The role of physical activity in improving the well-being of children and youth

Submission date	Recruitment status	Prospectively registered	
24/04/2015	No longer recruiting	[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
11/05/2015	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
25/02/2021	Other		

Plain English summary of protocol

Background and study aims

Taking part in physical activity, such as sports, is known to benefit children's mental health. Physical activity can help build social skills, self-esteem and positive well-being, and is linked to higher achievement at school. Unfortunately, many children and young people do not exercise enough. Physical inactivity is a growing problem in children, and it can affect their well-being, physical and mental health. Various school-based methods to increase physical activity among children have been effective in increasing activity and/or preventing inactivity. However, which aspects of these methods work best is not known, and there is no standard guideline for promoting physical activity in schools. There is also a need to see how best to promote and improve the mental health and well-being of children and adolescents. The aim of this study is to develop a school-based physical activity programme which also works to improve mental health and well-being among schoolchildren aged 9-12.

Who can participate?

Children aged 9-12 (4-6th grade) attending participating schools.

What does the study involve?

Participating schools are randomly allocated into one of two groups. Those in group 1 (intervention group) have physical activity programme training for key staff to deliver to participating children. Those in group 2 (control group) have no physical activity programme training for key staff, but are given the opportunity to have this training at the end of the study. All participating children complete online questionnaires at the beginning and end of the school year.

What are the possible benefits and risks of participating?

Children and young people taking part in the study may benefit from participating in a number of ways. For example, physical activity has been shown to improve the mental health of children. There is a minor risk of sustaining injuries when taking part in the intervention components, such as sports.

Where is the study run from?
University of Southern Denmark (Denmark)

When is the study starting and how long is it expected to run for? February 2014 to March 2017

Who is funding the study? TrygFonden (Denmark)

Who is the main contact? Associate Prof T Skovgaard tskovgaard@health.sdu.dk

Contact information

Type(s)

Public

Contact name

Dr Thomas Skovgaard

Contact details

Campusvej 55 Odense M Denmark DK-5230 +45 24984064 tskovgaard@health.sdu.dk

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Improving the well-being of children and youth: a multicomponent school-based physical activity intervention

Study objectives

A multicomponent school-based physical activity intervention will improve psychosocial well-being among school-aged children and youth (4th to 6th grade, 9-12 years).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Conforming to current legislation, the project was submitted to The Regional Scientific Ethical Committees for Southern Denmark. The committee decided that the project was exempt from the obligation to notify. Notification of this decision was forwarded via email 02/04/2014.

Study design

A four phased intervention:

- 1. Design phase consolidating the rationale for the intervention, the likely processes of change and further provision of evidence for proposed interventions (February 2014-July 2014).
- 2. Pilot phase including assessments of how the proposed intervention can be adapted to the school-setting. This entails systematic appraisals of sustainable ways to deliver the in-tervention as prescribed, and examining the key uncertainties that have been identified during the design phase. In the pilot intervention components will be tested to ensure that they are feasible to implement and deemed effective in relation to short-term and/or final outcomes. 4 schools take part in the pilot test (August 2014-April 2015).
- 3. Cluster randomized controlled trial in order to rigorously test the effectiveness of the full-scale, piloted intervention. 24 schools located in seven of the 98 Danish municipalities have been recruited as intervention or control units. The intervention period will cover a whole school year (August 2015-June 2016).
- 4. Program evaluation phase assessing the overall quality of the intervention and aiding decision-making about intervention improvement and potential for scaling-up. The program evaluation will combine qualitative and quantitative methods, and be designed to gather valid information on key processes and outcomes.

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Well-being and self-concept

Interventions

Participating schools will be randomly allocated to either the intervention group or the control group. The control group will be given the opportunity to implement the intervention one year later. Baseline measurements are conducted in the beginning of a school year, followed by final assessment in the end of the school year for all participating schools The intervention involves:

- 1. Establishment of a coordination group: at each participating school a group consisting of key stakeholders (teachers, principals and student representatives) is assembled in order to establish a foundation for the intervention.
- 2. Competence development program (CDP) for educators: CDP will train enrolled educators to support student motivation and participation in school-based PA. The CDP will also provide attendees with up-to-date knowledge on topics closely related to PA and psychosocial well-being (support proficiencies and motivate colleagues to take part).
- 3. Activities and materials for PE, recess and other parts of the curricular: initiate activities during the school day. These activities are aimed at all children and conducted during PE, recess and other parts of the curriculum and school day.
- 4. Targeted program for children with special needs/challenges: informed by the model of school change developed by the World Health Organisation and used in a number of mental health intervention projects. It uses a whole-school approach while being aware of students with special needs.

Intervention Type

Behavioural

Primary outcome(s)

Physical self-perception measured using the Children's Physical Self-Perception Profile (C-PSPP) and the Self-Perception Profile for children (SPPC). Measurements are carried out 08/2015 and 06/2015 by online survey.

Key secondary outcome(s))

Measured in 08/2015 and 06/2016 by online survey:

- 1. General well-being (Kidscreen-27)
- 2. Physical Activity Self-Efficacy Scale (PASES)
- 3. Physical Activity Enjoyment Scale (S-PACES)

Completion date

01/03/2017

Eligibility

Key inclusion criteria

Children aged 9-12 (4-6th grade) attending public school

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

9 years

Upper age limit

12 years

Sex

All

Kev exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

15/12/2014

Date of final enrolment

30/03/2015

Locations

Countries of recruitment

Study participating centre University of Southern Denmark

Exercise Epidemiology (ExE)/Research in Childhood Health (RICH)/Active Living (AL)
Department of Sports Science and Clinical Biomechanics (ISSCB)
Odense M
Denmark
DK-5230

Sponsor information

Organisation

University of Southern Denmark

ROR

https://ror.org/03yrrjy16

Funder(s)

Funder type

Charity

Funder Name

TrygFonden (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created Date	added Peer reviewed?	Patient-facing?
Results article	results	16/11/2017 25/02	2/2021 Yes	No
Protocol article	protocol	28/10/2016	Yes	No

Participant information sheet