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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

Submission date	**Recruitment status**	[_] Prospectively registered
07/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/06/2021	Other	[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

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
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 measure
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

Secondary outcome measures
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)

Overall study start date
01/09/2013

Completion date
20/12/2017

Eligibility

Key inclusion criteria
Pre-vocational students

Participant type(s)
All

Age group
Child

Sex
Both

Target number of participants
Target number of pre-vocational schools is 22. The total number of students included is 1000 per cluster arm, the total sample is 2000 children.

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
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Study participating centre
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Sponsor type
University/education

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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, 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

Publication and dissemination plan
The researchers intend to publish four scientific articles on this evaluation study and will present their findings at conferences. Two publications will arise from this study: a protocol & design article and one effect evaluation article both published in 2020.

Intention to publish date
01/06/2020

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?
Protocol article		01/06/2021	15/06/2021	Yes	No