

Tobacco prevention in schools

Submission date 30/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Back ground and study aims

In recent decades, many activities and programs have been implemented in Sweden to prevent young people's tobacco use, but rarely been evaluated in terms of effects and costs. In 2015, a systematic literature review of the ANDT area in Sweden (Alcohol, Narcotics, Doping and Tobacco) was published regarding preventive school programs. It showed that tobacco preventive effects in the short and medium term were very small. The scientific evidence was most often judged to be insufficient to be able to draw any conclusions.

An intervention program aimed at preventing young people from using tobacco started in Northern Sweden in 1993 and has since then developed further and spread to 80 municipalities in the country. This research project Topas (Tobacco preventive work in schools) will evaluate the program which includes six core components, by a comparison with a minimal intervention and a reference with usual condition schools.

The specific aims of the study are to evaluate the effects and costs of the intervention by answering the following questions: i) are young people's use of tobacco impacted by the intervention? - i.e. is the preventive effect greater if you work with the full intervention compared with a minimal intervention or "usual conditions" in the schools? ii) does membership as an adult partner in the full intervention impact the tobacco use of adults? iii) does the level of implementation of the intervention have an impact on the effect? iv) are the effects such that the intervention costs are justified?

The study is carried out in different population groups for each specific research question/outcome.

Who can participate?

The study involves high schools in eleven counties in Mid-Sweden. All pupils who start year seven in the participating schools, in the autumn semester 2018, can participate in the study. Other study groups are parents/guardians and contact persons at schools.

What does the study involve?

The tobacco intervention program under study include six core components, which are

compared with a minimal intervention including only one of the components. The intervention performed, with the school as a hub, target adolescents in grade 7-9 (age 12-15), but involve parents and other significant adults.

The six core components included are: i) A tobacco-free couple; a contract is established and signed between a child and an adult over the age of 18, of the child's own choice, at the beginning of grade 7. Signing the contract means that they should stay tobacco-free together until the child finishes grade 9. The adult involved is thereby making a commitment to be a good example and actively support the child to stay tobacco free, ii) Student information; the children are given information during class, a lesson about tobacco and about membership in the tobacco-free couple and at the end they are offered membership, iii) Parental information; parents /guardians are given information about tobacco and about membership giving the opportunity to support the children in staying tobacco-free, iv) Membership card; the children who form a Tobacco-free couple receive a membership card that can give discounts and/or chances to win prizes, v) Annual declaration; at the end of each school year (grade 7-9) a follow-up of the agreement is made by the couples signing a declaration that they have been tobacco-free during the past year. It also works as a lottery ticket for the child in a prize draw before the summer holidays, and vi) Structured teaching; age-appropriate school lessons are given about tobacco from different perspectives using interactive methodology.

The intervention component included in the minimal intervention is the last component mentioned above, i.e. structured teaching.

Recruited schools are randomly assigned to one of two intervention groups, one half of the schools in the tobacco program intervention group (six core components) and the other half in the minimal intervention group (structured teaching only). The students belonging to the respective schools receive the intervention to which the schools are randomized, and constitute the "units" where the outcome is measured. Schools that does not want to participate in the intervention, but still want to contribute to research, can choose to be an external reference school (usual condition - data collection only).

The study instruments consist of questionnaires to students, school staff, parents/guardians and adult partners in the tobacco-free couples.

In an observational comparison, the potential change of students tobacco use is followed through an annual questionnaire data collection. In order to collect process data (implementation of intervention components, time used for teaching, number of meetings) and of cost data (time spent on the intervention by staff, materials, premises costs, etc.), a web survey is filled in by a contact person at the intervention schools (both full and minimal interventions). After the baseline survey, the questionnaire is filled in monthly during the school years. The tobacco habits of parents/guardians to students at intervention schools will be studied using questionnaires.

What are the possible benefits and risks of participating?

If the interventions are proven successful, the students at the intervention schools through their participation may receive support for staying tobacco free. No immediate direct risks can be anticipated through participation in the study.

Where is the study run from?

The Topas study is being run by the Umeå University, Umeå and Karolinska Institute, Stockholm, Sweden. It takes place in high schools in Mid-Sweden.

When is the study starting and how long is it expected to run for?

The development of the study protocol started in December 2016 and the study is expected to run until May 2021.

Who is funding the study?

The Public Health Agency of Sweden

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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SE-901 85

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

00793-2016

Study information

Scientific Title

An effect and health economic evaluation of the tobacco prevention program Tobacco-free duo targeting young people in grade 7-9

Acronym

Topas

Study objectives

The aim of the study is to evaluate the effects and costs of the intervention by answering the following specific questions:

1. Are young people's use of tobacco impacted by the intervention? i.e. is the preventive effect greater if you work with the full intervention compared with a minimal intervention or "usual conditions" in the schools?
2. Does membership as an adult partner in the full intervention impact the tobacco use of adults?
3. Does the level of implementation of the intervention have an impact on the effect?
4. Are the effects such that the intervention costs are justified?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regionala Etikprövningsnämnden, Umeå (Regional Ethics Review Board, Umeå), 13/06/2017, ref. 2017/255-31.

Study design

Mixed design; a multicentre cluster randomized controlled trial (cRCT) supplemented with secondary analyses of the same material ("as treated" analysis), combined with a cross sectional cohort study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Tobacco use

Interventions

Intervention tested: The tobacco intervention program under study include six core components, which are compared with a minimal intervention including only one of the components. The intervention performed, with the school as a hub, target adolescents in grade 7-9 (age 12-15), but involve parents and other significant adults.

The six core components included are:

1. A tobacco-free couple; a contract is established and signed between a child and an adult over the age of 18, of the child's own choice, at the beginning of grade 7. Signing the contract means

that they should stay tobacco-free together until the child finishes grade 9. The adult involved is thereby making a commitment to be a good example and actively support the child to stay tobacco free.

2. Student information; the children are given information during class, a lesson about tobacco and about membership in the tobacco-free couple and at the end they are offered membership.
3. Parental information; parents/guardians are given information about tobacco and about membership giving the opportunity to support the children in staying tobacco-free.
4. Membership card; the children who form a Tobacco-free couple receive a membership card that can give discounts and/or chances to win prizes.
5. Annual declaration; at the end of each school year (grade 7-9) a follow-up of the agreement is made by the couples signing a declaration that they have been tobacco-free during the past year. It also works as a lottery ticket for the child in a prize draw before the summer holidays.
6. Structured teaching; age-appropriate school lessons are given about tobacco from different perspectives using interactive methodology.

The intervention component included in the minimal intervention is the last component mentioned above, i.e. structured teaching.

A number of schools that do not want to participate in the intervention, but want to contribute to research, can choose to be an external reference school. They continue school work with usual conditions but participate in data collection.

Randomization: We intend to recruit at least 40 compulsory schools with grades 7-9 in the RCT study. To be an elective school, it should:

1. accept the randomization and participation in the data collection
2. include all grades between year 7 and year 9
3. have at least 25 students in each grade 7-9
4. select a contact person for the school participation in the study

Recruited schools are randomly assigned to one of two intervention groups, one half of the schools in the tobacco program intervention group (six core components) and the other half in the minimal intervention group (structured teaching only). The students belonging to the respective schools receive the intervention to which the schools are randomized, and constitute the "units" where the outcome is measured. Schools that does not want to participate in the intervention, but still want to contribute to research, can choose to be an external reference school (usual condition - data collection only). At least ten references schools will be included.

Study instruments: the instruments consist of questionnaires to students, school staff, parents /guardians and adult partners in the tobacco-free couples.

In an observational comparison, the development of tobacco use is followed. It is done with a cross-sectional study once a year (2019-2021) among pupils in school year 7-9 at intervention schools that are not part of the cohort and at the external reference schools. In order to collect process data (implementation of intervention components, time used for teaching, number of meetings) and of cost data (time spent on the intervention by staff, materials, premises costs, etc.), a web survey is filled in by a contact person at the intervention schools (both full and minimal interventions). After the baseline survey, the questionnaire is filled in monthly during the school years.

Intervention Type

Other

Primary outcome measure

The number of students who have never smoked as much as a whole cigarette at the end of grade nine will be measured using the relative risk intervention:control group.

Secondary outcome measures

1. The number of students who have never smoked regularly (at least one cigarette per week for at least three months) in grade 9 will be measured as a percentage at follow-up among students who stated that they did not smoke regularly at baseline. To measure the effect we look at the relative risk of the intervention:control group.
2. The number of students who have never smoked as much as a whole cigarette at the end of grade nine will be measured as the average proportion among all pupils in grade nine in the schools concerned (full intervention, minimal intervention, not participating in RCT). To measure the effect we look at the prevalence ratio intervention:control group.
3. Quitting smoking among smoking parents of pupils (not having smoked during the last seven days) will be measured as proportion after one and two years. To measure the effect we look at the prevalence ratio of seven-days being smoking-free intervention: control group.
4. The number of students who have never smoked tobacco, used snus or other type of tobacco in grade 9 will be measured with the cumulative proportion that has indicated no smoking, no snus use, and no other tobacco use among students who were completely tobacco-free at baseline. To measure the effect we look at the relative risk of the intervention:control group.

Overall study start date

15/12/2016

Completion date

31/05/2021

Eligibility**Key inclusion criteria**

Students:

1. At the schools selected for the study.
2. In grade 7-9 (being 12-15 years of age).

Parents/guardians:

1. Parent of students in the cohort at the selected intervention schools grade 7-9.

Schools:

1. Contains grades 7-9.

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

We intend to recruit at least 40 schools with a total population of 3,000 pupils, half of whom are randomized to arm one and the other half to arm 2. We appreciate the population of the Usual condition-schools to approximately 500 students.

Total final enrolment

1776

Key exclusion criteria

Schools:

1. Previously participated in an intervention using the six core components.
2. Already conduct or intend to conduct other extensive tobacco prevention programs during the relevant school years.

Date of first enrolment

15/11/2017

Date of final enrolment

15/05/2018

Locations**Countries of recruitment**

Sweden

Study participating centre**Umeå University**

Epidemiology and Global Health

Norrlands universitetssjukhus

Umeå

Sweden

SE-901 85

Study participating centre**Karolinska Institute**

Department of Public Health Sciences

Stockholm

Sweden

SE-113 65

Sponsor information**Organisation**

Umeå University

Sponsor details

Epidemiology and Global health
Umeå
Sweden
SE-901 85

Sponsor type

University/education

Website

<https://www.umu.se>

ROR

<https://ror.org/05kb8h459>

Funder(s)**Funder type**

Government

Funder Name

Folkhälsomyndigheten Sweden, Public Health Agency of Sweden

Results and Publications**Publication and dissemination plan**

An article on the cRCT-study protocol is planned to be completed in the spring 2019. An article is to be written about the study protocol for the health economic study and is planned to be completed before the summer of 2019. An article will be written about the study process; the recruitment and on the baseline, planned to be completed late spring 2019. An article reporting the first years evaluation of outcome for students and parents/guardians is planned to be written at the end of 2019/beginning of 2020, as well as an article reporting on the first years intervention cost and a descriptive equality analysis. An article reporting the second years evaluation of outcome for students and parents/guardians is planned to be written in the spring 2021, as well as an article reporting on the second years intervention cost and a descriptive equality analysis. An article reporting the third year's evaluation of outcome for students is planned to be written/published in the autumn 2021. In 2022 an article is planned to be written regarding the third year's intervention cost and a descriptive equality analysis for the three year period, as well as an article on the long-term cost effect and equality analysis.

Intention to publish date

30/05/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are 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		27/12/2021	04/01/2022	Yes	No
Protocol article		29/10/2020	27/02/2023	Yes	No
Protocol article		12/08/2021	27/02/2023	Yes	No
Other publications	Study core component 1: The Child-Adult Contract	25/10/2023	25/10/2023	Yes	No