

Healthy High School: a high school intervention to improve well-being among students

Submission date 26/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In their first year at high school many students develop or continue unhealthy behaviours such as unhealthy eating habits, highly sedentary (inactive) lifestyle and poor sleeping habits, and many students feel stressed and lonely, all of which play an important role with regards to their well-being. In Denmark, few interventions have targeted high schools students (age group 16-19) as a setting for promotion of healthy lifestyle and well-being. The aim of this study is to develop, carry out and assess a sustainable high school intervention to promote well-being and a healthy school day among students.

Who can participate?

Students enrolled in school year 1 (15-17 years old) at the participating high schools

What does the study involve?

Participating high schools are randomly allocated into either the intervention or the control group. At intervention high schools students in school year 1 (≈age 16) receive the intervention programme during school year 2016/2017. The intervention programme includes student exercises, teacher manuals, a teacher script for a feature week (optional), a catalogue on how to conduct organizational changes in the high school, an app and Young & Active activities. The control schools continue as usual without any intervention (some of the components of the intervention are offered to the control schools after the end of the study). The students' well-being, physical activity, meal and eating habits, stress, sleep and sense of community are assessed using online surveys 1 month and 1 year later.

What are the possible benefits and risks of participating?

The high schools receive a free workshop introducing the study, free educational material and a free catalogue with suggestions for health promoting initiatives at the school. The students receive a free app with the aim to increase their knowledge and awareness about stress, sleep, movement and meals/eating habits. There is a minor risk of sustaining injuries when taking part in the intervention components that address physical activity. Further, the primary focus on a healthy lifestyle may increase the students' individual pressure or life expectations and induce feelings of stress or reduce their well-being.

Where is the study run from?

The Centre for Intervention Research in Health Promotion and Disease Prevention and The Child and Adolescent Health Research Programme, The National Institute of Public Health, University of Southern Denmark (Denmark)

Who is funding the study?

1. TrygFonden (Denmark)
2. Nordea-fonden (Denmark)

Who is the main contact?

1. Mrs Rikke Fredenslund Krølner
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2. Ms Katrine Rich Madsen
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Study website

<http://www.interventionsforskning.dk/child-health/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

02-2015-1364

Study information

Scientific Title

Healthy High School: a cluster randomised, multi-component, high school-based trial to improve well-being among students

Study objectives

1. That the intervention will increase the prevalence of students with high level of well-being by 6% among first year high school students in intervention schools compared to control schools
2. That the intervention is able to produce a persistent increase in the level of well-being among high school students in intervention schools compared to control schools after two years follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

There is no formal institution for ethical assessment and approval of questionnaire-based population studies in Denmark. Conforming to current national legislation, the project was submitted to The Regional Scientific Ethical Committees, The Capital Region of Denmark. The committee decided that the project was exempt from the obligation to notify. Notification of this decision was forwarded via email 04/03/2016, ref: J.nr 16018722. This project is registered at the Danish Data Protection Agency, ref: J.nr 2015-57-0008.

Study design

Cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Well-being, movement, meal and eating habits, stress, sleep and sense of community

Interventions

A strategic sample of 40 high schools, which had all participated in the Danish National Youth Study (DNYS) 2014, was invited to participate in the study. DNYS 2014 is a national questionnaire survey focusing on health behaviour, health and well-being among Danish high school students. All high schools in Denmark (n=137) were invited to participate in DNYS of which 119 high schools accepted the invitation. Data from DNYS was used to rank the high schools based on the students' answers to the Cantril Ladder of Life Scale. The 40 high schools with the lowest proportion of students with a high level of well-being (rating 7-10 on the Cantril Ladder) comprised the strategic sample and were invited to participate in the study. Schools were randomized into intervention and control groups by computer-based random number generation. Selection of target group, development of the intervention programme and evaluation design is guided by the Intervention Mapping protocol.

Students in high school year 1 (≈age 16) at the intervention schools receive the intervention programme (described below) during school year 2016/17 (nine months), whereas students at the control schools do not receive any intervention (no treatment). Intervention components will be offered to the control schools after the finalisation of the project.

Timeline:

Baseline survey: August 2016

Implementation of intervention in intervention high schools: August 2016-April 2017

First follow-up survey: May 2017

Second follow-up survey: April/May 2018

Intervention programme:

Program activities were organized within two settings (at high school and in the leisure time setting) and comprise four main components:

1. Curricular activities (high school setting)

Student exercises and a teacher manual to guided classroom activities that focus on four main subjects: stress, sleep, movement and meal/eating habits, to be integrated into four different school subjects. A total of 14 compulsory lessons (1 lesson = 2x45 minutes) and two optional lessons.

Teacher script for a feature week focusing on issues concerning healthy and unhealthy living (optional).

2. Catalogue focusing on organizational change (high school setting):

A catalogue with 17 initiatives (ten mandatory and seven optional) on how to conduct organizational changes in the high school to support the students' health and well-being, e.g. implementation of school health policies, implementation of activity breaks in classes, access to cold and clean water and time management courses for students.

3. Young & Active (high school setting):

Through peer-led innovation workshops students are inspired to initiate and participate in a

broad range of activities that focus on movement, sense of community and well-being. In continuation of the workshop, students are encouraged to carry on the activities and implement them at their high school. Further, the schools have the opportunity to apply for a start-up grant to initiate new activities at their high school. Participating students will be trained to conduct the workshop for future first grade students and thereby secure sustainability of Young & Active for future high school students.

4. An app (leisure time setting):

An app with the aim to support the student's healthy habits by influencing their knowledge and awareness of four main themes: stress, sleep, movement and meal and eating habits, including for instance:

4.1. Breakfast, healthy snacks and lunch recipes

4.2. Training programs and easy tips for increasing physical activity and reducing sedentary behaviour

4.3. Information about signs and symptoms of stress and examples of diverse techniques to prevent and reduce stress

4.4. Information about issues concerning sleep and advice on how to establish healthy sleep habits

4.5. An option to track sleep, physical activity and eating and meal habits on a daily basis

4.6. Competitions where school classes compete against other school classes and high schools involved in the intervention

Evaluation of the intervention

Process evaluation: The implementation of the intervention will be monitored by a thorough mixed methods process evaluation.

Effect evaluation: The primary aim of the effect evaluation will be to assess whether our goal of an increase in the prevalence students with a high level of well-being by 6% has been achieved at intervention schools. All further impacts of the intervention such as intended proximal effects and unintended positive and negative side effects will also be subject to evaluation. Outcomes will be analysed after the principle of intention-to-treat. To account for the cluster-design and repeated measurements, changes in well-being from baseline to first- and second follow-up will be analysed by multilevel multivariate regression analyses.

Intervention Type

Behavioural

Primary outcome measure

Well-being, measured using the WHO-Five Well-Being Index and the Cantril Ladder of Life Scale (online survey) at 1st and 2nd follow-up

Secondary outcome measures

1. Stress, measured by:

1.1. The 10-item Perceived Stress Scale (online survey)

1.2. Stress intensity and stress frequency (online survey and SMS survey)

2. Sleep, measured by:

2.1. Sleep quantity (online survey)

2.2. Sleep quality (online survey)

3. Movement, measured by:

- 3.1. Hours of moderate-to-vigorous physical activity per week (online survey)
- 3.2. Average daily physical activity measured in a subsample (accelerometer)
- 3.3. Hours of daily sedentary time (online survey, accelerometer)

4. Meal and eating habits, measured by:

- 4.1. Daily intake of breakfast (online survey)
- 4.2. Daily intake of lunch (online survey)
- 4.3. Daily intake of water (online survey)

5. Sense of community, measured by:

- 5.1. Sense of community at high school (online survey)
- 5.2. School class sense of community (online survey)

All secondary outcome measures will be measured at both 1st and 2nd follow-up.

Overall study start date

01/01/2014

Completion date

01/06/2019

Eligibility

Key inclusion criteria

- 1. Attending high schools with a minimum of two school year 1 classes that participated in the Danish National Youth Study 2014, in which 66% of all Danish High Schools attended
- 2. First year students attending the general upper secondary education provision of the Gymnasium (the stx programme) in the school year 20016/2017

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

6097 students (15 intervention schools comprising 2950 students and 16 control schools comprising 3147 students)

Total final enrolment

5201

Key exclusion criteria

- 1. Students attending International upper secondary school classes
- 2. Students in classes participating in the Team Danmark programme
- 3. High schools with a majority of boarding school students

Date of first enrolment

06/04/2016

Date of final enrolment

20/05/2016

Locations

Countries of recruitment

Denmark

Study participating centre

National Institute of Public Health, University of Southern Denmark

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Sponsor information

Organisation

TrygFonden

Sponsor details

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Sponsor type

Charity

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ROR

<https://ror.org/02rcazp29>

Organisation

Nordea-fonden

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Sponsor type

Charity

Website

<http://nordeafonden.dk/english>

ROR

<https://ror.org/03qadc961>

Funder(s)

Funder type

Charity

Funder Name

TrygFonden

Alternative Name(s)

Tryg Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Denmark

Funder Name

Nordea-fonden

Alternative Name(s)

Nordea Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Denmark

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available in anonymous form upon request from Rikke Fredenslund Krølner (rkr@si-folkesundhed.dk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/01/2020	24/01/2020	Yes	No
Results article	Process evaluation	04/02/2022	07/02/2022	Yes	No
Other publications		27/03/2020	08/06/2023	Yes	No
Results article		01/09/2021	08/06/2023	Yes	No
Results article	First follow up	18/01/2023	08/06/2023	Yes	No