ISRCTN36701918 https://doi.org/10.1186/ISRCTN36701918

Evaluation of the school-based intervention Charge Your Brainzzz promoting sleep in adolescents

Submission date
29/10/2019

Recruitment status
No longer recruiting

Registration date
08/11/2019

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Inadequate sleep is widespread among adolescents and many studies report a decrease in their sleep duration and quality. Short sleep duration and quality have a negative impact on learning ability, memory and concentration, and consequently school performance. Sleep deprivation also has other mental and physical consequences. Schools can be an appropriate setting for programs that promote healthy sleep in adolescents, as school-based programs were already found to be successful for other health-related behaviors such as physical activity and obesity. The context of school provides an environment for learning and a large part of the youth population can be reached. However, effective programs that focus on sleep are currently lacking in the Netherlands. For this purpose, the school-based educational program ‘Charge Your Brainzzz’ was developed by the Dutch Brain Foundation (Hersenstichting Nederland) to promote healthy sleeping in Dutch adolescents by improving knowledge and attitudes towards sleep and sleep hygiene practices. The program consists of three sleep-education lessons and a serious game provided as homework. The aim of this study is to examine the effectiveness of the Charge Your Brainzzz intervention on adolescents' sleep duration and sleep quality. Also, changes in adolescents’ sleep hygiene and behavioral determinants are examined.

Who can participate?
Second- and third- grade students at participating high schools

What does the study involve?
Schools are randomly allocated to either the intervention or control group. The intervention group participate in the Charge Your Brainzzz program, while control groups do not participate in the program. Both groups are asked to fill in a sleep diary and a questionnaire at three points in time. The study lasts about 4 months. By participating in the study, classes can win a group excursion.

What are the possible benefits and risks of participating?
Students could improve their sleep behavior while being exposed to the intervention. In addition, school classes could win a group excursion when participating in this study. Five group

excursions will be raffled in this trial. Students' awareness regarding sleep behavior could increase when participating in this study, which may lead to undesired changes in thoughts on sleep behavior. However, this risk is considered minimal.

Where is the study run from?
Vrije Universiteit Amsterdam and the Municipal Health Service Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
March 2018 to February 2019

Who is funding the study?
The Dutch Brain Foundation (Hersenstichting) (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
WC2017-093

Study information

Scientific Title
Mixed methods evaluation of a school-based intervention promoting sleep in adolescents: a cluster-randomized controlled trial

Study objectives
It is hypothesized that the intervention is effective in improving sleep behavior (i.e. sleep duration and sleep quality), sleep hygiene and behavioral determinants (i.e. knowledge, attitude, subjective norm, self-efficacy and intention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was evaluated on 28/05/2018 by the Medical Ethical Committee of the Amsterdam UMC (VUmc) (BS7, room H-443, Postbus 7057, 1007 MB Amsterdam, Netherlands; Tel: +31 (0) 204445585; Email: metc@vumc.nl). They decided official approval was not required for this study as the Medical Research Involving Human Subject Acts (WMO) did not apply (ref: 2018.248). Active written consent from students and their parents or caretakers are necessary prior to enrolment in the study.

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sleep behavior (i.e. sleep duration and sleep quality), sleep hygiene and behavioral determinants (i.e. knowledge, attitude, subjective norm, self-efficacy and intention)

Interventions
After agreement to participate, high schools are allocated to either the intervention or control group by matching based on educational level and number of participating classes within a school. Blinding was not possible as the intervention is an educational program carried out by teachers.

The intervention is the school-based educational program 'Charge Your Brainzzz', which consists of three lessons and a serious game provided as homework. The control schools will not receive the intervention.

Both groups are asked to fill in a sleep diary and a questionnaire at baseline, post intervention (max. 2 weeks after intervention) and follow-up (+/- 3 months after the intervention). The study lasts approximately 4 months.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline, post intervention (max. 2 weeks after intervention) and follow-up (+/- 3 months after the intervention)
1. Sleep duration and sleep quality, measured by a 7-day digital sleep diary, based on the validated Consensus Sleep Diary

2. Sleep hygiene practices, sleep reduction and behavioral determinants (i.e. knowledge, attitude, subjective norm, self-efficacy and intention), measured by a digital questionnaire

Key secondary outcome(s))
1. Students' acceptance and appreciation of the intervention measured by a digital questionnaire (only for the intervention group) at follow-up (+/- 3 months after the intervention)
2. Qualitative data on implementation processes, obtained by interviews with participating teachers from the intervention schools post-intervention (+/- 2 weeks after the intervention)

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Grade 2 or grade 3 students of Dutch high schools
2. Lower General Secondary Education or higher

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
972

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/05/2018

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
Netherlands

Study participating centre

Vrije Universiteit Amsterdam
De Boelelaan 1105
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Vrije Universiteit Amsterdam

ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Charity

Funder Name
Hersenstichting

Alternative Name(s)
Hersenstichting Nederland, Nederlandse Hersenstichting

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are currently 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?
Results article		21/03/2022	27/10/2022	Yes	No
Other publications	Process evaluation	12/08/2025	12/08/2025	Yes	No