

Do school-based smoking preventive interventions have unintended effects?

Post hoc analysis of the Focus cluster randomised controlled trial

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BMJ Open Do school-based smoking preventive interventions have unintended effects? Post hoc analysis of the Focus cluster randomised controlled trial

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ABSTRACT

Objectives Public health interventions are designed to improve specific health-related outcomes; however, they may also produce negative side effects, such as substitution use, psychological or social harms. Knowledge about the unintended effects of school-based smoking preventive interventions is sparse. Hence, this study examined these potential unintended effects of the smoking-reducing intervention, Focus, among students in the vocational education and training setting.

Design Cluster randomised controlled trial stratified by school type with 5 months follow-up.

Setting and participants Across Denmark, eight schools were randomised to the intervention group (n=844 students, response proportion 76%) and six schools to the control group (n=815 students, response proportion 75%). This study focused solely on students who smoked at baseline (N=491).

Interventions The intervention was developed systematically based on theory and a thoroughly mixed-methods needs assessment. Intervention components included a comprehensive school tobacco policy (smoke-free school hours) supported by a 3-day course for school staff and launched by an edutainment session for students; class-based lessons and a quit-and-win competition; and individual telephone smoking cessation support.

Outcomes Alternative tobacco and nicotine products (regular use of smokeless tobacco, hookah and e-cigarettes), regular cannabis use, boredom and loneliness at school, stress and perceived stigmatisation among smokers.

Results We found no statistically significant unintended effects of the intervention. Nonetheless, insignificant findings indicated that students in the intervention group were less likely to be bored during school hours (OR 0.59, 95% CI 0.32 to 1.10) and experience stress (OR 0.62, 95% CI 0.35 to 1.10), but more likely to report feeling stigmatised compared with the control group (OR 1.55, 95% CI 0.71 to 3.40).

Conclusions Overall, findings suggested no unintended effects of the Focus trial with respect to substitution use, psychological, nor group or social harms. Future research is encouraged to report potential harmful outcomes of smoking preventive interventions, and interventions should be aware of the possible stigmatisation of smokers.

Trial registration number ISRCTN16455577.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A programme theory was developed with a priori specification of both intended and potential unintended effects of the intervention.
- ⇒ The intervention was thoroughly designed with inclusion of the target group and other relevant actors to accommodate potential unintended effects.
- ⇒ The intervention was evaluated in a cluster randomised controlled trial.
- ⇒ Since lost to follow-up could have resulted in attrition bias, multiple imputation of missing data was performed.
- ⇒ Other unmeasured side effects may have been produced as response to the intervention, for example, unintended effects among teachers at the schools.

INTRODUCTION

The main intention of public health interventions is to positively impact human life. In complex public health interventions, a programme theory is often developed in which a set of key components or activities are identified to enhance healthy behaviours or to prevent unhealthy behaviours, leading to positive health-related outcomes.^{1 2} While the literature on the possible unintended effects of public health interventions is sparse,³ a realist review from 2017 demonstrated that school smoking policies can trigger unintended responses that might counteract the purposes of the intervention.⁴ Increased attention to possible unintended effects of public health interventions may provide in-depth knowledge of what works for whom under which circumstances and why.^{3 5} Further, conducting studies on negative unintended effects has been highlighted as crucial to prevent replication of harms in future interventions.⁶

Interventions operating on multiple levels targeting the structural and individual levels are considered key in changing behaviours.

In this regard, numerous public health efforts have been introduced to prevent and reduce smoking,^{7–10} and in the school setting, the highest intervention effects have been found for complex multilevel and multicomponent interventions.⁸ This applies especially to interventions operating on a school structural level, such as school tobacco policies and enforced smoking bans in school hours, in combination with class-based and individualised components.^{9 10} The students enrolled in the vocational education and training (VET) setting generally differ from those attending general high schools, for example, students are often characterised by a lower socioeconomic status (SES) and a higher smoking prevalence.^{11–13} Prior research within the VET setting found that smoke-free school ground policy was associated with less smoking,¹⁴ and social and educational activities reduced students' progression from occasional to daily smoking.¹⁵ Still, the existing research concerned with smoking preventive interventions in this setting is sparse. For this reason, we developed a multilevel and multicomponent intervention 'Focus' to reduce smoking among youth in the VET setting.¹⁶ We evaluated the effect of the intervention in a cluster randomised controlled trial (RCT) in which we found no overall effects of the intervention on smoking; however, at schools with full intervention, that is, implementation of both the structural, class-based and individual components of the intervention, students were less likely to smoke at follow-up compared with the control group.¹⁷ Moreover, selected subgroups of the intervention, that is, girls and schools with healthcare programmes, had higher benefits from the intervention compared with their counterparts in the control group. Although we tried to avoid harmful unintended effects through a thorough development of the Focus intervention, there is still a potential risk of the intervention producing such effects. Moreover, there is generally a call for evaluations and research to report intended as well as unintended effects of interventions to guide and inform future efforts aimed towards increasing public health.⁶

Lorenc and Oliver's framework of unintended effects of public health interventions¹⁸ describe several mechanisms which may be present in the Focus intervention and lead to unexpected effects which could counteract the purposes of the intervention.¹⁸ First, as an example of direct harms previous research has raised the concern that introduction of comprehensive smoking bans in school may lead to an increase in other substance use (also called substitution use), including alternative tobacco and nicotine products (smokeless tobacco, ie, snus, snuff and chewing tobacco, hookah and e-cigarettes) or cannabis.¹⁹ This may be ascribed to an increased focus on smoking and smoking-related harms^{20 21} and subsequently, students with a high degree of nicotine dependency may use alternative tobacco and nicotine products as means to quit smoking or alleviate nicotine withdrawal symptoms.²² Second, restricting smoking in school could potentially create psychological harms as it may negatively impact the well-being of students who smoke daily

during school hours. Hence, in school settings with high smoking prevalence, cigarettes have several psychological and social functions,²³ and social interactions previously associated with smoking in peer-relations may disappear after implementation of smoke-free school-hours, which can hamper social relationships and increase feelings of loneliness.^{15 24} Moreover, if smoking cigarettes is no longer accepted as an activity in school, it may introduce boredom in breaks if no alternative activities are offered.²⁴ Students who are unable to smoke during school hours may also lack the opportunity to use smoking as a coping mechanism towards negative emotions and, consequently, experience higher stress levels.^{25 26} Finally, the intervention could potentially create group and social harms by singling out those who smoke as problematic, which can contribute to stigmatisation of this group, both from the surrounding environment and from themselves. This has been demonstrated in prior research, although not in this particular context.²⁷ Moreover, increased stigmatisation may lead to other unexpected effects that may counteract the purposes of the intervention, including poor mental health, increased desire to smoke or abstaining from seeking help.^{28–31}

Guided by Lorenc and Oliver's framework,¹⁸ we aimed to examine if the Focus intervention produced the following types of unintended effects among students, namely (1) direct harms (substitution use) measured by alternative tobacco and nicotine product use as well as cannabis use, (2) psychological harms measured by boredom in breaks and loneliness during school hours as well as stress levels and (3) group and social harms measured by perceived stigmatisation. The study focuses on daily smokers at baseline, as we expect that potential unintended effects of the intervention would especially occur among students who experienced a part of their every day (school) life being restricted or removed with the introduction of a comprehensive smoking ban. Hence, we do not anticipate the occasional smokers to experience negative consequences similar to that of daily smokers. This could be attributed to their lack of self-identification as 'smokers'—but instead as individuals who smoke for a period,^{32 33} and therefore, they would not necessarily identify themselves as primary targets of the intervention.

METHODS

Study design

The Focus intervention was evaluated in a cluster RCT comprising an intervention group that was exposed to intervention elements and a control group encouraged to continue with usual practice. A detailed description of the study design is reported elsewhere.¹⁶

Study population, recruitment and randomisation

Schools offering basic course of VET or preparatory basic education (PBE) were recruited to this study. PBE is offered to individuals under the age of 25 who need

professional or personal support to enter another youth education, and a specific focus of PBE schools is preparing youth for enrolment at VET schools.^{34 35} Generally, students within these educational settings are between 16 and 25 years old, and the intervention was targeted at this age group. The randomisation of schools into intervention and control groups was conducted at the school level stratified by four school types (1) social and healthcare VET schools, (2) commercial VET schools, (3) technical VET schools and (4) PBE schools. Schools were recruited in two rounds over the course of 3 months (January 2018 to April 2018 and again from January 2019 to April 2019) to ensure that the schools had sufficient time to implement the intervention before school start in August. Seven VET schools were randomly assigned to the intervention group (n=4) or control group (n=3) during the first round. Because it was difficult to recruit VET schools with 'technology, construction and transportation' courses, the second round included PBE schools. In this round, three VET schools and four PBE schools were randomly assigned to the intervention group (n=4; two PBE schools and two VET schools) or control group (n=3; two PBE schools and one VET school). Subsequently, 14 Danish schools were enrolled in this study (N(students)=1659), of which 844 students were assigned to the intervention group (response proportion 76%) and 815 to the control group (response proportion 75%). In total, 432 students in the intervention group and 374 students in the control group were lost to follow-up at 5 months after baseline. A more detailed description of the sample flow is reported elsewhere.¹⁷

Intervention schools were visited by the project team with the aim of supporting implementation of the intervention (see also the Focus study protocol for further details¹⁶). Baseline data were collected at semester start after the summer holiday. At the end of the semester (approximately 5 months after), the follow-up assessment was conducted.

The Focus intervention

The intervention was developed following the recommended stages within the Behaviour Change Wheel,³⁶ based on a qualitative needs assessment study and pilot test of intervention components.¹⁶ The Focus intervention included several components and operated at the structural, class and individual levels of the school. A specific focus of the intervention was to accommodate potential negative unintended effects of the comprehensive school tobacco policy among students who smoke. According to self-determination theory, maintenance of a new health behaviour (such as to stop smoking during school hours) requires that individuals make sense of the new behaviour, develop the required skills for change and internalise motivation for change.^{37 38}

The school environmental components of the intervention included a school tobacco policy: schools should implement and enforce smoke-free school hours, thus, banning smoking completely during school hours. This

was supported by two other components: Course about how to talk to students about smoking delivered to school staff. This included staff education in empathic and non-judgemental communication, even if students were to violate the school tobacco policy; Edutainment session on smoking delivered to students and school staff with themes about nicotine dependence and advice to handle a school day without smoking (www.act-on-it.dk).

The class-based components included (1) Educational materials which comprised eight sessions about attitudes and beliefs about smoking as well as the involvement of students in creating class ethos and social activities during breaks. The material had a specific focus on the social curriculum; promotion of social school activities such as board games or table tennis as alternatives to smoking; and altering beliefs that smoking relieves negative emotions. Students were also able to discuss their own beliefs and experiences regarding smoking and quitting, their views on the consequences of smoking and the benefits of smoking cessation. Many individuals use smoking as a coping mechanism to handle stressful situations,^{25 26} which was specifically addressed in one module about how to handle stress and restlessness, for example, breathing exercises and power breaks. (2) Quit-and-win competition. The class with the highest reduction of carbon monoxide levels won a social activity for the entire class. The competition aimed to catch students' attention and interest in the intervention.³⁹ Moreover, the component sought to promote students' motivation to reduce their smoking with an immediate and visible reward and strengthen their sense of class connectedness.

The individual component included proactive smoking cessation support from the National Quitline in Denmark (www.stoplinien.dk) with multiple call-back sessions. Hence, students received information in the edutainment session in which they could anonymously write their phone numbers with the aim of proactive telephone support from the Quitline. Moreover, posters were placed on school premises about the cessation support, and information about the Quitline was provided to school staff who participated in the staff course. Providing easy access to smoking cessation support was designed to support students' abilities and skills to quit smoking.¹⁶

Measures

As previously presented, this study focused on three types of potential harms produced by the intervention, namely direct harms (substitution use) measured by alternative tobacco and nicotine product use as well as cannabis use, psychological harms measured by boredom in breaks and loneliness during school hours as well as stress levels, and group and social harms measured by perceived stigmatisation. The included outcomes concerned with the unintended effects were developed and specified before the intervention start,¹⁶ and most were also prespecified in the trial registration; however, specific outcomes (cannabis use, stress, boredom and stigmatisation) were included after registration of the intervention, and

because a formal protocol amendment was not made, these outcomes concerned should be considered post hoc outcomes. Results for the primary outcome (cigarette consumption, smoking status and secondary outcomes) have been reported previously.¹⁷

Direct harms/substitution use

Alternative tobacco and nicotine product use

Regular use of smokeless tobacco, hookah and e-cigarette use, respectively, were assessed at baseline and 5 months follow-up by asking students 'Have you ever used the following...?' (1) smokeless tobacco, (2) hookah and (3) E-cigarettes.' Responses were categorised into regular use (daily and occasional) versus no current use (used it a few times, had previously used, or never used).

Regular cannabis use was also assessed by dichotomising students' responses to use of cannabis into regular use versus no current use. Cannabis use was solely measured at follow-up.

Psychological harms

Boredom in breaks during school hours

Students were asked at follow-up whether they experienced breaks in school to be boring, and response options were dichotomised into boredom in breaks (often or very often) versus being bored sometimes or rarely in breaks.

Moderate to high level of loneliness during school hours was measured at follow-up using a modified version of the Three-Item Loneliness Scale (T-ILS)⁴⁰: 'Think about your school. How often do you feel... (1) isolated from others? (2) that you lack companionship? and (3) left out?'. The items were summarised to a scale and categorised into low (3–4), moderate (5–6) and high (7–9) level of loneliness. In this study, loneliness during school hours was dichotomised into moderate to high level versus low level of loneliness.

High level of stress was assessed at follow-up with two questions: (1) 'Do you feel stressed?' with response options 0=not at all, 1=yes, a little and 2=yes, a lot, (2) 'How often do you feel stressed?' with four response options ranging from 0=never/almost never to 3=daily. The items were summarised to a scale and dichotomised into high level of stress (4–5) versus low to moderate level of stress (0–3).

Group and social harms

Perceived stigmatisation among smokers

Stigmatisation related to smoking was measured at follow-up using the Internalised Stigma of Smoking Inventory with three subscales of stigma, including self-stigma, felt stigma and discrimination.⁴¹ The self-stigma subscale had the following items 'To which extent do you agree/disagree with the following statements...?' (1) I am ashamed or embarrassed that I am a smoker, (2) I am disappointed in myself for being a smoker and (3) I feel inferior to others who are not smokers.' The felt stigma subscale comprised these items: 'To which extent do you agree/disagree with the following statements...?' (1)

People ignore me or take me less seriously just because I am a smoker, (2) Others think that I cannot achieve much in life because I am a smoker and (3) Nobody would be interested in getting close to me because I am a smoker.' The discrimination subscale consisted of two items: 'To which extent do you agree/disagree with the following statements...?' (1) People discriminate against me because I am a smoker and (2) People treat me disrespectfully just because I am a smoker.' All items had response options ranging from 1=completely disagree to 4=completely agree. For each subscale, responses were dichotomised into experience with stigmatisation (responding agree or completely agree to at least one item of the subscale) versus no stigmatisation.

Implementation measure was assessed according to school principals' answers to a questionnaire about the delivered intervention components. According to their responses, the implementation measure was categorised into (1) implementation of the school-level and class-level intervention components (intervention delivered in full; n=4 schools, 134 students), (2) implementation of some class-level components or withdrawal of components during the evaluation period (partial intervention; n=4 schools, 134 students) and (3) control schools (n=6 schools, 227 students).

Covariates included gender (male vs female), age (as a continuous variable) and SES, all measured at baseline. SES was measured by students' family occupational social class assessed using four items about father's and mother's occupational status ranging from 1=high SES to 5=low SES and 6=receiving social benefits.⁴² SES was determined by the highest-ranking parent and was categorised into high (1–2), medium (3–4) and low (5–6).

Statistical analysis

All analyses were carried out by using SAS V.9.4. Descriptive statistics were used to compare students who smoked at baseline in the intervention group and the control group. For the main analyses, an intention-to-treat approach was used including all students who smoked at baseline. The analyses were based on multiple imputations (MI) of missing data using several variables, which included school variables, sociodemographic variables, individual smoking-related behaviour and beliefs about smoking and smoking within social relations. MI was conducted in two steps; first, missing values in the baseline dataset were imputed, and afterwards, missing values at follow-up were imputed based on baseline and follow-up data. Two times of 20 rounds of imputations were performed using the PROC MI procedure in SAS. The first round excluded the school class variable, while the other included the variable to account for dependency across school classes. The PROC MIANALYZE procedure in SAS was used to estimate intervention effects by summarising the imputed datasets.

Multilevel logistic regression modelling was used to estimate intervention effects at 5 months follow-up on all unintended outcomes at follow-up, which were treated

dichotomously. Baseline age, gender and SES were included as covariates as well as the baseline value of the outcome if measured (regular use of smokeless tobacco, hookah and e-cigarettes were measured at baseline), and the stratification variable, school type. Each model also included the class variable as a random effect to account for the clustering effect. The analyses were based on students who smoked daily at baseline. Further, we examined the impact of implementation by conducting a per-protocol analysis. Finally, differential effects of the intervention on unintended outcomes were examined according to school type. School type was divided into (1) VET schools: social and healthcare, (2) VET schools: technical and commercial and (3) PBE schools. A $p < 0.05$ determined statistical significance.

Patient and public involvement

The study did not involve patients or the public in the development of research questions and outcome measures, the design of the study, nor in the recruitment to and conduction of the study.

RESULTS

In total, 29.7% (n=491) of students smoked daily at baseline, of which 31.3% smoked daily in the intervention group and 27.9% smoked daily in the control group (results not shown). Out of the 491 students who smoked at baseline, 54% were in the intervention group, and 46% were in the control group (table 1). The median

age of students was 18 years, and about half of students were female. No notable differences were found between the intervention and the control group, although more students who smoked daily at baseline attended technical and commercial VET schools (39.7%) compared with the intervention group (28.4%), while more students in the intervention group attended PBE schools (29.9%) compared with the control group (22.9%).

Overall, no statistically significant differences between the intervention and control groups were found for any of the unintended outcomes at 5 months follow-up among students who were daily smokers at baseline (table 2). Some non-statistically significant tendencies were found; daily smokers in the intervention group were less likely to be bored in breaks during school hours (OR 0.59, 95% CI 0.32 to 1.10) and experience high levels of stress (OR 0.62, 95% CI 0.35 to 1.10) compared with daily smokers in the control group. Further, there was a non-significant tendency that daily smokers in the intervention group were more likely to use cannabis regularly (OR 1.68, 95% CI 0.67 to 4.20) and to report felt stigma (OR 1.55, 95% CI 0.71 to 3.40) compared with daily smokers in the control group.

The per-protocol analysis did not show statistically significant differences between level of implementation and unintended outcomes—except fewer daily smokers attending schools with partial intervention experienced high levels of stress (OR 0.47, 95% CI 0.25 to 0.88) compared with daily smokers in the control

Table 1 Baseline characteristics of students in the Focus trial stratified by condition, complete cases of daily smokers, N=491

	Total (N=491) n (%)	Intervention group (n=264, 54%) n (%)	Control group (n=227, 46%) n (%)
Average number of smokers per class (mean, (SD))	5.6 (4.4)	6.9 (6.3)	5.8 (4.8)
School type			
VET schools: social and healthcare	195 (39.7)	110 (41.7)	85 (37.4)
VET schools: technical and commercial	165 (33.6)	75 (28.4)	90 (39.7)
PBE schools	131 (26.7)	79 (29.9)	52 (22.9)
Age, years (median (IQR))	18 (17–22)	18 (17–23)	18 (17–22)
<18 years	177 (36.1)	90 (34.1)	78 (38.3)
Women	255 (51.9)	141 (53.4)	114 (50.2)
Family occupational social class			
High (I+II)	67 (13.7)	42 (15.9)	25 (11.0)
Middle (III+IV)	197 (40.1)	98 (37.1)	99 (43.6)
Low (V+VI)	138 (28.1)	73 (27.7)	65 (28.6)
Unclassifiable	89 (18.1)	51 (19.3)	38 (16.7)
Regular smokeless tobacco use	55 (11.3)	24 (9.1)	31 (13.8)
Regular hookah use	99 (20.2)	49 (18.6)	50 (22.2)
Regular e-cigarette use	113 (23.2)	65 (24.7)	48 (21.3)
Regular use of either smokeless tobacco, hookah or e-cigarettes	189 (38.7)	96 (36.5)	93 (41.3)
Missing proportion of 0.6%. PBE, preparatory basic education; VET, vocational education and training.			

**Table 2** Logistic regression analyses of the associations between the intervention group (vs the control group) and unintended outcomes measured at 5 months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40×491)

Unintended outcome at follow-up	Intervention group (n=40×264)	Control group (n=40×227)	Adjusted*	
	%	%	OR	95% CI
Alternative tobacco and nicotine product use				
Regular smokeless tobacco use	22.4	28.8	0.78	0.40 to 1.54
Regular hookah use	23.2	22.4	1.28	0.61 to 2.67
Regular e-cigarette use	37.2	34.1	1.17	0.65 to 2.10
Regular use of either smokeless tobacco, hookah or e-cigarettes	56.1	57.2	1.10	0.64 to 1.88
Regular cannabis use	11.0	7.2	1.68	0.67 to 4.20
Well-being				
Boredom in breaks during school hours	22.6	32.2	0.59	0.32 to 1.10
Loneliness during school hours	18.1	16.8	1.15	0.53 to 2.50
High level of stress	66.6	75.1	0.62	0.35 to 1.10
Stigmatisation				
Self-stigma	33.6	35.2	0.97	0.54 to 1.75
Felt stigma	12.0	9.5	1.55	0.71 to 3.40
Discrimination	1.8	1.9	–	–

Due to low student representation in the discrimination subscale, regression analyses were not possible.
*Adjusted for gender, socioeconomic status, age and baseline variable if available (regular smokeless tobacco, hookah and e-cigarette use).

group (table 3). Non-statistically significant tendencies suggested that daily smokers at schools with full intervention were less likely to be bored in breaks during school hours (OR 0.52, 95% CI 0.24 to 1.12) but more likely to report felt stigma (OR 2.15, 95% CI 0.84 to 5.53) compared with daily smokers in the control group.

Table 4 displays the differential effects of the intervention on unintended outcomes by school type. Results showed that daily smokers at the technical and commercial VET intervention schools were less likely to be bored in breaks during school hours compared with their counterparts in the control group (OR 0.27, 95% CI 0.10 to 0.75).

DISCUSSION

The multilevel and multicomponent intervention, Focus, was developed to reduce smoking in the VET setting. The programme theory of the intervention specifically addressed unintended outcomes among students related to substitution use, psychological, group and social harms as potential risks when implementing the intervention.¹⁶ Findings from this study suggested no significant unintended effects of the Focus intervention. Nonetheless, results indicated some positive side effects in terms of students in the intervention group being less bored in breaks during school hours and reporting lower stress levels compared with the control group. Thus, these results should be viewed positively in the sense that the Focus intervention did not seem to create harm in the target group—even though the intervention comprised comprehensive smoking preventive components and a

complete ban on smoking during school hours. On the other hand, results did indicate that students at schools with full intervention were more likely to report stigmatisation in terms of felt stigma.

Previous studies have suggested strong connections between tobacco use and stress levels.^{25 26} Consequently, a hypothesised potential unintended effect of the intervention was higher self-reported stress levels among students at intervention schools who were unable to smoke during school hours. However, a tendency towards lower stress levels among students in the intervention group was found. More specifically, per-protocol analyses suggested that especially students attending schools with partial intervention experienced less stress compared with the control group, while no differences were found for students attending schools with full intervention. An explanation may be that the school tobacco policy was to a lesser extent implemented or not implemented at all, while the schools still received the staff course, the edutainment session, the competition and gave information about smoking cessation support. Hence, students may still have been able to smoke during school hours (and subsequently, use smoking to, for example, cope with negative emotions), while also receiving sources of support and activities aimed at promoting social relationships. In this regard, it should be noted that the connection between smoking and stress is complex. While cigarettes are often used as a means to alleviate stress levels,²⁵ previous research has demonstrated that smokers experience higher stress levels compared with non-smokers,⁴³ and nicotine in cigarettes can intensify

Table 3 Per-protocol analyses with control group as reference group with unintended outcomes measured at 5 months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40×491)

Unintended outcome at follow-up	%	Adjusted*	
		OR	95% CI
Regular use of either smokeless tobacco, hookah or e-cigarettes			
Control group	57.2	1 (ref.)	
Partial intervention	61.1	1.09	0.58 to 2.09
Full intervention	51.5	1.10	0.57 to 2.11
Regular cannabis use			
Control group	7.2	1 (ref.)	
Partial intervention	14.3	2.04	0.72 to 5.80
Full intervention	7.7	1.28	0.41 to 4.05
Well-being			
Boredom in breaks during school hours			
Control group	32.2	1 (ref.)	
Partial intervention	27.2	0.65	0.30 to 1.40
Full intervention	17.9	0.52	0.24 to 1.12
Loneliness during school hours			
Control group	16.8	1 (ref.)	
Partial intervention	16.4	1.02	0.42 to 2.46
Full intervention	19.8	1.29	0.49 to 3.38
High level of stress			
Control group	75.1	1 (ref.)	
Partial intervention	59.9	0.47	0.25 to 0.88
Full intervention	73.5	0.87	0.41 to 1.84
Stigmatisation among smokers			
Self-stigma			
Control group	35.2	1 (ref.)	
Partial intervention	30.9	0.88	0.44 to 1.77
Full intervention	36.6	1.08	0.53 to 2.22
Felt stigma			
Control group	9.5	1 (ref.)	
Partial intervention	10.5	1.12	0.41 to 3.03
Full intervention	15.4	2.15	0.84 to 5.53

Due to low student representation in the discrimination subscale, regression analyses were not possible, leading to its exclusion from the table.
 *Adjusted for gender, socioeconomic status, age and baseline variable if available (regular smokeless tobacco use, hookah and e-cigarette use).

stress levels and damage the young brain.⁴⁴ Additionally, research has indicated that smoking cessation leads to reductions in stress levels.⁴⁵ Therefore, given the relatively short follow-up period in this study, there may be more long-term effects in the group of students who discontinued smoking during the intervention on stress levels.

Another notable finding in this study was that students in the intervention group reported experiencing less boredom during school hours in comparison to the control group. Due to important social implications of smoking (eg, smoking as a means to build social relationships in school⁴⁶), it was hypothesised that the intervention might increase boredom by removing students' opportunities to smoke with others in breaks. However,

the intervention specifically sought to accommodate this issue by encouraging the intervention schools to provide alternatives to smoking, such as board games and table tennis. Especially, VET intervention schools experienced lower levels of boredom than their counterparts in the control group. Thus, future research should further examine the mechanisms at VET schools that have contributed to lower levels of boredom among students during school hours. Importantly, findings from this study support efforts to strengthen the social environment among students, which has also previously been found to impact students in the VET setting positively.¹⁵

Finally, this study found a non-significant tendency towards students experiencing higher stigmatisation from others in the intervention group compared with

**Table 4** Subgroup analyses stratified by school type of the associations between the intervention group (vs the control group) and unintended outcomes measured at 5 months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40×491)

Unintended outcome at follow-up	Intervention group (n=40×264)	Control group (n=40×227)	Adjusted*	
	%	%	OR	95% CI
Regular use of either smokeless tobacco, hookah or e-cigarettes				
VET schools: social and healthcare	49.0	47.0	1.16	0.43 to 3.09
VET schools: technical and commercial	62.2	70.2	0.65	0.24 to 1.79
PBE schools	61.1	51.5	2.07	0.58 to 7.39
Regular cannabis use				
VET schools: social and healthcare	8.3	4.4	–	–
VET schools: technical and commercial	12.2	6.5	–	–
PBE schools	19.0	13.0	1.84	0.44 to 7.71
Well-being				
Boredom in breaks during school hours				
VET schools: social and healthcare	21.0	19.5	1.05	0.36 to 3.11
VET schools: technical and commercial	18.3	42.8	0.27	0.10 to 0.75
PBE schools	32.5	34.7	0.78	0.18 to 3.39
Loneliness during school hours				
VET schools: social and healthcare	17.7	11.3	1.68	0.54 to 5.27
VET schools: technical and commercial	17.8	18.3	1.12	0.33 to 3.83
PBE schools	18.4	23.3	0.75	0.18 to 3.13
High level of stress				
VET schools: social and healthcare	75.2	77.3	0.82	0.37 to 1.81
VET schools: technical and commercial	62.2	73.7	0.52	0.16 to 1.67
PBE schools	68.5	73.9	0.64	0.20 to 2.04
Stigmatisation among smokers				
Self-stigma				
VET schools: social and healthcare	35.1	32.8	1.14	0.46 to 2.85
VET schools: technical and commercial	30.8	39.9	0.66	0.27 to 1.64
PBE schools	33.0	31.2	0.98	0.26 to 3.62
Felt stigma				
VET schools: social and healthcare	9.9	10.4	0.87	0.27 to 2.76
VET schools: technical and commercial	17.8	10.2	2.07	0.53 to 8.05
PBE schools	7.9	6.6	–	–

Due to low student representation in the discrimination subscale, regression analyses were not possible, leading to its exclusion from the table. Similarly, the small percentages of students in VET schools reporting cannabis use, as well as PBE schools experiencing felt stigma, resulted in exclusion from the analyses.

*Adjusted for gender, socioeconomic status, age and baseline variable if available (available variables include regular smokeless tobacco, hookah and e-cigarette use).

PBE, preparatory basic education; VTE, vocational education and training.

the control group—especially those students attending schools with full intervention. Little research has investigated stigmatisation as a response to stronger smoking policies. One study comparing schools across seven European countries with diverse smoking policies concluded that strong tobacco policies did not increase the level of stigmatisation.²⁷ The potential stigmatisation of students is an area of concern that warrants attention. Smoking-related stigma has been widely discussed in prior literature,^{29 30} with studies suggesting that initiatives aimed to

increase smoking-related stigma could potentially have a positive impact on reducing the overall smoking prevalence or at least the desire to quit smoking.^{29 30 47} This is supported by the main analysis of Focus suggesting that full intervention schools have fewer daily and regular smokers at follow-up, while no effect was seen in schools that have only partially implemented the intervention.¹⁷ One hypothesised mechanism is that public stigma of smoking may lead to an internalised smoking-related stigma and hence, an increased desire to quit smoking.²⁹

Nevertheless, ethical considerations should be carefully considered within this context, particularly in light of the fact that some individuals may employ smoking as a coping mechanism for various challenges in their lives, such as stress reduction or alleviation of psychological symptoms.^{25 26} Research has also shown that self-stigmatisation may negatively affect the mental health of individuals and help-seeking behaviours in the context of smoking.^{28 29} Therefore, efforts aimed at increasing perceived stigma among individuals who smoke could prove to be counterproductive.

The present study focused on three types of unintended harms (direct harms, psychological harms, group and social harms) addressed in the programme theory of Focus¹⁶ and guided by a conceptual framework.¹⁸ Two other types of harms are outlined in this framework, which were not specifically studied in this paper.¹⁸ First, opportunity harms concern the risk of resources being allocated to ineffective interventions that could have been used on more effective initiatives or more urgent public health issues.¹⁸ While the Focus study was resource demanding and the overall effect was limited, we found significant intended effects on smoking status among students at schools with full intervention and subgroups (specific school types and girls). All structural change is difficult and demands attention and resources at an organisational level—and the Focus study draws from best-practice and previous research in reducing smoking among students using a multilevel approach with multiple components.^{8–10} Nonetheless, future research may further investigate whether all or only some of the intervention components affected students' tobacco use or other health behaviours, which can guide and inform future interventions in this setting and may reveal potential for tailoring future interventions more effectively and carefully.

Second, equity harms concern the risk of interventions affecting students divergently according to various socio-demographic factors.¹⁸ The Focus study was designed to reduce smoking in a setting with generally more lower SES youth with higher smoking prevalence.^{11 12} As the intervention was implemented in a school setting, the possibility of reaching high-risk groups was high⁴⁸—thus, with respect to equity harm concerns, this study was specifically designed to accommodate this issue. Generally, smoking preventive interventions have shown limited effects among adolescents from lower socioeconomic backgrounds,^{49 50} and the most well-documented initiative to not increase social inequality in smoking is increased tobacco prices.⁵⁰ This calls for more political actions towards tobacco prices in combination with structural and individualised efforts in the school setting to equalise social inequalities in smoking. It is worth noting that—even within the context of this setting with lower SES students—the intervention may have benefited those with the highest SES to a larger extent, as demonstrated in previous research.⁴⁹ This aspect was beyond the scope of this particular study on unintended effects experienced

by students who smoke daily but is an important area for future research.

Strengths and limitations

Several methodological strengths apply to this study. Specifically, a programme theory was developed with unintended effects of the intervention considered, and the intervention was thoroughly designed with the inclusion of the target group and other relevant partners (eg, the Danish Cancer Society) to ensure proper implementation and relevance among the students.¹⁶ Further, the Focus intervention was evaluated in a cluster RCT which is considered a huge advantage for assessing the effects of interventions. Meanwhile, some methodological weaknesses should also be considered in the context of this study. First, many students did not respond to the follow-up questionnaire which reduced the statistical power markedly. Multiple imputation of missing data was used to account for possible attrition bias using a range of factors relevant to the outcomes. Nonetheless, the sample size was substantially limited in some of the subgroup analyses increasing the risk of type II error, which could partly explain the insignificant results. We, therefore, also present and discuss non-significant tendencies. Further research is warranted to investigate potential unintended effects of smoking preventive interventions using a larger sample size of students. Moreover, some of the measurements of the unintended effects were measured in the follow-survey only, which precluded adjustment for potential baseline differences. Another limitation of this study could be the fact that unintended effects were solely investigated according to the factors outlined in the programme theory and measured in the surveys. Other side effects may have been produced and not addressed in this study. Qualitative methods may play an essential role in capturing unexpected effects of the intervention. For instance, a qualitative evaluation of another intervention in the VET setting found that removing smoking breaks also removed some of the possibilities for teachers and students to connect.¹⁵ The Focus study draws on a mixed-methods approach in evaluating the intervention, and some of the preliminary findings from the qualitative process evaluation revealed that teachers often found enforcement of school smoking policies difficult. Many teachers felt pressure in terms of daily prioritising sanctions of students who smoked versus offering support to students for whom smoking was the least of their problems. Further, more experienced smokers often violated the smoking policy rules because they found it too challenging to refrain from smoking due to personal problems and distress. The unintended effects assessed in this study were solely measured among students; however, as emphasised in the qualitative process evaluation, future research may also focus on potential unintended effects among teachers and other school staff.



Implications for practice

Several implications can be derived from this study. As this study is one of the few reporting potential unintended effects following implementation of a complex smoking preventive intervention, findings may guide future research in the area. Moreover, formulation and theorisation of hypotheses about possible side effects in the intervention development as well as involving, for example, students and teachers in the design of intervention components may lead to fewer unexpected negative side effects. Prior analyses of Focus indicate that the school tobacco policy drives the reduction of smoking in the participating schools while the other components may support the implementation but cannot stand alone. For example, the students may experience the class competition as enjoyable,⁵¹ which may motivate them to adhere to the school tobacco policy but cannot stand alone. Studies among younger adolescents that have examined smoke-free class competition programmes show no long-term effects on smoking outcomes⁵²; nevertheless, it has not been investigated as an add-on to implementing a strict school tobacco policy. The Focus study was implemented before national legislation prohibited smoking in youth education. Hence, smoke-free school hours were implemented by law in Danish youth education by 31 July 2021. The law regulates students' smoking behaviour, but school staff is still allowed to use tobacco products outside school grounds during school hours. Despite the new legislation, recent data show many young people continue to smoke during school hours.^{53 54} Similar findings have been reported elsewhere.⁵⁵ Understanding reasons for low implementation and how to prevent potential unintended effects of these structural initiatives are of crucial importance. This may imply that students experience autonomy and involvement in the design of tobacco policies, the social school culture and planning of social activities. Finally, research shows that adolescents are often unaware of their level of nicotine dependency and attempt to quit on their own without counselling or nicotine replacement therapy, despite many being already highly dependent on nicotine.⁵⁶ There is a continuing need for supporting students' abilities to succeed with not smoking in school, for example, via proactive smoking cessation support.

Conclusions

This study suggested overall no unintended effects of the Focus intervention in terms of substitution use, psychological harms, nor group or social harms. Thus, findings may highlight the importance of including relevant actors, that is, students, teachers and the organisation as well as stakeholders in the development of complex school-based interventions to prevent unintended effects among students. Future research may further investigate potential harms produced by interventions using a mixed-methods approach to discover unintended effects not addressed in the original programme theory.

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Patient consent for publication Not applicable.

Ethics approval This study was conducted in accordance with Danish rules of ethics and legislature and is approved by the Danish Data Protection Agency (ref: 17/12006). The National Committee on Health Research Ethics concluded that formal ethics approval was not required because no human biological material was involved (ref: 20182000-83). The Focus study was introduced to students as a study about smoking, health behaviours and well-being. Students were informed that their participation was voluntary, information was used for research purposes only and treated with confidentiality, and they were able to withdraw from the study at any given time. Participants provided written informed consent prior to participating in the surveys by ticking a box at the beginning of the questionnaires.

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