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The X:IT II Study - school-based prevention of smoking

Submission date	Recruitment status	[_] Prospectively registered
06/09/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/10/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2023	Respiratory	

Plain English summary of protocol

Background and study aims

In Denmark, as well as in most Westernized countries, smoking is now more prevalent among adolescents from lower socioeconomic positions (SEP). Only eight percent of 15-year old Danish adolescents from higher social classes smoke daily or sometimes, whereas up to 37% of adolescents whose parents live from welfare benefits are smokers. Furthermore, adolescents from low SEP seem less likely to quit smoking in adulthood. Programmes addressing health and health behaviour in childhood or adolescence have the potential to prevent or decrease socioeconomic inequalities in health behaviours later in life, and public health interventions to reduce risk behaviours e.g. smoking, should aim at being equally effective across socioeconomic groups, or at being especially effective among individuals from low socioeconomic position. In order to develop effective interventions which work across social groups, it is important to study the social patterning of the effect of intervention methods. The X:IT I study was a school- based study to prevent smoking among 13- to 15-year old students targeting all students. The X:IT I study was the first large-scale Danish smoking intervention to be effective in reducing uptake of smoking in adolescents in Denmark. The qualitative process evaluation found that the X:IT I study did not reach students and parents from low social classes. Therefore, all X:IT I materials have been revised and specifically directed at adolescents and parents from lower social classes and at those who might have academic challenges. The aims of this study include: investigate the social patterning of the implementation and effects of the X:IT I study, based on the knowledge acquired from the X:IT I study, develop and implement a smoking intervention especially focusing on adolescents and parents from low socioeconomic background, the X:IT II study and to conduct scientific process and effect evaluations of X:IT II including studies of social differences in the implementation and effects.

Who can participate?

Students in grade seven, eight, and nine (aged 13 years to 15 years).

What does the study involve?

All schools receive the same programme. X:IT II include three main intervention components: smoke-free school grounds, parental involvement comprising two dimensions including smoke-free contract between the pupil and an adult person, preferably a parent and smoke-free dialogues, and finally a smoke-free curriculum based on self-efficacy training and outcome

expectancies. Students from high and low social classes are compared in a difference-in-difference design.

What are the possible benefits and risks of participating?
Participants may benefit from the benefits of not smoking with prevention of the well-known risks of smoking. There are no direct risks of participating, although some indirect risks can be mentioned such as being marginalized if you are a smoker and the psychosocial consequences of this.

Where is the study run from?
This study is being run by the National Institute of Public Health University of Southern Denmark (Denmark) and takes place in schools in Denmark.

When is the study starting and how long is it expected to run for?
January 2017 to July 2020

Who is funding the study?
The Danish Cancer Society (Denmark)

Who is the main contact?
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Contact information

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Scientific

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Protocol serial number
71199

Study information

Scientific Title
The X:IT II Study - A Smoking Intervention aimed at adolescents from low social class background

Acronym
X:IT II

Study objectives
Hypotheses:
1. The X:IT intervention material, carefully developed to take into account the intellectual skills and academic performance of adolescents' and their parents', will improve the reach of the intervention among low SEP
2. The X:IT study will have an overall effect of a 25% reduction in smoking uptake at age 13
3. The X:IT study will reduce smoking uptake among low SEP adolescents to the same extent or more than among adolescents with a high SEP background

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. When inviting the schools to participate, headteachers received

written information about the study. Students and their parents were informed about the study. They were informed that participation was voluntary, that their information would be used for research purposes only and treated confidentially. The study is registered at the Danish Data Protection Agency, ref: 17/53093.

Primary study design
Interventional

Study design
School-based intervention study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Smoking prevention

Interventions
The X:IT intervention includes three main components:

1. Completely smoke-free school grounds for both students and teachers during school hours and other school-related events. Law on Smoke-free institutions was given in Denmark in 2012. The literature showed that higher levels of perceived enforcement of anti-smoking policy at the school level were inversely associated with the prevalence of past-30-day smoking behaviors among students. Therefore, the intervention also includes enforcement of this law.
2. Parents are to be involved in two ways – by signing a smoke-free contracts between the student and an adult person, preferably a parent, each year for all three intervention years (in grad 7, 8, and 9), and by conducting smoke-free dialogues with the child. By signing a smoke-free contract the adolescent promises to stay smoke free for the next year. Signing the contract is a manifestation of an active choice of non-smoking. One of the parents or another adult co-signs the contract. With the contract, the signatory promises to conduct a smoke-free dialogue with the adolescent and to support the adolescent's choice of staying smoke-free. Having a smoke-free dialogue involves that the parent clearly takes exception to adolescent smoking, asks the child about thoughts about and experiences with tobacco. This kind of constructive communication has shown to be effective. The adolescents are motivated to make a personal choice, and engaging the parents communicates a clear opposition to adolescent smoking. Students remaining smoke-free for one year are able to win a prize.
3. A smoke-free curriculum based on self-efficacy training and outcome expectancies is supposed to take place at school for at least 8 hours each year for three years. The literature showed that information-giving curriculum incorporated in multi-modal programs seem to be successful. Programs based on social influence approaches, including aspects like:
3.1. Correcting adolescents' perceptive overestimation of the smoking prevalence
3.2. Recognizing high-risk situations
3.3. Increasing awareness of media, peer, and family influences
3.4. teaching and practicing refusal skills
5.3. Making public commitments not to smoke more effective.
The teaching program for the X:IT intervention was developed based on the above awareness. The actual educational material, "Gå op i røg" (Up in Smoke), was developed in conjunction with scholars who had educational experience. The teachers can choose methods of teaching as well

as supplementary exercises and materials. The material targets students, 13 to 15 years of age. It is designed to be used in diverse subjects such as science, humanities and social science. Goals in the National Executive Order of Education can be fulfilled by using the material.

Smoke-free contracts are provided to the students at school to bring home for signing with a parent. Copies can be downloaded here: www.xit-web.dk. A webpage designed for the parents with inspiration for these talks are available. The webpage has four entrances, one with general information, one for parents who smoke themselves, one for parents with smoking children, and one for parents and children who wants to learn more about smoking: http://www.snakomtobak.dk/
All materials for teaching, including detailed information for teachers, are available online : www.xit-web.dk

Smoke-free school grounds: enforcement must be discussed at the school board.
Smoke-free curriculum: a school coordinator must keep track of what and how much each school-class has been taught. The individual teachers in the diverse subjects must deliver the actual teaching.
A one-day work-shop to initiate the intervention is held for head-teachers, school coordinators, and teachers.

The teaching is provided during school hours either as 2-hour sessions or as workshop days.The intervention takes place at local public or private schools in Denmark. Smoke-free contracts will be signed once a year for three years (year 7, 8, and 9). The smoke-free curriculum has to take place for at least 8 hours each year for three years (year 7, 8, and 9)

The intervention is for all students and parents. As smoking is more prevalent in low social class, the educational material and parent information is developed and designed to secure that all groups will be reached.

Implementation fidelity will be assessed by four domains: adherence, dose, quality of delivery, and participant responsiveness according to the theory by Dusenbury et al (2003). Questionnaire data obtained from students and teachers will be used.

Intervention Type
Behavioural

Primary outcome(s)
1. Frequency of smokers at grade seven, eight and nine measured at baseline, 1,2 and 3 follow-up by student self-reported questionnaires
1.2. Frequency of smoking will be analyzed at individual, class and school level, and stratified by gender and socioeconomic level
2. Degree of implementation after first, second, and third year of intervention by student self-reported questionnaires and project coordinator questionnaires

Key secondary outcome(s)
Intermediate outcomes of the intervention:
1. Individual outcomes:
1.1. Enhanced self-efficacy for smoking
1.2. Increased knowledge about smoking
1.3. Change in norms and attitudes towards smoking
1.4. Performed smoke-free dialogue with parents

2. Group level outcomes
2.1. Increased probability of smoke-free environments at home and at schools
2.2. Changed norms and attitudes against smoking at schools
2.3. Reduced availability of tobacco
2.4. Increased probability of not being exposed to smoking students, teachers and parents
Analyses in the project will have a special focus on subgroup analyses especially gender and socioeconomic position.
3. Sustainability
3.1. At second follow-up it will be measured whether participation in Project X:IT has initiated environmental changes and capacity building by questionnaires to project coordinators at schools and in municipalities. Furthermore, we will measure whether the project continues at intervention schools and is initiated at control schools.
4. Differences in frequency of drunkenness and marijuana use between intervention and control schools
5. Differences in students' wellbeing between intervention and control schools

Completion date
01/07/2020

Eligibility

Key inclusion criteria
All students at participating schools enrolled in grade 7 (age 13 years to 15 years)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
2307

Key exclusion criteria
Schools for children with special needs.

Date of first enrolment
01/03/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Denmark

Study participating centre
National Institute of Public Health, University of Southern Denmark
Øster Farimagsgade 5A
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Sponsor information

Organisation
University of Southern Denmark

ROR
https://ror.org/03yrrjy16

Funder(s)

Funder type
Charity

Funder Name
The Danish Cancer Society

Results and Publications

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		04/09/2020	07/09/2021	Yes	No
Results article		16/08/2021	07/09/2021	Yes	No
Results article		16/04/2021	07/09/2021	Yes	No
Results article		06/01/2021	07/09/2021	Yes	No
Results article		23/01/2021	07/09/2021	Yes	No
Results article		06/01/2021	07/09/2021	Yes	No
Results article		01/05/2020	07/09/2021	Yes	No
Results article		21/02/2022	08/11/2023	Yes	No
Protocol article	protocol	02/05/2019	15/01/2021	Yes	No
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