# A school-based intervention to improve mental health, cognitive function and academic performance in adolescents

| Submission date              | <b>Recruitment status</b> No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|------------------------------|--|--|--|--|
| 15/04/2021                   |  | <pre>Protocol</pre>                        |  |  |
| Registration date 27/04/2021 | Overall study status Ongoing                   | Statistical analysis plan                  |  |  |
|                              |  | Results                                    |  |  |
| Last Edited                  | <b>Condition category</b><br>Other             | Individual participant data                |  |  |
| 23/05/2025                   |  | [X] Record updated in last year            |  |  |

#### Plain English summary of protocol

Background and study aims

Most adolescents do not meet physical activity recommendations and there has been an increase in mental health problems. Adolescents report decreased time reading and there is a large variation in reading comprehension depending on socio-economic background. There is inadequate evidence on what types of school-based interventions improve mental health, cognitive function and academic performance and how to implement such interventions. The aim of this study is to develop an effective multi-component school-based intervention that will target both physical activity and homework support during an extended school day and evaluate its effects on mental health and cognitive function as well as academic performance. The following research questions will be investigated:

- 1. What are the barriers and facilitators for extending the school day perceived by teachers, school leaders and students? What are the preferred implementation strategies for physical activity and homework support in the school context?
- 2. What are the effects of a school-based programme including physical activity and homework support during an extended school day on mental health, cognitive function and academic performance?
- 3. Are there any differences in the effects of the intervention in relation to gender, socioeconomic status, baseline levels of anxiety, cognitive function, academic performance, fitness, physical activity patterns and time spent on homework?
- 4. How is the programme implemented with regard to dose, fidelity, feasibility and acceptability? What are the barriers and facilitators identified in the implementation of the intervention?

#### Who can participate?

- 1. Principals and a selection of teachers and student representatives as well as representatives from relevant public institutions.
- 2. Adolescents aged 14-15 (grade 8) in the participating schools.
- 3: Teachers and a sample of students from the intervention schools

What does the study involve?

This research project will evaluate both the health outcomes and the implementation process in three sub-studies.

Study 1 (Spring 2021): Data will be collected through workshops in four schools with a selection of principals, teachers and student representatives as well as representatives from relevant public institutions. At the workshop, the project will be presented followed by a discussion about perceptions of barriers and facilitators of the planned intervention, equality perspectives, and suggestions on feasible implementation strategies for the intervention components. In addition, the study will provide new knowledge on contextual adaptations and implementation strategies in the school context. All workshops will be audio-recorded, transcribed and analysed using content analysis. The results will be used to develop implementation strategies in study 2.

Study 2 (2021-2024): Fifty-four schools with 2700 adolescents aged 14-15 years will be randomly allocated to the intervention or control group. Two waves are planned: the first wave starting in the fall of 2021 and the second wave starting in the fall of 2022. The intervention will be based on evidence-based principles for supporting sustainable motivation and behaviour and will run over a school year. It will be performed during an extended school day, 60 minutes three times per week, during one school year and include different types of teacher-led physical activities, homework support with activity breaks, and walking and listening to a digital book. The activities will be led by school staff to make the programme integrated and sustainable.

Data will be collected before, after and 1 year after the intervention (final follow-up measurements in May/June of 2024). The primary outcomes will be physical activity patterns measured by accelerometry, anxiety assessed with a questionnaire and cognitive function (working and episodic memory) measured with computer-based tests. Questionnaires will be used to measure health-related quality of life, motivation to physical activity, stress, self-esteem, hyperactivity, screen time, time spent on homework and health behaviours. Body weight and height will be measured, as well as academic performance by grades and fitness with a step-test. Parental educational level will be used as an indicator of socioeconomic status. Information about the school environment and policy will be collected from teachers.

Study 3 (2022-2024): Teachers' documentation about performed activities, student participation and any adaptations to the intervention protocol will be analysed. The feasibility and acceptability will be explored by focus groups and interviews, focusing on facilitators and barriers, the potential influence of gender and student needs on intervention delivery and outcome. Teachers and students will be invited to focus groups with 6-8 participants in each focus group. In addition, a selection of teachers and students will be invited to interviews. All focus groups and interviews will be audio-recorded, transcribed and analysed.

What are the possible benefits and risks of participating?

Some of the data collection will be performed in groups and the participants might feel uncomfortable. The participants might also be uncomfortable answering certain questions i.e. on mental health. The benefits include a membership for the students to an audiobook service.

Where is the study run from?

The Swedish School of Sport and Health Sciences (Gymnastik- och idrottshögskolan) (Sweden)

When is the study starting and how long is it expected to run for? September 2020 to June 2026

Who is funding the study?

Knowledge Foundation (grant no. 20210002), Skandia, The Kamprad Family Foundation for Entrepreneurship, Research & Charity, The Swedish ESF Council, and the Strategic Research Area in Health Care Science (SFO-V) at Karolinska Institutet.

Who is the main contact? Gisela Nyberg gisela.nyberg@gih.se

## 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

Nil known

# Study information

#### Scientific Title

A school-based intervention to improve mental health, cognitive function, and academic performance in adolescents: a cluster-randomized controlled trial

#### Study objectives

The primary hypothesis is that due to the multi-component intervention the adolescents will favourably change their physical activity patterns and time spent on homework as compared to

the control group. The secondary hypothesis is that these changes in activity patterns and behaviours will in turn have positive effects on mental health, cognitive function and academic performance. The third hypothesis is that gender, socioeconomic status, baseline levels of anxiety, cognitive function, academic performance, fitness, physical activity patterns, and time spent on homework will moderate or mediate the effects of the intervention.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 13/04/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2021-00911

#### Study design

Interventional single-blinded cluster randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Prevention

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

Improving brain function, i.e. mental health and cognitive function as well as academic performance in adolescents

#### Interventions

The list of schools that will participate will be computer randomized as this will be a cluster-randomized trial, with each school representing one cluster. The randomization will be done in blocks of 12.

The intervention will be performed during an extended school day, 60 minutes three times per week, during one school year and include:

- 1. Different types of teacher-led physical activities
- 2. Homework support with activity breaks
- 3. Walking and listening to an audiobook

The control group will have unchanged school schedules.

#### Intervention Type

Behavioural

#### Primary outcome(s)

- 1. Physical activity patterns measured by accelerometry at baseline, post-intervention and 1-year follow-up.
- 2. Anxiety assessed with a questionnaire (SCAS-S) at baseline, post-intervention and 1-year follow-up
- 3. Cognitive function (working memory and episodic memory) measured with a computer-based test battery at baseline, post-intervention and 1-year follow-up

## Key secondary outcome(s))

- 1. Academic performance measured by grades from registry data at baseline, post-intervention and 1-year follow-up
- 2. Health-related quality of life measured using KIDSCREEN-27 (questionnaire) at baseline, post-intervention and 1-year follow-up
- 3. Stress measured using single-item stress question, SISQ (questionnaire) at baseline, post-intervention and 1-year follow-up
- 4. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSES) (questionnaire) at baseline, post-intervention and 1-year follow-up
- 5. Hyperactivity and inattention measured using the Strengths and Difficulties Questionnaire (SDQ) (questionnaire) at baseline, post-intervention and 1-year follow-up
- 6. Motivation to physical activity using the Behavioural Regulation in Exercise Questionnaire, adapted BREQ (questionnaire) at baseline, post-intervention and 1-year follow-up
- 7. Cardiorespiratory fitness estimated with a 3-minute step-test at baseline, post-intervention and 1-year follow up
- 8. Body weight and height measured according to standardised procedures at baseline, post-intervention and 1-year follow-up
- 9. Self-reported screen-time at baseline, post-intervention and 1-year follow-up
- 10. Self-reported time spent on homework at baseline, post-intervention and 1-year follow-up
- 11. Self-reported health behaviours at baseline, post-intervention and 1-year follow-up
- 12. Information about the school-environment collected using a questionnaire at baseline, post-intervention and 1-year follow-up

#### Completion date

30/06/2026

# **Eligibility**

#### Key inclusion criteria

Study 1 (qualitative interviews):

Inclusion criteria:

- 1. Teachers and principals working in schools in Sweden
- 2. Students from schools in Sweden aged 14-15 years old
- 3. Representatives from stakeholders in the area, such as teachers and principals from schools that have increased physical activity and homework support in their schools and representatives from relevant public institutions

Study 2 (quantitative):

Inclusion criteria (schools):

1. Schools in Sweden (principals will be contacted)

Inclusion criteria (participants):

- 1. All students attending grade 8 in schools in Sweden (aged 14-15 years)
- 2. Teachers from the included schools

Study 3 (mix of qualitative and quantitative):

Inclusion criteria:

- 1. Students in grade 8 from the intervention schools
- 2. Teachers and principals from the intervention schools

#### Participant type(s)

Mixed

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

14 years

#### Upper age limit

15 years

#### Sex

All

#### Key exclusion criteria

Study 1 (qualitative interviews):

Exclusion criteria (students):

1. Not able to speak and understand Swedish

#### Study 2 (quantitative):

Exclusion criteria (schools):

- 1. Schools that have an extra focus on sports
- 2. Schools where grade 8 include less than 15 students
- 3. Prinicipal of the school unwilling to accept randomisation

#### Exclusion criteria (students and teachers):

1. Those students that cannot participate in some aspects of the data collection due to disability or language barriers might be excluded from some of the analyses

Study 3 (mix of qualitative and quantitative):

Exclusion criteria (students):

1. Not able to speak and understand Swedish

#### Date of first enrolment

26/04/2021

#### Date of final enrolment

30/06/2025

## Locations

#### Countries of recruitment

Sweden

#### Study participating centre

The Swedish School of Sport and Health Sciences (Gymnastik- och idrottshögskolan)

Lidingövägen 1

# Sponsor information

#### Organisation

Swedish School of Sport and Health Sciences

#### **ROR**

https://ror.org/046hach49

# Funder(s)

## Funder type

Charity

#### **Funder Name**

**Knowledge Foundation** 

#### Alternative Name(s)

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

United States of America

#### **Funder Name**

Skandia

#### **Funder Name**

The Kamprad Family Foundation for Entrepreneurship, Research & Charity

#### **Funder Name**

#### Funder Name

Strategic Research Area in Health Care Science (SFO-V) at Karolinska Institutet

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

### IPD sharing plan summary

Not expected to be made available

## **Study outputs**

| Output type                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Participant information sheet | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| Study website                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |