







Is it possible to reduce smoking at Danish vocational high schools?

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| Submission date 14/06/2018 | Recruitment status No longer recruiting |  Prospectively registered |
| | |  Protocol not yet added |
| Registration date 15/06/2018 | Overall study status Completed |  SAP not yet added |
| | |  Results added |
| Last Edited 09/01/2024 | Condition category Not Applicable |  Raw data not yet added |
| | |  Study completed |

Plain English Summary

Background and study aims

Smoking is one of the most important public health problems. Most smokers start to smoke in their early teens. The Danish National Youth study showed that 37% of vocational high school students were daily smokers compared to 12% of general high school students. In Denmark, vocational education mostly attracts students from lower socioeconomic backgrounds, a group where smoking is more persistent. A recent study in the vocational school setting showed that smoking provided the opportunity for development of social relations and that providing social alternatives to smoking may prevent daily smoking initiation. Still, it can be very difficult to quit smoking for students who smoke daily. The belief that there are psychological and social benefits to smoking may be a major predictor of smoking. Moreover, access to smoking cessation support and influences of perceived social norms about smoking seem to be important environmental factors in quitting smoking among vocational high school students. Establishing a smoke-free norm among youth requires changes in the environmental conditions. Specifically, there is evidence that comprehensive school tobacco policies that are strictly enforced are associated with less smoking. Therefore, a school-based intervention, which targeted the smoking visibility and norms at school as well as individual motivation, was developed. The aim of this study is to examine if this dual-strategy reduces the percentage of vocational high school students who smoke and reduces the number of daily cigarettes among already established daily smokers.

Who can participate?

Students at the participating Danish vocational schools schools in the basic course classes, i.e. the first part of a full vocational education (aged 16 to 20)

What does the study involve?

Vocational high schools are randomly allocated to the intervention group or the comparison group. Schools in the intervention group must implement and enforce a comprehensive school tobacco policy and provide easy access to support. At the class-level, two main components are implemented: a smoke-free curriculum comprising dialogues and exercises and a class-based

competition. Schools in the comparison group continue with normal practice. The number of cigarettes smoked per day is assessed by questionnaire at the start of the study and after the intervention.

What are the possible benefits and risks of participating?

Participants may benefit from stopping or not starting smoking, preventing the well-known risks of smoking. The students may also benefit from less social pressure. There are no direct risks of participating. Some indirect risks should be mentioned such as marginalization of smokers or the reverse effect of the smoking policy if some students perceive smoking as a personal choice and therefore may start or continue smoking during school hours.

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?

August 2017 to July 2020

Who is funding the study?

Danish Cancer Society (Denmark)

Who is the main contact?

Dr Susan Andersen

sua@niph.dk

Study website

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

Contact information

Type(s)

Scientific

Contact name

Dr Susan Andersen

Contact details

University of Southern Denmark

National Institute of Public Health

Stuðiestræde 6

Copenhagen

Denmark

1455

+45 (0)6550 7816

sua@niph.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

71152

Study information

Scientific Title

A cluster randomized controlled trial evaluating the effectiveness of a school-based intervention to reduce smoking in young people

Acronym

Focus

Study hypothesis

The primary hypothesis is that a multi-level and multi-component school-based intervention targeting vocational high school students will reduce the average number of cigarettes per day by:

1. Helping daily smokers reducing smoking and
2. Reducing the smoking initiation and progression to daily smoking among non-smokers and occasional smokers

The aim of this study is to investigate the effectiveness as well as the acceptability and feasibility of the intervention components by (a) ascertaining whether schools can be recruited and (b) undertaking a process evaluation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

There is no formal institution for the ethical assessment and approval of questionnaire-based population studies in Denmark. The study has been considered by the Danish Ethical Committee and they concluded that formal ethics approval was not required (ref: 20182000-83). This study is registered at the Danish Data Protection Agency, ref: 17/12006

Study design

Cluster randomized controlled design and associated ethnographic study

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 to request a patient information sheet

Condition

Smoking prevention and reduction

Interventions

Block randomization will be performed using a computer-generated random number list prepared by an investigator with no involvement in the trial. Groups will be randomly allocated to intervention or comparison groups (1:1) with stratification for type of school (social and health care programs, commercial programs and technical or combination programs). Comparison schools continue with normal practice.

The trialists will recruit schools sequentially; in August 2018 (for the autumn semester of 2018), and in August 2019 (for the autumn semester of 2019). They will use an adaptive design. Based on baseline data collected in the autumn semester of 2018, the design is adapted leading to redetermination of the trial's sample size.

For the three following reasons, there is uncertainty about the ability to recruit schools:

1. Implementing smoke-free school policy (i.e., no smoking during school hours) may refrain schools from enrollment in the study.
2. Vocational education in Denmark is offered by about 80 schools and many schools are organized in large units (i.e., campus), which necessitate close collaboration between different organizations, and reduce the number of units available for enrollment.
3. Two patient organizations have received a large grant for implementing smoke-free school policy (i.e., no smoking during school hours) at Danish vocational schools; the schools may prefer this project because they do not need to use resources on research-based activities (i.e., time spend on fulfilling questionnaire, the uncertainty of randomization etc.).

This multi-component intervention is based on ecological frameworks suggesting that behavior can be influenced on multiple levels including individual, social, organizational, and policy.

The intervention will comprise five areas aimed at:

School-level:

1. School smoking policy - enforcement of a smoke-free school policy (i.e., staff and students are not allowed to smoke during school hours) composed by the school management.
2. Theatre show concerning smoking (named "Act on it") with the purpose of giving information about risks, consequences, and how to manage a school day without smoking by anticipating what might prevent students from smoking, identifying how they can overcome any potential difficulties, and giving general encouragement. Moreover, the aim is to persuade students that their own personal risk of illness is personally relevant, and correcting their belief that they are able to stop smoking at any time.
3. Smoking cessation support - students or staff seeking help quitting or handling smoking during the school day can give their telephone number during the theatre show or send an SMS. Within two weeks, the National Quitline will phone them and they will be offered three sessions of telephone counselling for smoking cessation or smoking reduction. The aim of the support is to provide quit strategies and guidance, and foster a personalized relationship with support and

feedback from coaches trained in smoking cessation to help students find motivation, confidence, and skills for lasting change or to provide guidance on managing a smoke-free school day (i.e. autonomy-supportive interpersonal style to counsel the smokers). Moreover, the counsellor will refer the students to smoking cessation programs in their municipality or school, if any.

Class level (incoming basic course classes):

4. Eight lessons over eight weeks on attitudes, beliefs, and social influence- the aim is to start an exploration phase to assess and support the students' own awareness and interest in reducing, quitting, or in not initiating smoking.

The teaching program is based on themes like:

4.1. Correcting adolescents' perceptive overestimation of smoking prevalence

4.2. Recognizing high-risk situations

4.3. Increasing awareness of peer, and family influences

4.4 Addressing the perceived positive beliefs about the social and psychological consequences of smoking

4.5 Providing opportunities for student input on how to build positive interpersonal relationships.

4.6. Implementing social activities during breaks with the purpose of offering social alternatives to smoking.

5. Class competition based on measurements of carbon monoxide levels. Students in the intervention group will be invited to have the carbon monoxide levels in their breath measured at baseline and 2 months after baseline to participate in the competition. The intervention class with the biggest overall reduction of carbon monoxide will win a prize. The aim is to motivate students to assist each other with preventing or reducing smoking, and allowing students to explore how their smoking behavior affects their carbon monoxide levels.

Implementation fidelity will be based on questionnaire-based data obtained from students, teachers, and principals. Moreover, a qualitative process evaluation will be carried out.

The comparison group receives no intervention, but continues with usual practice. The total duration of the intervention is 20 weeks (corresponding to the autumn semester); however, the class-based intervention is only lasting the first 8 weeks of the semester. There will be follow-up at the end of the semester (i.e., post-intervention).

Intervention Type

Behavioural

Primary outcome measure

Self-reported number of cigarettes per day, assessed by student questionnaire at baseline and post-intervention (intervention and comparison groups). The trialists also plan to undertake 6 and 12 month follow-up. However, this will only be reported if the response rate is acceptable.

Secondary outcome measures

Student outcomes, measured by questionnaire unless otherwise stated, at baseline and 4 months (at the end of the semester) (intervention and comparison groups). The trialists also plan data collections at 10 and 16 months; however, this will only be reported if the response rate is acceptable:

1. Self-reported smoking status

2. Self-reported intention to quit smoking/not to take up smoking

3. Self-reported nicotine dependence according to the Heavy Smoking Index (HSI)

4. Self-reported smoking during school hours
5. Perceived social norms about smoking
6. Smoking cessation self-efficacy/refusal skills (among smokers)
7. Beliefs about social and psychological benefits of smoking
8. Perceived student and teacher support
9. School connectedness
10. Perceived access to smoking cessation support
11. Acceptability of intervention components (student responsiveness)
12. Self-reported use of e-cigarettes, snuff, or hookah
13. School dropout (register-based)

Teacher outcomes, measured by questionnaire at baseline and 2 months (only the intervention group):

1. Self-reported smoking status
2. Perceived social norms regarding smoking at school
3. Implementation readiness (motivation, general capacity, specific capacity) (pre-intervention)
4. Level of implementation fidelity (adherence, dose, quality, responsiveness) (post-intervention)

Principal outcomes, measured by questionnaire at baseline and 4 months (only the intervention group):

1. Implementation readiness (motivation, general capacity, specific capacity) (pre-intervention)
2. Level of implementation fidelity (adherence, dose, quality, responsiveness) (post-intervention)

The primary and secondary student outcome measures will be analyzed for different subpopulations defined by gender, age and socioeconomic position (student questionnaire) and by implementation readiness and degree of implementation (principal questionnaire and teacher questionnaire).

Sustainability: whether the project continues at intervention schools and is initiated at control schools.

Overall study start date

01/08/2017

Overall study end date

01/07/2020

Eligibility

Participant inclusion criteria

Schools:

1. Are vocational high schools
2. Have students in basic course classes

Students:

1. Entering the basic course of a vocational upper-secondary education
2. Are in a school and a class participating in the study

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

The trialists have calculated that $n = 10$ schools with an average of 100 students (i.e., five schools in the intervention group and five schools in the control group; in total 1,000 students) will be necessary to have power of 80% at an alpha of 5% to detect a reduction by 25% in the number of cigarettes smoked per day at post-intervention (e.g. from 15 cigarettes to 11 cigarettes among daily smokers). The cluster design was taken into account with an assumed intracluster correlation coefficient for schools (ICC) of 0.025. The ICC was estimated based on data from the Danish National Youth Study; a national survey among general and vocational high school students conducted in 2014.

Participant exclusion criteria

Does not meet inclusion criteria

Recruitment start date

06/08/2018

Recruitment end date

31/08/2019

Locations**Countries of recruitment**

Denmark

Study participating centre

National Institute of Public Health, University of Southern Denmark

Studiestræde 6

Copenhagen

Denmark

1455

Sponsor information**Organisation**

University of Southern Denmark

Sponsor details

National Institute of Public Health

Copenhagen

Denmark
1455

Sponsor type
University/education

Website
<http://www.si-folkesundhed.dk/>

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

Funder(s)

Funder type
Not defined

Funder Name
Kræftens Bekæmpelse

Alternative Name(s)
Danish Cancer Society, The Danish Cancer Society, DCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Denmark

Results and Publications

Publication and dissemination plan
The study protocol will be published in autumn 2018. Publication of the study results is planned in a high-impact peer reviewed journal around one year after the end of the overall trial.

Intention to publish date
01/07/2021

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 | results | 02/03/2023 | 03/03/2023 | Yes | No |
| Other publications | Post hoc analysis | 08/01/2024 | 09/01/2024 | Yes | No |