is facilitated by a team of research assistants who help implement the SALVO, along with other stakeholders such as teachers and the school's principal.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Physical activity (sedentary behavior, active commuting to school, sports activities, total physical activity) is measured using a validated Physical Activity Questionnaire (hours/week) at baseline, 1 and 2 years follow up

### **Key secondary outcome(s)**

Physical performance level (coordination, flexibility, endurance, strength, speed and body height and body weight) measured using the Eurofit test battery at baseline, 1 and 2 years follow up. The measurements include: long jump (cm), bent arm hang (seconds), 10x5 mini shuttle run (seconds), sit & reach (cm), plate tapping (seconds), sit-ups (number/30 seconds), grip strength (kg), body weight (kg), body length (cm), sum of skinfolds (mm)

### **Completion date**

20/12/2017

## **Eligibility**

### **Key inclusion criteria**

Pre-vocational students

### **Participant type(s)**

All

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Sex**

All

### **Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/02/2014

**Date of final enrolment**

01/07/2014

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Amsterdam University of Applied Sciences Faculty of Sports and Nutrition**

Dr Meurerlaan 8

Amsterdam

Netherlands

1067 SM

**Study participating centre**

**University of Applied Sciences Arnhem/Nijmegen**

Heyendaalse weg 141

Nijmegen

Netherlands

6524 TM

## Sponsor information

**Organisation**

Amsterdam University of Applied Sciences

**ROR**

<https://ror.org/00y2z2s03>

## Funder(s)

**Funder type**

Government

**Funder Name**

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

**Alternative Name(s)**

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Netherlands

**Funder Name**

ZonMw

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## Results and Publications

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

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

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		01/06/2021	15/06/2021	Yes	No