

X:IT evaluation of a school-based intervention to reduce smoking

Submission date 16/01/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/04/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Although the harmful effects of tobacco have been known for many years, we have not succeeded in preventing young people from taking up smoking. Many young people still start smoking, and the number of young smokers has only decreased slightly during the last 10 years. Starting smoking at age 15 increases your risk of becoming a daily smoker as an adult. Therefore, it is very important to prevent smoking among children and young adolescents. The aim of this study is to develop and test a school-based anti-smoking program to reduce the number of smokers by 25% over a three-year period.

Who can participate?

Students in grade 7 at the start of the study

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 receive the anti-smoking program, whereas students at the control group schools do not. The anti-smoking program has three main components: eight anti-smoking lessons a year; students sign a contract promising to stay smoke free for the next year; and no smoking is allowed on the school premises. Furthermore, the study includes workshops for the staff, newsletters for the schools, a website with guidelines for parents and information for schools, and presentation of the study at parent school meetings each year. The study runs for three years (grade 7-9), with an annual follow-up in the spring of each year to measure how many students smoke.

What are the possible benefits and risks of participating?

The schools receive free educational materials and free workshops introducing the study and later sharing experiences of the study. Furthermore, participating schools receive a report describing the health behaviours of the adolescents in their school. The students among other things increase their knowledge about the risks of smoking, the social factors influencing decisions to smoke or not, and the role of the media in adolescent smoking. All students who stay smoke-free for a year have the chance to win a prize. There are no known risks to participants.

Where is the study run from?

Centre for Intervention Research in Health Promotion and Disease Prevention at the National Institute of Public Health, University of Southern Denmark

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

January 2010 to June 2013

Who is funding the study?

1. The Danish Cancer Society (Denmark)
2. Centre for Intervention Research in Health Promotion and Disease Prevention (Denmark)

Who is the main contact?

Anette Andersen

anan@niph.dk

Study website

<http://www.xit-web.dk/>

Contact information

Type(s)

Scientific

Contact name

Mrs Anette Andersen

Contact details

Øster Farimagsgade 5A

Copenhagen

Denmark

1353

+45 (0)65 50 77 77

anan@niph.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

X:IT - a three-year multi-component, school-based, cluster randomized trial to reduce smoking among 13-15 year olds in Denmark

Acronym

X:IT

Study objectives

To reduce prevalence of smokers by 25% over a three-year period, at grade 9 in intervention schools compared to control schools.

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. The study is registered at the Danish Data Protection Agency, 15/04/2010, ref: 2010-54-0930

Study design

Cluster randomized controlled design with three-year follow-up

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Patient information can be found at www.xit-web.dk/materialer/pjecer-og-foraeldreinformation (Danish)

Health condition(s) or problem(s) studied

Smoking

Interventions

Students in grade 7, 8 and 9 at 51 intervention schools receive the X:IT intervention program during the school years 2010/11, 2011/12 and 2012/13, whereas students at 43 control schools do not receive any intervention. The intervention lasts for three school years, e.g. from August 2010 till May 2013. Baseline data was collected August 2010, first follow-up survey May/June 2011, second follow-up survey May/June 2012 and third follow-up survey May/June 2013. The intervention focuses at three arenas/levels which influence adolescents lives:

1. Parent involvement

1.1. Students and parents sign a smoke-free contract each year for three years

1.2. Parents are encouraged to undertake a smoke-free dialogue with their child each year for three years

2. Smoke free curriculum, 8 lessons every year for three years with new teaching materials, for more information see www.op-i-roeg.dk

3. Smoke free schools throughout the intervention period. Information for municipalities, schools and parents are available on www.xitweb.dk

Intervention Type

Behavioural

Primary outcome measure

1. Frequency of smokers at grade seven, eight and nine measured at baseline, 1,2 and 3 follow-up by student self-reported questionnaires

1.1. Measures of smoking will be supplemented by analyses of number of cigarettes smoked and age at debut

1.2. Frequency of smoking will be analyzed at individual, class and school level

Secondary outcome measures

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. Increase probability of smoke-free environments at home and at schools

2.2. Changed norms and attitudes against smoking at schools

2.3. Reduce availability of tobacco

2.4. Increase 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

Overall study start date

01/01/2010

Completion date

30/06/2013

Eligibility

Key inclusion criteria

All students at participating schools enrolled in grade 7 at baseline (August 2010)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

4.468 students (2538 in the intervention group, 1930 in the control group) at 51 intervention schools and 43 control schools from 17 municipalities cross nationally

Key exclusion criteria

1. Schools not run by municipalities
2. Schools for children with special needs

Date of first enrolment

01/01/2010

Date of final enrolment

30/06/2013

Locations

Countries of recruitment

Denmark

Study participating centre

Øster Farimagsgade 5A

Copenhagen

Denmark

1353

Sponsor information

Organisation

Centre for Intervention Research in Health Promotion and Disease Prevention (Denmark)

Sponsor details

National Institute of Public Health

University of Southern Denmark

Øster Farimagsgade 5A

Copenhagen

Denmark

1353

+45 (0)65 50 77 77

anan@niph.dk

Sponsor type

Government

Website

<http://www.interventionsforskning.dk/>

ROR

<https://ror.org/03yrrjy16>

Funder(s)

Funder type

Government

Funder Name

Kræftens Bekæmpelse

Alternative Name(s)

Danish Cancer Society, The Danish Cancer Society, DCS

Funding Body Type

Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Denmark

Funder Name

Center for Intervention Research in Health Promotion and Disease Prevention (Denmark)

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	28/05/2014		Yes	No
Results article	results	17/09/2016		Yes	No