ISRCTN92755979 https://doi.org/10.1186/ISRCTN92755979

Implementation evaluation of the school-based weight gain prevention program - [Dutch Obesity Intervention in Teenagers] (DOiT)

Submission date
20/11/2012

Recruitment status
No longer recruiting

Registration date
28/11/2012

Overall study status
Completed

Last Edited
06/11/2015

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The Dutch Obesity Intervention in Teenagers (DOiT) is a school-based program to prevent weight gain in 12 to 14 year old students. We are carrying out a study at 20 schools implementing the DOiT program to compare the quality of implementation of the program. Our goal is to find factors that help or hinder the DOiT program so that we can adjust the strategy of the program and thereby prevent weight gain in Dutch adolescents.

Who can participate?
Teachers, students and their parents at prevocational schools in the Netherlands.

What does the study involve?
Participating schools are randomly allocated to either the intervention group or the control group. Students at the intervention group schools participate in the DOiT program. Students at the control group schools receive regular education. Before the start of the DOiT program and after 20 months, we measure the students' body weight, height, skinfold thickness, waist and hip circumference, and students complete a diet and physical activity questionnaire. After each DOiT lesson teachers complete a log, and at the start of the study and after 10 and 20 months teachers complete a questionnaire about the factors that help or hinder the implementation of DOiT. At the end of each school year a subgroup of teachers and the coordinator are invited for an in-depth interview to gain more insight into the implementation of the DOiT program.

What are the possible benefits and risks of participating?
Students who take part in the DOiT lessons will be supported to change their diet and physical activity levels. There are no risks to participants.

Where is the study run from?
At prevocational schools throughout the Netherlands.

When is the study starting and how long is it expected to run for?
February 2011 to July 2013.

Who is funding the study?
SNS REAAL Fonds, The Netherlands.

Who is the main contact?
Femke van Nassau

Study website
http://www.doitproject.com

Contact information

Type(s)
Scientific

Contact name
Miss Femke van Nassau

Contact details
VUmc MS Center Amsterdam
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Exploring facilitating factors and barriers to the nationwide dissemination of a Dutch school-based weight gain prevention program "DOiT"

Acronym
DOiT

Study objectives
It is hypothesised that the students who receive the fully implemented DOiT program will be less overweight and will have more healthy energy-balance related behaviours compared to students who receive regular education at the control schools.

Ethics approval required
Old ethics approval format

Ethics approval(s)
VU University Medical Center Ethics Board, 11/07/2011 ref: 2011/216

Study design
Cluster-controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight adolescents

Interventions
DOiT is a school-based overweight prevention program for 12 to 14-year olds. DOiT focuses on five EBRBs:
1. Reducing intake of sugar-sweetened beverages
2. Reducing intake of high-energy snacks
3. Reducing screen time
4. Increasing levels of physical activity (i.e. active transport and sports participation)
5. Daily and healthy breakfast consumption

The program consists of a classroom, an environmental and a parental component. The program covers twelve fixed theory lessons, four physical education (PE) lessons, equally divided over two school years,
and three optional additional lessons.

1. The theory lessons in year one aim to increase awareness and knowledge of EBRBs. The lessons in year two focus on the influence of the (obesogenic) environment.
2. The environmental component aims to raise awareness of the school environment, finding solutions to reduce negative influences within the environment and setting a plan for improvement.
3. The parental component focuses on stimulating social support of the parents and raising awareness of the availability and accessibility of healthy products and activities in the home environment.

The DOiT materials include a 'schoolbook' accompanied by worksheets, a student toolkit (pedometer, food/exercise diary and an online computer-tailored advice) and a parental information booklet.

DOiT is supported by an extensive teacher manual with a login for extra materials provided at the DOiT website.

Students at control schools receive regular education (no treatment).

Intervention Type
Behavioural

Primary outcome measure
The primary outcome is the dissemination process measured by teacher questionnaires, logbooks and interviews.

Teacher questionnaire
At baseline, 10 months and 20 months, all teachers involved in the implementation of DOiT are asked to complete an online questionnaire about the impeding and facilitating factors of the implementation of DOiT. The majority of the questionnaire consists of structured questions, measured on a bipolar five-point Likert scale. A few open-ended questions are added. The questionnaire is based on existing
questionnaires, used in the previous DOiT evaluation and the Krachtvoer evaluation study. The questionnaire contains questions regarding the context, recruitment, satisfaction, maintenance, and
potential relevant implementation-related determinants of the program. Additionally, the questionnaire contains items on other ongoing studies and other innovations or school health-promotion programs.

Teacher logbook
After each lesson teachers are requested to complete an online log. Completing the log takes approximately 5 minutes per lesson. Using this log, we aim to administer completeness of implementation by having teachers indicate if the lesson was taught, when it was taught and how the lesson was prepared and implemented. Teachers can tick off what activities were executed in preparation of the lesson on a list of proposed activities according to the teacher manual and how much time they spend on these activities. Teachers tick off what materials were used during the lesson, what lesson activities were implemented and if the implementation complied with the prescription in the teacher manual. Finally, teachers report how much time they spent in the classroom and rate their satisfaction with the lesson on a ten point rating scale.

Interview
At the end of each school year, i.e. in total two times during the research period, a sub-group of teachers and the coordinator are invited for an in-depth interview to gain more insight into the implementation of the DOiT program, its content, recruitment, fidelity and satisfaction with the dissemination strategy, and overall satisfaction with DOiT. Furthermore, facilitators and barriers for implementation, intentions and opportunities for future implementation of DOiT are discussed.

Secondary outcome measures

The secondary outcome is the effect of the program on the students' objectively measured body mass index, skinfold thickness and waist circumference and self-reported energy balance-related behaviours among students.

Body composition
Before the start of DOiT and after 20 months, we measure body weight, body height, skinfold thickness, waist and hip circumference.
1. Body weight is measured and recorded within 0.1 kg with a calibrated electronic flat scale (Seca 888).
2. Body height is measured and recorded with an accuracy of 1 mm using a portable stadiometer.
3. Skinfold thickness (i.e. m.triceps, m.biceps, m.suprailiacalis, m.subscapularis) is measured on the left side of the body to the nearest 0.2 mm
4. Waist and hip ratio are measured with a Seca 206 waist circumference measure (Seca, Hamburg, Germany) to accuracy of 0.5 cm

Energy balance-related behaviours
Before the start of DOiT and after 20 months, students are asked to complete the DOiT questionnaire in a classroom. The DOiT questionnaire addresses the following EBRBs:
1. Consumption of sugar-sweetened beverages
2. Consumption of high sugar/high fat snacks
3. Physical activity (sports and active transport)
4. Screen time (TV viewing and computer use)
5. Breakfast behaviour

Overall study start date
01/02/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
Participating schools need to meet the following criteria:
1. Willing to implement DOiT during 2 subsequent school years
2. A signed agreement of participation in the study during that period (2011-2013)
3. Willingness to appoint a DOiT coordinator who will be the linking agent between the research team and the school
4. Being able to participate with at least 3 classes of the first two years of their pre-vocational education
5. Willingness to provide space and time for measurements.

There are no individual inclusion criteria for study participation.

Participant type(s)
Patient

Age group
Child

Sex

Both

Target number of participants
640 students at the implementing schools and 640 students at the control schools

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
VUmc MS Center Amsterdam
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
SNS REAAL Fonds (Netherlands)

Sponsor details
Postbus 13364
Utrecht
Netherlands
3507 LJ

Sponsor type
Government

Website
http://www.snsreaalfonds.nl/

ROR
https://ror.org/04tf4mr55

Funder(s)

Funder type
Charity

Funder Name
SNS REAAL Fonds (Netherlands) ref: 20109966

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	19/12/2013		Yes	No
Results article	results	01/12/2014		Yes	No
Results article	results	24/12/2014		Yes	No