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Do school-based smoking preventive interventions have unintended effects? Findings from a Danish cluster-randomized controlled trial in the vocational education setting

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**Do school-based smoking preventive interventions have unintended effects?
Findings from a Danish cluster-randomized controlled trial in the vocational
education setting**

By Simone G. Kjeld^{1*}, Lau C. Thygesen¹, Dina Danielsen¹, Marie P. Jensen¹, Rikke F. Krølner¹,
Charlotta Pisinger^{2,3,4}, and Susan Andersen¹

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¹National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark

²Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, The Capital
Region of Denmark

³University of Copenhagen, Faculty of Health Sciences, Department of Public Health, Denmark

⁴Danish Heart Foundation, Copenhagen, Denmark

***Corresponding author:**

Simone Gad Kjeld

National Institute of Public Health, University of Southern Denmark

Studiestræde 6, 1455 Copenhagen K

E-mail: simk@sdu.dk

Phone number: +45 65507768

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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, e.g., substitution use, psychological or social harms. The knowledge about the unintended effects of school-based smoking preventive interventions is sparse. Hence, this study aimed to examine these potential unintended effects of the smoking-reducing intervention, Focus, among students in the vocational education and training (VET) setting.

Design: Cluster-randomized controlled trial stratified by school type with five-months follow-up

Setting and participants: Across Denmark, eight schools were randomized to the intervention group (n=1,028 students, response proportion 76%) and six schools to the control group (n=815 students, response proportion 75%).

Interventions: The intervention was developed systematically based on the behavior change wheel theory and a thoroughly mixed methods needs assessment. The intervention included a comprehensive school tobacco policy (smoke-free school hours) supported by a three-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 stigmatization 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, CI: 0.32;1.10) and experience stress (OR: 0.62, CI: 0.35;1.10), but more likely to report feeling stigmatized compared with the control group (OR: 1.55, CI: 0.71;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 seeking to reduce smoking should be aware of avoiding possible stigmatization of smokers.

Trial registration: <https://www.isrctn.com/ISRCTN16455577>, date of registration 14/06/2018

Keywords: smoking, cigarettes, smoking prevention, intervention, vocational schools, cluster randomized controlled trial, unintended effects

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Strengths and limitations of this study

1. A program theory was developed with a priori specification of both intended and potential unintended effects of the intervention
2. The intervention was thoroughly designed with inclusion of the target group and other relevant actors to accommodate potential unintended effects
3. The intervention was evaluated in a cluster-randomized controlled trial
4. Since loss to follow-up could have resulted in attrition bias, multiple imputation of missing data was performed
5. Other unmeasured side-effects may have been produced as response to the intervention, e.g., unintended effects among teachers at the schools.

Introduction

The main intention of public health interventions is to positively impact human life. Complex public health interventions are often guided by a program theory in which a set of key components or activities are identified to enhance healthy behaviors, e.g., physical activity or healthy food intake or to prevent unhealthy behaviors, e.g., smoking or alcohol use, leading to positive health-related outcomes.^{1 2} However, less attention has been drawn to the possible side-effects of public health interventions.³ Bonell et al. stated that *“public health interventions involve human agency and are interruptions to complex social systems, so it is unsurprising that unintended effects can occur.”*⁴ Increased attention to these possible unintended effects of public health interventions may help understand and gain 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.⁴

Tobacco use is considered the main preventable risk factor of years of life lost and mortality worldwide,⁶ and about one-fourth of all annual deaths can be ascribed to a smoking-related cause in Denmark.⁷ Both internationally and nationally, numerous initiatives have been introduced to prevent and reduce smoking.⁸⁻¹¹ In the school setting, multi-level and multi-component interventions have shown the highest intervention effects on youth smoking uptake.⁹ 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 individualized efforts.^{10 11} Although a large body of research has reported on the effects of school-based interventions on smoking-related outcomes, less is known about the potential unintended effects of these interventions. Though a realist review from 2017 demonstrated that school smoking policies can trigger unintended responses that might counteract the purposes of the intervention.¹²

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There are well-known social inequalities in smoking behaviors, and socially disadvantaged groups are more likely to initiate and continue smoking.^{13 14} Research suggests that smoking preventive initiatives may differently impact individuals from diverse socioeconomic backgrounds, but the findings are not unidimensional.¹⁵ Still, price increases and targeted cessation support are suggested to have the highest impact in equalizing social inequalities in smoking.¹⁵ In the vocational education setting, students are often characterized by a lower SES and a higher smoking prevalence compared with students at general high schools.¹⁶⁻¹⁸ The existing research in this setting is still relatively sparse; nonetheless, previous studies suggested that smoke-free school grounds were associated with less smoking,¹⁹ and implementation of social and educational activities reduced students' progression from occasional to daily smoking.²⁰ For this reason, we developed a multi-level and multi-component trial (the Focus intervention) to reduce smoking among youth in the vocational education setting drawing on previous research and best-practice for reducing smoking among high-risk groups of youth.²¹ The intervention focused particularly on structural smoking policies, including smoke-free school hours, which means that neither students, staff, nor visitors may smoke during school hours. We evaluated the effect of the intervention in a cluster-randomized controlled trial (RCT) in which we found no overall effects of the intervention on daily cigarette consumption nor smoking status; however, at schools with full intervention, i.e., implementation of both structural, class-based, and individual components of the intervention, students were less likely to smoke at follow-up compared with the control group. Moreover, selected subgroups of the intervention, i.e., girls and schools with a specific healthcare focus, had higher benefits from the intervention compared to their counterparts in the control group (unpublished data).

Although we tried to avoid harmful unintended effects through a thorough intervention development, we sought to examine if the Focus intervention had unintended effects among students. 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.

More specifically, we investigate the following hypotheses guided by Lorenc and Oliver's framework of unintended effects in public health interventions:²²

Hypothesis 1: Direct harms. Introducing comprehensive smoking bans in school may lead to an increase in other substance use, including alternative tobacco and nicotine products (smokeless tobacco, i.e., snus, snuff, and chewing tobacco, hookah, and e-cigarettes) or cannabis, i.e., substitution use.²³ This may be ascribed to an increased focus on smoking and smoking-related

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harms^{24 25} and subsequently, students with a high degree of nicotine dependence may use alternative tobacco and nicotine products as means to quit smoking or alleviate nicotine withdrawal symptoms.²⁶

Hypothesis 2: Psychological harms. Restricting smoking in school may negatively impact the well-being of students who smoke daily during school hours (including feelings of loneliness, stress, and boredom in breaks during school hours). In school settings with high smoking prevalence, cigarettes have several psychological and social functions. Hence, social interactions previously associated with smoking may disappear after implementation of smoke-free school-hours, which can hamper social relationships and increase feelings of loneliness.^{20 27} Moreover, if smoking cigarettes is no longer accepted as an activity in school, it may introduce boredom.²⁷ Finally, students who are unable to smoke during school hours may experience nicotine withdrawal symptoms and they may lack the opportunity to use smoking as a coping mechanism towards negative emotions and, consequently, experience higher stress levels.^{28 29}

Hypothesis 3: Group and social harms. The intervention may create harm by singling out one group, i.e., students who smoke, which can contribute to stigmatization of this group, both from the surrounding environment and from themselves, due to an increased awareness of harms from smoking.^{30 31}

METHODS

Study design

The Focus intervention was evaluated in a cluster-randomized controlled trial (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 intervention components and development is reported elsewhere.²¹ The recruitment of schools took place from January 2018 to April 2018 and again from January 2019 to April 2019 in schools across Denmark. The time frames enabled schools to implement the intervention at the semester start in August.

Study population, recruitment, and randomization

Fourteen schools offering vocational education and training (VET) or preparatory basic education (PBE) were recruited. 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.^{32 33} The randomization 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. Intervention schools were visited by the project team with the aim of supporting

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implementation of the intervention (see also the Focus study protocol for further details²¹). Baseline data was collected at semester start after the summer holiday. At the end of the semester (approx. five months after), the follow-up assessment was conducted.

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The Focus intervention

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The intervention was developed following the recommended stages within the Behavior Change Wheel³⁴, based on a qualitative needs assessment study and pilot test of intervention components.²¹ 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 behavior (such as to stop smoking during school hours) requires that individuals make sense of the new behavior, develop the required skills for change, and internalize motivation for change.^{35 36}

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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-judgmental 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).

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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,^{28 29} which was specifically addressed in one module about how to handle stress and restlessness, e.g., 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 aim of the competition was to catch students' attention and interest in the intervention.³⁷ 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.

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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.²¹

Measures

As presented in the hypotheses, we examined the unintended effects of the Focus intervention using a conceptual framework following Lorenc and Oliver.²² 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 stigmatization.

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 five-months follow-up by asking students "Have you ever used the following...? 1) Smokeless tobacco, 2) Hookah, and 3) E-cigarettes." Responses were categorized into regular use (daily and occasional) vs. no current use (used it a few times, had previously used, or never used).

Regular cannabis use was also assessed by dichotomizing students' responses to use of cannabis into regular use vs. 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 dichotomized into boredom in breaks (often or very often) vs. 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)³⁸ "Think about your school. How often do you feel... 1) isolated from others? 2) that you lack

companionship? 3) left out?”. The items were summarized to a scale and categorized into low (3-4), moderate (5-6), and high (7-9) level of loneliness. In this study, loneliness during school hours were dichotomized into moderate to high level vs. 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 summarized to a scale and dichotomized into high level of stress (4-5) vs. low to moderate level of stress (0-3).

Group and social harms

Perceived stigmatization among smokers. Stigmatization related to smoking was measured at follow-up using the Internalized Stigma of Smoking Inventory with three subscales of stigma, including self-stigma, felt stigma, and discrimination.³⁹ 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, 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, 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, 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 dichotomized into experience with stigmatization (responding agree or completely agree to at least one item of the subscale) vs. no stigmatization.

Covariates included gender (male vs. female), age (as a continuous variable), and socioeconomic status (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.⁴⁰ SES was determined by the highest-ranking parent and was categorized into high (1-2), medium (3-4), and low (5-6).

Statistical analysis

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All analyses were carried out using SAS v. 9.4. Descriptive statistics were used to compare students in the intervention group and the control group at baseline. For the main analyses, an intention-to-treat approach was utilized including all students with responses at baseline. The main analyses were based on multiple imputations (MI) of missing data using several variables. 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 summarizing the imputed datasets.

Multilevel logistic regression modeling was used to estimate intervention effects on all unintended outcomes at follow-up which were treated dichotomously. Baseline age, gender, and SES were used 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) to increase precision of estimates. The analyses were based on students who smoked daily at baseline. Further, we examined the impact of implementation by conducting a per-protocol analysis using survey responses from school principals. Here, schools were categorized into full intervention (schools with both structural-, class-, and individual-level intervention components) and partial intervention (schools with class- or individual-level components only or who withdrew components during the evaluation period, e.g., the school-based smoking policy) vs. the control group. 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*-value below 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.

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Results

In total, 14 Danish schools were enrolled in this study (N=1,659), of which 844 students were assigned to the intervention group (response proportion 76%) and 815 to the control group (response proportion 75%). The median age of students was 18 years, and about half of students were female (Table 1). On several variables, no notable differences were found between the intervention and the control group, although students in the intervention group were slightly older, comprised more students at PBE schools, and fewer at technical and commercial VET schools compared with the control group. In total, 29.7% 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.

Table 1. Baseline characteristics of students in the Focus trial stratified by condition, complete cases, N=1,659

	Total (N=1,659)	Intervention group (n=844)	Control group (n=815)
	n (%)	n (%)	n (%)
Average number of students per class [mean, (SD)]	16.3 (10.1)	15.6 (11.1)	17.4 (8.4)
School type			
VET schools: social and healthcare	584 (35.2)	299 (35.4)	285 (35.0)
VET schools: technical and commercial	744 (44.9)	340 (40.3)	404 (49.6)
PBE schools	331 (20.0)	205 (24.3)	126 (15.5)
Age, years [median (IQR)]	18 (17;22)	18 (17;22)	17 (17;20)
<18 years	852 (51.4)	410 (48.6)	442 (54.2)
≥18 years	807 (48.6)	434 (51.4)	373 (45.8)
Women	833 (50.2)	443 (52.5)	390 (47.9)
Family occupational social class			
High (I+II)	251 (15.3)	131 (15.6)	120 (14.9)
Middle (III+IV)	678 (41.2)	323 (38.5)	355 (43.9)
Low (V+VI)	423 (25.7)	222 (26.5)	201 (24.9)
Unclassifiable	251 (15.3)	162 (19.3)	132 (16.3)
Baseline smoking status			
Daily smoking	491 (29.7)	264 (31.3)	227 (27.9)
Occasional smoking	181 (10.9)	89 (10.6)	92 (11.3)
Previous smoking	102 (6.2)	46 (5.5)	56 (6.9)
Tried once or twice	263 (15.9)	127 (15.1)	136 (16.7)
Never smoked	619 (37.4)	317 (37.6)	302 (37.2)
Regular smokeless tobacco use	120 (7.3)	57 (6.8)	63 (7.8)
Regular hookah use	172 (10.4)	87 (10.3)	85 (10.5)
Regular e-cigarette use	196 (11.9)	110 (13.1)	86 (10.6)
Regular use of either smokeless tobacco, hookah, or e-cigarettes	352 (21.2)	180 (21.3)	172 (21.1)

Note. Baseline characteristics among complete cases with a missing range on included variables between 0.2%-1.5%

Overall, no statistically significant differences between the intervention and control groups were found for any of the unintended outcomes at five-months follow-up among daily smokers at

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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;1.10) and experience high levels of stress (OR: 0.62, 95% CI: 0.35;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;4.20) and to report felt stigma (OR: 1.55, 95% CI: 0.71;3.40) compared with daily smokers in the control group.

Table 2. Logistic regression analyses of the associations between the intervention group (versus the control group) and unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

Unintended outcome at follow-up	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*		
	%	%	OR	95% CI	p
Alternative tobacco and nicotine product use					
Regular smokeless tobacco use	22.4	28.8	0.78	0.40;1.54	0.49
Regular hookah use	23.2	22.4	1.28	0.61;2.67	0.51
Regular e-cigarette use	37.2	34.1	1.17	0.65;2.10	0.57
Regular use of either smokeless tobacco, hookah, or e-cigarettes	56.1	57.2	1.10	0.64;1.88	0.74
Regular cannabis use	11.0	7.2	1.68	0.67;4.20	0.27
Well-being					
Boredom in breaks during school hours	22.6	32.2	0.59	0.32;1.10	0.10
Loneliness during school hours	18.1	16.8	1.15	0.53;2.50	0.72
High level of stress	66.6	75.1	0.62	0.35;1.10	0.11
Stigmatization among smokers ^a					
Self-stigma	33.6	35.2	0.97	0.54;1.75	0.93
Felt stigma	12.0	9.5	1.55	0.71;3.40	0.27
Discrimination	1.8	1.9	-	-	-

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

^aOnly reported among daily smokers at baseline

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;0.88) compared with daily smokers in the control 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;1.12) but more likely to report felt stigma (OR: 2.15, 95% CI: 0.84;5.53) compared with daily smokers in the control group.

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Table 3. Per-protocol analyses with control group as reference group with unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

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

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

^aOnly reported among daily smokers at baseline

Table 4 displays the differential effects of the intervention on unintended outcomes by school type. Daily smokers at the technical and commercial VET intervention schools were significantly 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;0.75).

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Table 4. Subgroup analyses stratified by school type of the associations between the intervention group (versus the control group) and unintended outcomes measured at five months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

Outcome	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*	
	%	%	OR	95% CI
Alternative tobacco and nicotine product use				
Regular use of either smokeless tobacco, hookah, or e-cigarettes				
VET schools: Social and healthcare	49.0	47.0	1.16	0.43;3.09
VET schools: Technical and commercial	62.2	70.2	0.65	0.24;1.79
PBE schools	61.1	51.5	2.07	0.58;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;7.71
Well-being				
Boredom in breaks during school hours				
VET schools: Social and healthcare	21.0	19.5	1.05	0.36;3.11
VET schools: Technical and commercial	18.3	42.8	0.27	0.10;0.75
PBE schools	32.5	34.7	0.78	0.18;3.39
Loneliness during school hours				
VET schools: Social and healthcare	17.7	11.3	1.68	0.54;5.27
VET schools: Technical and commercial	17.8	18.3	1.12	0.33;3.83
PBE schools	18.4	23.3	0.75	0.18;3.13
High level of stress				
VET schools: Social and healthcare	75.2	77.3	0.82	0.37;1.81
VET schools: Technical and commercial	62.2	73.7	0.52	0.16;1.67
PBE schools	68.5	73.9	0.64	0.20;2.04
Stigmatization among smokers ^a				
Self-stigma				
VET schools: Social and healthcare	35.1	32.8	1.14	0.46;2.85
VET schools: Technical and commercial	30.8	39.9	0.66	0.27;1.64
PBE schools	33.0	31.2	0.98	0.26;3.62
Felt stigma				
VET schools: Social and healthcare	9.9	10.4	0.87	0.27;2.76
VET schools: Technical and commercial	17.8	10.2	2.07	0.53;8.05
PBE schools	7.9	6.6	-	-

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

^aOnly reported among daily smokers at baseline

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Discussion

The multi-level and multi-component intervention, Focus, was developed to reduce smoking in the VET setting. The program theory of the intervention specifically addressed unintended outcomes among students related to substitution use, psychological, and group and social harms as potential risks when implementing the intervention.²¹ 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 stigmatization in terms of felt stigma.

Previous studies have suggested strong connections between tobacco use and stress levels,^{28 29} and smokers often report relief of stress as an important reason to smoke. Consequently, a hypothesized 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. The explanation may be that structural policies were to a lesser extent implemented or not implemented at all, while the schools still received some class-based and individualized intervention components. Hence, students may still have been able to smoke during school hours (and subsequently, able to use smoking to cope with negative emotions), while also receiving education in smoking and related harms as well as alternative strategies to cope with negative emotions and desires to smoke.

Another tendency found in this study was that students in the intervention group experienced less boredom during school hours compared with the control group. Due to important social implications of smoking (e.g., smoking as a means to build connections in school⁴¹), it was hypothesized 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 providing alternatives to smoking breaks. Especially VET intervention schools experienced significantly 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

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students during school hours. Importantly, findings from this study support efforts to strengthen the social environment among students, which have also previously been found to impact students in the VET setting positively.²⁰

Lastly, this study found a non-significant tendency towards students experiencing higher stigmatization from others in the intervention group compared with the control group – especially those students attending schools with full intervention. Little research has investigated stigmatization 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 stigmatization.³⁰ More research within this area is needed to determine potential associations, which we were unable to establish with statistical significance in this study. This could be due to a lack of statistical power or a lack of actual associations.

The present study focused on three types of unintended harms (direct harms, psychological harms, and group and social harms) addressed in the program theory of Focus²¹ and guided by a conceptual framework.²² Two other types of harms are outlined in this framework, which were not specifically studied in this paper. 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.²² 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 large attention and resources at an organizational level – and the Focus study draws from best-practice and previous research in reducing smoking among students using a multi-level approach with multiple components.⁹⁻¹¹ Nonetheless, future research may further investigate whether all or only some of the intervention components affect students' tobacco use or other health behaviors, which can guide and inform future interventions in this setting and may reveal potential for tailoring future interventions more effectively and carefully. Secondly, *equity harms* concern the risk of interventions affecting students divergently according to various sociodemographic factors.²² The Focus study was designed to reduce smoking in a setting with generally more lower SES youth with higher smoking prevalence.^{16 17} As the intervention was implemented in a school setting, the possibility of reaching high-risk groups was high⁴² – 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,^{15 43} and the most well-documented initiative to not increase social inequality in smoking is increased tobacco prices.¹⁵ This calls for more political actions towards tobacco prices in combination with structural and individualized efforts in the school setting to equalize social inequalities in smoking.

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Strengths and limitations

Several methodological strengths apply to this study. Specifically, a program 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 (e.g., the Danish Cancer Society) to ensure proper implementation and relevance among the students.²¹ Further, the Focus intervention was evaluated in a cluster-randomized controlled trial, 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 nonsignificant tendencies. Further research is warranted to investigate potential unintended effects of smoking preventive interventions using a larger sample size of students.

Another limitation of this study could be the fact that unintended effects were solely investigated according to the factors outlined in the program theory and measured in the baseline and follow-up surveys. Other side-effects may have been produced 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.²⁰ 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 prioritizing 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 emphasized 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 theorization

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of hypotheses about possible side-effects in the intervention development as well as involving e.g., students and teachers in the design of intervention components may lead to fewer unexpected negative side-effects. The Focus study was implemented before national legislation prohibited smoking in youth educations. Hence, smoke-free school hours were implemented by law in Danish youth educations by July 31st, 2021. The law regulates students' smoking behavior, but school staff is still allowed to use tobacco products outside school grounds during school hours. Despite the new legislation, recent data shows many young people continue to smoke during school hours.^{44 45} Similar findings have been reported elsewhere.⁴⁶ 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 counseling or nicotine replacement therapy, despite many being already highly dependent on nicotine.⁴⁷ There is a continuing need for supporting students' abilities to succeed with not smoking in school, e.g., 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, i.e., students, teachers, and the organization 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 program theory.

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Data Availability Statement

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Data that support the findings of this study is available from the University of Southern Denmark (SDU). Data is available from the corresponding upon reasonable request and with permission from SDU. Requests to access research data should be directed to simk@sdu.dk.

Ethics Statement

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 behaviors, 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.

Author Contributions

All authors took part in the conceptualization or design of this study. Data collection was carried out by DD, MPJ, and SA. SGK, LCT, and SA carried out the main analyses, and SGK drafted the initial manuscript. LCT, DD, MPJ, CP, RFK, and SA critically reviewed and revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interests

The authors declare no conflicts of interests.

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References

1. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;374:n2061.
2. Funnell SC, Rogers PJ. Purposeful program theory: Effective use of theories of change and logic models: John Wiley & Sons 2011.
3. Oliver K, Lorenc T, Tinkler J, et al. Understanding the unintended consequences of public health policies: the views of policymakers and evaluators. *BMC Public Health* 2019;19(1):1057.
4. Bonell C, Jamal F, Melendez-Torres GJ, et al. 'Dark logic': theorising the harmful consequences of public health interventions. *Journal of Epidemiology and Community Health* 2015;69(1):95-98.
5. Bonell C, Fletcher A, Morton M, et al. Realist randomised controlled trials: A new approach to evaluating complex public health interventions. *Soc Sci Med* 2012;75(12):2299-306.
6. US Department of Health and Human Services. The health consequences of smoking—50 years of progress: a report of the surgeon general. US Department of Health and Human Services: Citeseer, 2014.
7. Eriksen L, Davidsen M, Jensen HAR, et al. Sygdomsbyrden i Danmark: risikofaktorer [The burden of disease in Denmark: risk factors]: The Danish Health Authority 2016.
8. Jarlstrup NS, Juel K, Pisinger CH, et al. International Approaches to Tobacco Use Cessation Programs and Policy in Adolescents and Young Adults: Denmark. *Current Addiction Reports* 2018;5(1):42-53.
9. Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database of Systematic Reviews* 2013(4)
10. Galanti MR, Coppo A, Jonsson E, et al. Anti-tobacco policy in schools: upcoming preventive strategy or prevention myth? A review of 31 studies. *Tob Control* 2014;23(4):295-301.
11. Bast LS, Due P, Bendtsen P, et al. High impact of implementation on school-based smoking prevention: the X:IT study—a cluster-randomized smoking prevention trial. *Implement Sci* 2016;11(1):125.
12. Schreuders M, Nuyts PAW, van den Putte B, et al. Understanding the impact of school tobacco policies on adolescent smoking behaviour: A realist review. *Social Science & Medicine* 2017;183(Supplement C):19-27. doi: <https://doi.org/10.1016/j.socscimed.2017.04.031>
13. Clare P, Bradford D, Courtney RJ, et al. The relationship between socioeconomic status and 'hardcore' smoking over time—greater accumulation of hardened smokers in low-SES than high-SES smokers. *Tob Control* 2014;23(e2):e133-8.
14. Song F, Elwell-Sutton T, Naughton F, et al. Future smoking prevalence by socioeconomic status in England: a computational modelling study. *Tob Control* 2021;30(4):380-85.
15. Smith CE, Hill SE, Amos A. Impact of population tobacco control interventions on socioeconomic inequalities in smoking: a systematic review and appraisal of future research directions. *Tob Control* 2021;30(e2):e87-e95.
16. Jarlstrup NS, Andersen MB, Kjeld SG, et al. § RØG-En undersøgelse af tobak, adfærd og regler: Basisrapport 2020 [§SMOKE—A study of tobacco, behavior and regulations: Basis report]. 2020
17. Chyderiotis S, Benmarhnia T, Spilka S, et al. Why do apprentices smoke much more than high school students? Understanding educational disparities in smoking with a Oaxaca-blinder decomposition analysis. *BMC Public Health* 2020;20(1):924.
18. Statistics Denmark. Erhvervsudannelser i Danmark 2019 [Vocational schools in Denmark 2019]. In: Denmark S, ed., 2019.
19. Andersen S, Pisinger V, Rod MH, et al. Associations of school tobacco policies and legislation with youth smoking: a cross-sectional study of Danish vocational high schools. *BMJ Open* 2019;9(7)
20. Andersen S, Rod MH, Ersbøll AK, et al. Effects of a settings-based intervention to promote student wellbeing and reduce smoking in vocational schools: A non-randomized controlled study. *Soc Sci Med* 2016;161:195-203.
21. Jakobsen GS, Danielsen D, Jensen MP, et al. Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. *Tob Prev Cessat* 2021;7:42.
22. Lorenc T, Oliver K. Adverse effects of public health interventions: a conceptual framework. *J Epidemiol Community Health* 2014;68(3):288-90.

UNINTENDED EFFECTS OF SMOKING PREVENTION

23. Kjeld SG, Lund L, Andersen S, et al. Socioeconomic Differences in Cigarette Smoking and Alternative Tobacco Product Use Among Adolescents in a School-Based Smoking Preventive Intervention: Findings From the Second Year of the X:IT II Study. *Frontiers in Public Health* 2022;10
24. Mpousiou DP, Sakkas N, Soteriades ES, et al. Evaluation of a school-based, experiential-learning smoking prevention program in promoting attitude change in adolescents. *Tobacco Induced Diseases* 2021;19(June):1-10.
25. Kjeld SG, Glenstrup S, Bast LS. Gender and socioeconomic disparities in reasons for not smoking cigarettes among Danish adolescents. *BMC Research Notes* 2021;14(1):33.
26. Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA* 2019;322(21):2095-103.
27. Piko BF, Varga S, Wills TA. A Study of Motives for Tobacco and Alcohol Use Among High School Students in Hungary. *Journal of Community Health* 2015;40(4):744-49.
28. Lawless MH, Harrison KA, Grandits GA, et al. Perceived stress and smoking-related behaviors and symptomatology in male and female smokers. *Addictive Behaviors* 2015;51:80-83.
29. Kassel JD, Stroud LR, Paronis CA. Smoking, stress, and negative affect: correlation, causation, and context across stages of smoking. *Psychol Bull* 2003;129(2):270-304.
30. Robert P-O, Grard A, Mélard N, et al. The effect of school smoke-free policies on smoking stigmatization: A European comparison study among adolescents. *PLOS ONE* 2020;15(7):e0235772.
31. Lozano P, Thrasher JF, Forthofer M, et al. Smoking-Related Stigma: A Public Health Tool or a Damaging Force? *Nicotine Tob Res* 2020;22(1):96-103.
32. Ministry of Children and Education. Produktionsskoler [Production schools]. 2020.
33. Aarkrog V. The standing and status of vocational education and training in Denmark. *Journal of Vocational Education & Training* 2020;72(2):170-88.
34. Michie S, Hyder N, Walia A, et al. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav* 2011;36(4):315-9.
35. Braveman P, Egerter S, Williams DR. The Social Determinants of Health: Coming of Age. *Annual Review of Public Health* 2011;32(1):381-98. doi: 10.1146/annurev-publhealth-031210-101218
36. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000;55(1):68-78.
37. Gilbert C, Moss D. Biofeedback and biological monitoring. . In: Moss D, McGrady A, Davies T, et al., eds. *Handbook of Mind-Body Medicine for Primary Care*. Thousand Oaks, CA: Sage Publications 2003.
38. Hughes ME, Waite LJ, Hawkey LC, et al. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. *Res Aging* 2004;26(6):655-72.
39. Brown-Johnson CG, Cataldo JK, Orozco N, et al. Validity and reliability of the Internalized Stigma of Smoking Inventory: An exploration of shame, isolation, and discrimination in smokers with mental health diagnoses. *Am J Addict* 2015;24(5):410-8.
40. Christensen U, Krølnær R, Nilsson CJ, et al. Addressing Social Inequality in Aging by the Danish Occupational Social Class Measurement. *Journal of Aging and Health* 2014;26(1):106-27.
41. Aho H, Koivisto AM, Paavilainen E, et al. The relationship between peer relations, self-rated health and smoking behaviour in secondary vocational schools. *Nurs Open* 2019;6(3):754-64.
42. Kaftarian S, Robertson E, Compton W, et al. Blending prevention research and practice in schools: critical issues and suggestions. *Prev Sci* 2004;5(1):1-3.
43. Mercken L, Moore L, Crone MR, et al. The effectiveness of school-based smoking prevention interventions among low- and high-SES European teenagers. *Health Educ Res* 2012;27(3):459-69.
44. Andersen MB, Bast LS. § RØG—En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021 [§ SMOKE—A study of tobacco, behavior and regulations: selected tendencies 2021]. 2021
45. Petersen MT, Lund L, Bast LS. §RØG—En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021, rapport 3 [§SMOKE—A study of tobacco, behavior and regulations: Selected tendencies 2021, report 3]. 2022

UNINTENDED EFFECTS OF SMOKING PREVENTION

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4 46. Schreuders M, Klompmaker L, van den Putte B, et al. Adolescent Smoking in Secondary Schools that Have
5 Implemented Smoke-Free Policies: In-Depth Exploration of Shared Smoking Patterns. *Int J Environ Res Public*
6 *Health* 2019;16(12)
7
8 47. Suls JM, Luger TM, Curry SJ, et al. Efficacy of smoking-cessation interventions for young adults: a meta-analysis.
9 *Am J Prev Med* 2012;42(6):655-62.
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For peer review only

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3,4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	4,5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5 ^{1,2}
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		1
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	1
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication,	Whether interventions pertain to the cluster level, the individual participant level or both	6

		including how and when they were actually administered		
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	1,2
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		5 ^{1,2}
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5 ^{1,2}
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	5 ^{1,2}

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	1,2
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	1,2
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	18
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		n/a
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9
Results				

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	10 ²
Recruitment	14a	Dates defining the periods of recruitment and follow-up		5,6
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	11-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses		12-13

		and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	See CONSORT for harms
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant) 16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14,15
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	19
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

¹Jakobsen et al. (2021). Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. Tobacco Prevention and Cessation, 7, 1-12. <https://doi.org/10.18332/TPC/133934>

² Kjeld SG, Thygesen LC, Danielsen D, Jakobsen GS, Jensen MP, Holmberg T, Bast LS, Lund L, Pisinger C, Andersen S. Effectiveness of the multi-component intervention Focus on reducing smoking among students in the vocational education setting: A stratified cluster randomized controlled trial. Under review.

Table 2. Checklist of Items To Include When Reporting Harms in Randomized, Controlled Trials*

Standard CONSORT Checklist: Paper Section and Topic	Standard CONSORT Checklist: Item Number	Descriptor	Reported on Page Number
Title and abstract	1	If the study collected data on harms and benefits, the title or abstract should so state.	1,2
Introduction Background	2	If the trial addresses both harms and benefits, the introduction should so state.	3-5
Methods Participants Interventions Objectives Outcomes	3 4 5 6	List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardized and validated definitions, and description of new definitions). Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).	6-8
Sample size Randomization Sequence generation Allocation concealment Implementation Blinding (masking) Statistical methods	7 8 9 10 11 12	Describe plans for presenting and analyzing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses).	9
Results Participant flow	13	Describe for each arm the participant withdrawals that are due to harms and their experiences with the allocated treatment.	n/a
Recruitment Baseline data Numbers analyzed Outcomes and estimation Ancillary analyses Adverse events	14 15 16 17 18 19	Provide the denominators for analyses on harms. Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent.† Describe any subgroup analyses and exploratory analyses for harms.‡	9-13
Discussion Interpretation Generalizability Overall evidence	20 21 22	Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalizability, and other sources of information on harms.§	14-17

* This proposed extension for harms includes 10 recommendations that correspond to the original CONSORT checklist.

† Descriptors refer to items 17, 18, and 19.

‡ Descriptor refers to items 20, 21, and 22.

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Do school-based smoking preventive interventions have unintended effects? Findings from a Danish cluster-randomized controlled trial in the vocational education setting

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**Do school-based smoking preventive interventions have unintended effects?
Findings from a Danish cluster-randomized controlled trial in the vocational
education setting**

By Simone G. Kjeld^{1*}, Lau C. Thygesen¹, Dina Danielsen¹, Marie P. Jensen¹, Rikke F. Krølner¹,
Charlotta Pisinger^{2,3,4}, and Susan Andersen¹

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¹National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark

²Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, The Capital
Region of Denmark

³University of Copenhagen, Faculty of Health Sciences, Department of Public Health, Denmark

⁴Danish Heart Foundation, Copenhagen, Denmark

***Corresponding author:**

Simone Gad Kjeld

National Institute of Public Health, University of Southern Denmark

Studiestræde 6, 1455 Copenhagen K

E-mail: simk@sdu.dk

Phone number: +45 65507768

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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 (VET) setting.

Design: Cluster-randomized controlled trial stratified by school type with five-months follow-up

Setting and participants: Across Denmark, eight schools were randomized 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 three-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 stigmatization 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, CI: 0.32;1.10) and experience stress (OR: 0.62, CI: 0.35;1.10), but more likely to report feeling stigmatized compared with the control group (OR: 1.55, CI: 0.71;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 stigmatization of smokers.

Trial registration: <https://www.isrctn.com/ISRCTN16455577>, date of registration 14/06/2018

Keywords: smoking, cigarettes, smoking prevention, intervention, vocational schools, cluster randomized controlled trial, unintended effects

UNINTENDED EFFECTS OF SMOKING PREVENTION

Strengths and limitations of this study

1. A program theory was developed with a priori specification of both intended and potential unintended effects of the intervention
2. The intervention was thoroughly designed with inclusion of the target group and other relevant actors to accommodate potential unintended effects
3. The intervention was evaluated in a cluster-randomized controlled trial
4. Since loss to follow-up could have resulted in attrition bias, multiple imputation of missing data was performed
5. Other unmeasured side-effects may have been produced as response to the intervention, e.g., 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 program theory is often developed in which a set of key components or activities are identified to enhance healthy behaviors or to prevent unhealthy behaviors, leading to positive health-related outcomes.^{1 2} Interventions operating on multiple levels targeting the structural and individual levels are considered key in changing behaviors. In this regard, numerous public health efforts have been introduced to prevent and reduce smoking,³⁻⁶ and in the school setting, the highest intervention effects have been found for complex multi-level and multi-component interventions.⁴ 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 individualized components.^{5 6}

The students enrolled in the vocational educational and training (VET) setting generally differ from those attending general high schools, e.g., students are often characterized by a lower socioeconomic status (SES) and a higher smoking prevalence.⁷⁻⁹ Prior research within the VET setting found that smoke-free school ground policy was associated with less smoking,¹⁰ and social and educational activities reduced students' progression from occasional to daily smoking.¹¹ Still, the existing research concerned with smoking preventive interventions in this setting is sparse. For this reason, we developed a multi-level and multi-component intervention 'Focus' to reduce smoking among youth in the VET setting.¹² We evaluated the effect of the intervention in a cluster-randomized controlled trial (RCT) in which we found no overall effects of the intervention on smoking; however, at schools with full intervention, i.e., 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.¹³ Moreover, selected subgroups of the intervention, i.e.,

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girls and schools with healthcare programs, had higher benefits from the intervention compared to their counterparts in the control group.

While the literature on the possible unintended effects of public health interventions is sparse,¹⁴ a realist review from 2017 demonstrated that school smoking policies can trigger unintended responses that might counteract the purposes of the intervention.¹⁵ 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.^{14 16} Further, conducting studies on negative unintended effects has been highlighted as crucial to prevent replication of harms in future interventions.¹⁷ 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.¹⁷

Lorenc and Oliver’s framework of unintended effects of public health interventions,¹⁸ 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 Firstly, 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, i.e., 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

Secondly, 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.^{11 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}

UNINTENDED EFFECTS OF SMOKING PREVENTION

Finally, the intervention could potentially create *group and social harms* by singling out those who smoke as problematic, which can contribute to stigmatization 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 stigmatization 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, we aimed to examine if the Focus intervention produced the following types of unintended effects among students, namely (i) *direct harms* (substitution use) measured by alternative tobacco and nicotine product use as well as cannabis use, (ii) *psychological harms* measured by boredom in breaks and loneliness during school hours as well as stress levels, and (iii) *group and social harms* measured by perceived stigmatization. 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-randomized controlled trial (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.¹²

Study population, recruitment, and randomization

Schools offering basic course of vocational education and training (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 16-25 years old, and the intervention was targeted this age group. The randomization 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

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over the course of three 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)=1,659), 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 five months after baseline. A more detailed description of the sample flow is reported elsewhere.¹³

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 details¹²). Baseline data was collected at semester start after the summer holiday. At the end of the semester (approximately five months after), the follow-up assessment was conducted.

The Focus intervention

The intervention was developed following the recommended stages within the Behavior Change Wheel,³⁶ based on a qualitative needs assessment study and pilot test of intervention components.¹² 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 behavior (such as to stop smoking during school hours) requires that individuals make sense of the new behavior, develop the required skills for change, and internalize 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-judgmental 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).

UNINTENDED EFFECTS OF SMOKING PREVENTION

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, e.g., 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.¹²

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 stigmatization. The included outcomes concerned with the unintended effects were developed and specified before the intervention start,¹² and most were also pre-specified in the trial registration; however, specific outcomes (cannabis use, stress, boredom, and stigmatization) 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.¹³

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4 *Direct harms/substitution use*
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6 *Alternative tobacco and nicotine product use.* Regular use of smokeless tobacco,
7 hookah, and e-cigarette use, respectively, were assessed at baseline and five-
8 months follow-up by asking students “Have you ever used the following...? 1)
9 Smokeless tobacco, 2) Hookah, and 3) E-cigarettes.” Responses were categorized
10 into regular use (daily and occasional) vs. no current use (used it a few times, had
11 previously used, or never used).
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16 *Regular cannabis use* was also assessed by dichotomizing students’ responses to
17 use of cannabis into regular use vs. no current use. Cannabis use was solely
18 measured at follow-up.
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22 *Psychological harms*
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24 *Boredom in breaks during school hours.* Students were asked at follow-up whether
25 they experienced breaks in school to be boring, and response options were
26 dichotomized into boredom in breaks (often or very often) vs. being bored sometimes
27 or rarely in breaks.
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31 *Moderate to high level of loneliness during school hours* was measured at follow-up
32 using a modified version of the Three Item Loneliness Scale (T-ILS)⁴⁰ “Think about
33 your school. How often do you feel... 1) isolated from others? 2) that you lack
34 companionship? 3) left out?”. The items were summarized to a scale and categorized
35 into low (3-4), moderate (5-6), and high (7-9) level of loneliness. In this study,
36 loneliness during school hours were dichotomized into moderate to high level vs. low
37 level of loneliness.
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42 *High level of stress* was assessed at follow-up with two questions, 1) “Do you feel
43 stressed?” with response options 0 = Not at all, 1 = Yes, a little, and 2 = Yes, a lot, 2)
44 “How often do you feel stressed?” with four response options ranging from 0 =
45 Never/almost never to 3 = Daily. The items were summarized to a scale and
46 dichotomized into high level of stress (4-5) vs. low to moderate level of stress (0-3).
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51 *Group and social harms*
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53 *Perceived stigmatization among smokers.* Stigmatization related to smoking was
54 measured at follow-up using the Internalized Stigma of Smoking Inventory with three
55 subscales of stigma, including self-stigma, felt stigma, and discrimination.⁴¹ The self-
56 stigma subscale had the following items “To which extent do you agree/disagree with
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UNINTENDED EFFECTS OF SMOKING PREVENTION

the following statements...? 1) I am ashamed or embarrassed that I am a smoker, 2) I am disappointed in myself for being a smoker, 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, 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, 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 dichotomized into experience with stigmatization (responding agree or completely agree to at least one item of the subscale) vs. no stigmatization.

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 categorized into 1) implementation of the school- 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 socioeconomic status (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 categorized into high (1-2), medium (3-4), and low (5-6).

Statistical analysis

All analyses were carried out 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 utilized 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 behavior 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

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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 summarizing the imputed datasets.

Multilevel logistic regression modeling was used to estimate intervention effects at five-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*-value below 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.

UNINTENDED EFFECTS OF SMOKING PREVENTION

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% was in the intervention group, and 46% was 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%).

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

	Total (N=491)	Intervention group (n=264, 54%)	Control group (n=227, 46%)
	n (%)	n (%)	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)

Note. Missing proportion of 0.6%.

Overall, no statistically significant differences between the intervention and control groups were found for any of the unintended outcomes at five-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;1.10) and experience high levels of stress (OR: 0.62, 95% CI: 0.35;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,

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4 95% CI: 0.67;4.20) and to report felt stigma (OR: 1.55, 95% CI: 0.71;3.40) compared with daily
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6 smokers in the control group.
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8 **Table 2. Logistic regression analyses of the associations between the intervention group (versus the control group)**
9 **and unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple**
10 **imputation of missing data (N=40x491).**

Unintended outcome at follow-up	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*		
	%	%	OR	95% CI	p
Alternative tobacco and nicotine product use					
Regular smokeless tobacco use	22.4	28.8	0.78	0.40;1.54	0.49
Regular hookah use	23.2	22.4	1.28	0.61;2.67	0.51
Regular e-cigarette use	37.2	34.1	1.17	0.65;2.10	0.57
Regular use of either smokeless tobacco, hookah, or e-cigarettes	56.1	57.2	1.10	0.64;1.88	0.74
Regular cannabis use	11.0	7.2	1.68	0.67;4.20	0.27
Well-being					
Boredom in breaks during school hours	22.6	32.2	0.59	0.32;1.10	0.10
Loneliness during school hours	18.1	16.8	1.15	0.53;2.50	0.72
High level of stress	66.6	75.1	0.62	0.35;1.10	0.11
Stigmatization					
Self-stigma	33.6	35.2	0.97	0.54;1.75	0.93
Felt stigma	12.0	9.5	1.55	0.71;3.40	0.27
Discrimination	1.8	1.9	-	-	-

29 *adjusted for gender, socioeconomic status, age, and baseline variable if available (regular smokeless tobacco, hookah, and e-
30 cigarette use)

31 *Note.* Due to low student representation in the discrimination subscale, regression analyses were not possible.
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35 The per-protocol analysis did not show statistically significant differences between level of
36 implementation and unintended outcomes – except fewer daily smokers attending schools with
37 partial intervention experienced high levels of stress (OR: 0.47, 95% CI: 0.25;0.88) compared with
38 daily smokers in the control group (Table 3). Non-statistically significant tendencies suggested that
39 daily smokers at schools with full intervention were less likely to be bored in breaks during school
40 hours (OR: 0.52, 95% CI: 0.24;1.12) but more likely to report felt stigma (OR: 2.15, 95% CI:
41 0.84;5.53) compared with daily smokers in the control group.
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Table 3. Per-protocol analyses with control group as reference group with unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

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

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

Note. Due to low student representation in the discrimination subscale, regression analyses were not possible, leading to its exclusion from the table.

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;0.75).

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Table 4. Subgroup analyses stratified by school type of the associations between the intervention group (versus the control group) and unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

Outcome	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*	
	%	%	OR	95% CI
Alternative tobacco and nicotine product use				
Regular use of either smokeless tobacco, hookah, or e-cigarettes				
VET schools: Social and healthcare	49.0	47.0	1.16	0.43;3.09
VET schools: Technical and commercial	62.2	70.2	0.65	0.24;1.79
PBE schools	61.1	51.5	2.07	0.58;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;7.71
Well-being				
Boredom in breaks during school hours				
VET schools: Social and healthcare	21.0	19.5	1.05	0.36;3.11
VET schools: Technical and commercial	18.3	42.8	0.27	0.10;0.75
PBE schools	32.5	34.7	0.78	0.18;3.39
Loneliness during school hours				
VET schools: Social and healthcare	17.7	11.3	1.68	0.54;5.27
VET schools: Technical and commercial	17.8	18.3	1.12	0.33;3.83
PBE schools	18.4	23.3	0.75	0.18;3.13
High level of stress				
VET schools: Social and healthcare	75.2	77.3	0.82	0.37;1.81
VET schools: Technical and commercial	62.2	73.7	0.52	0.16;1.67
PBE schools	68.5	73.9	0.64	0.20;2.04
Stigmatization among smokers				
Self-stigma				
VET schools: Social and healthcare	35.1	32.8	1.14	0.46;2.85
VET schools: Technical and commercial	30.8	39.9	0.66	0.27;1.64
PBE schools	33.0	31.2	0.98	0.26;3.62
Felt stigma				
VET schools: Social and healthcare	9.9	10.4	0.87	0.27;2.76
VET schools: Technical and commercial	17.8	10.2	2.07	0.53;8.05
PBE schools	7.9	6.6	-	-

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

Note. 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.

Discussion

The multi-level and multi-component intervention, Focus, was developed to reduce smoking in the VET setting. The program 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.¹² 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 stigmatization in terms of felt stigma.

Previous studies have suggested strong connections between tobacco use and stress levels.^{25 26} Consequently, a hypothesized 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 structural policies were to a lesser extent implemented or not implemented at all, while the schools still received some class-based and individualized intervention components. Hence, students may still have been able to smoke during school hours (and subsequently, be able to use smoking to e.g., cope with negative emotions), while also receiving education in smoking and related harms as well as alternative strategies to cope with negative emotions and desires to smoke. 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 to non-smokers,⁴³ and nicotine in cigarettes can intensify 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 (e.g., smoking as a means to build social relationships in school⁴⁶), it was hypothesized 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 providing 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.¹¹

Lastly, this study found a non-significant tendency towards students experiencing higher stigmatization from others in the intervention group compared with the control group – especially those students attending schools with full intervention. Little research has investigated stigmatization 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 stigmatization.²⁷ The potential stigmatization 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} One hypothesized mechanism is that public stigma of smoking may lead to an internalized 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-stigmatization may negatively affect the mental health of individuals and help-seeking behaviors 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 program theory of Focus¹² 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

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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 organizational level – and the Focus study draws from best-practice and previous research in reducing smoking among students using a multi-level approach with multiple components.⁴⁻⁶ Nonetheless, future research may further investigate whether all or only some of the intervention components affected students' tobacco use or other health behaviors, which can guide and inform future interventions in this setting and may reveal potential for tailoring future interventions more effectively and carefully.

Secondly, *equity harms* concern the risk of interventions affecting students divergently according to various sociodemographic factors.¹⁸ The Focus study was designed to reduce smoking in a setting with generally more lower SES youth with higher smoking prevalence.^{7 8} 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 individualized efforts in the school setting to equalize social inequalities in smoking. It is worth noting that – even within the context of this setting with lower SES students – the intervention may have benefitted 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 program 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 (e.g., the Danish Cancer Society) to ensure proper implementation and relevance among the students.¹² Further, the Focus intervention was evaluated in a cluster-randomized controlled trial, 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

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subgroup analyses increasing the risk of type II error, which could partly explain the insignificant results. We therefore also present and discuss nonsignificant tendencies. Further research is warranted to investigate potential unintended effects of smoking preventive interventions using a larger sample size of students.

Another limitation of this study could be the fact that unintended effects were solely investigated according to the factors outlined in the program theory and measured in the baseline and follow-up surveys. Other side-effects may have been produced 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.¹¹ 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 prioritizing 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 emphasized 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 theorization of hypotheses about possible side-effects in the intervention development as well as involving e.g., students and teachers in the design of intervention components may lead to fewer unexpected negative side-effects. The Focus study was implemented before national legislation prohibited smoking in youth educations. Hence, smoke-free school hours were implemented by law in Danish youth educations by July 31st, 2021. The law regulates students' smoking behavior, but school staff is still allowed to use tobacco products outside school grounds during school hours. Despite the new legislation, recent data shows many young people continue to smoke during school hours.^{51 52} Similar findings have been reported elsewhere.⁵³ 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

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that adolescents are often unaware of their level of nicotine dependency and attempt to quit on their own without counseling or nicotine replacement therapy, despite many being already highly dependent on nicotine.⁵⁴ There is a continuing need for supporting students' abilities to succeed with not smoking in school, e.g., 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, i.e., students, teachers, and the organization 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 program theory.

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Data Availability Statement

Data that support the findings of this study is available from the University of Southern Denmark (SDU). Data is available from the corresponding upon reasonable request and with permission from SDU. Requests to access research data should be directed to simk@sdu.dk.

Ethics Statement

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 behaviors, 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

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provided written informed consent prior to participating in the surveys by ticking a box at the beginning of the questionnaires.

Author Contributions

All authors took part in the conceptualization or design of this study. Data collection was carried out by DD, MPJ, and SA. SGK, LCT, and SA carried out the main analyses, and SGK drafted the initial manuscript. LCT, DD, MPJ, CP, RFK, and SA critically reviewed and revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interests

The authors declare no conflicts of interests.

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References

1. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;374:n2061.
2. Funnell SC, Rogers PJ. Purposeful program theory: Effective use of theories of change and logic models: John Wiley & Sons 2011.
3. Jarlstrup NS, Juel K, Pisinger CH, et al. International Approaches to Tobacco Use Cessation Programs and Policy in Adolescents and Young Adults: Denmark. *Current Addiction Reports* 2018;5(1):42-53.
4. Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database of Systematic Reviews* 2013(4)
5. Galanti MR, Coppo A, Jonsson E, et al. Anti-tobacco policy in schools: upcoming preventive strategy or prevention myth? A review of 31 studies. *Tob Control* 2014;23(4):295-301.
6. Bast LS, Due P, Bendtsen P, et al. High impact of implementation on school-based smoking prevention: the X:IT study-a cluster-randomized smoking prevention trial. *Implement Sci* 2016;11(1):125.
7. Jarlstrup NS, Andersen MB, Kjeld SG, et al. § RØG-En undersøgelse af tobak, adfærd og regler: Basisrapport 2020 [§SMOKE—A study of tobacco, behavior and regulations: Basis report]. 2020
8. Chyderiotis S, Benmarhnia T, Spilka S, et al. Why do apprentices smoke much more than high school students? Understanding educational disparities in smoking with a Oaxaca-blinder decomposition analysis. *BMC Public Health* 2020;20(1):924.
9. Statistics Denmark. Erhvervsuddannelser i Danmark 2019 [Vocational schools in Denmark 2019]. 2019.
10. Andersen S, Pisinger V, Rod MH, et al. Associations of school tobacco policies and legislation with youth smoking: a cross-sectional study of Danish vocational high schools. *BMJ Open* 2019;9(7)
11. Andersen S, Rod MH, Ersbøll AK, et al. Effects of a settings-based intervention to promote student wellbeing and reduce smoking in vocational schools: A non-randomized controlled study. *Soc Sci Med* 2016;161:195-203.
12. Jakobsen GS, Danielsen D, Jensen MP, et al. Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. *Tob Prev Cessat* 2021;7:42.
13. Kjeld SG, Thygesen LC, Danielsen D, et al. Effectiveness of the multi-component intervention 'Focus' on reducing smoking among students in the vocational education setting: a cluster randomized controlled trial. *BMC Public Health* 2023;23(1):419.
14. Oliver K, Lorenc T, Tinkler J, et al. Understanding the unintended consequences of public health policies: the views of policymakers and evaluators. *BMC Public Health* 2019;19(1):1057.
15. Schreuders M, Nuyts PAW, van den Putte B, et al. Understanding the impact of school tobacco policies on adolescent smoking behaviour: A realist review. *Soc Sci Med* 2017;183(Supplement C):19-27.
16. Bonell C, Fletcher A, Morton M, et al. Realist randomised controlled trials: A new approach to evaluating complex public health interventions. *Soc Sci Med* 2012;75(12):2299-306.
17. Bonell C, Jamal F, Melendez-Torres GJ, et al. 'Dark logic': theorising the harmful consequences of public health interventions. *J Epidemiol Community Health* 2015;69(1):95-98.
18. Lorenc T, Oliver K. Adverse effects of public health interventions: a conceptual framework. *J Epidemiol Community Health* 2014;68(3):288-90.
19. Kjeld SG, Lund L, Andersen S, et al. Socioeconomic Differences in Cigarette Smoking and Alternative Tobacco Product Use Among Adolescents in a School-Based Smoking Preventive Intervention: Findings From the Second Year of the X:IT II Study. *Frontiers in Public Health* 2022;10
20. Mpousiou DP, Sakkas N, Soteriades ES, et al. Evaluation of a school-based, experiential-learning smoking prevention program in promoting attitude change in adolescents. *Tobacco Induced Diseases* 2021;19(June):1-10.
21. Kjeld SG, Glenstrup S, Bast LS. Gender and socioeconomic disparities in reasons for not smoking cigarettes among Danish adolescents. *BMC Research Notes* 2021;14(1):33.
22. Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA* 2019;322(21):2095-103.
23. Danielsen D, Jensen TS, Kjeld SG, et al. Context matters in smoking prevention: evaluating smoke-free school hours in Danish vocational schools. *Health Promot Int* 2023;38(2).

UNINTENDED EFFECTS OF SMOKING PREVENTION

24. Piko BF, Varga S, Wills TA. A Study of Motives for Tobacco and Alcohol Use Among High School Students in Hungary. *Journal of Community Health* 2015;40(4):744-49.
25. Lawless MH, Harrison KA, Grandits GA, et al. Perceived stress and smoking-related behaviors and symptomatology in male and female smokers. *Addictive Behaviors* 2015;51:80-83.
26. Kassel JD, Stroud LR, Paronis CA. Smoking, stress, and negative affect: correlation, causation, and context across stages of smoking. *Psychol Bull* 2003;129(2):270-304.
27. Robert P-O, Grard A, Mélard N, et al. The effect of school smoke-free policies on smoking stigmatization: A European comparison study among adolescents. *PLOS ONE* 2020;15(7):e0235772.
28. Burgess DJ, Fu SS, van Ryn M. Potential Unintended Consequences of Tobacco-Control Policies on Mothers Who Smoke: A Review of the Literature. *American Journal of Preventive Medicine* 2009;37(2, Supplement):S151-S58.
29. Evans-Polce RJ, Castaldelli-Maia JM, Schomerus G, et al. The downside of tobacco control? Smoking and self-stigma: A systematic review. *Social Science & Medicine* 2015;145:26-34.
30. Lozano P, Thrasher JF, Forthofer M, et al. Smoking-Related Stigma: A Public Health Tool or a Damaging Force? *Nicotine & Tobacco Research* 2018;22(1):96-103.
31. Helweg-Larsen M, Sorgen LJ, Pisinger C. Does it help smokers if we stigmatize them? A test of the stigma-induced identity threat model among U.S. and Danish smokers. *Soc Cogn* 2019;37(3):294-313.
32. Villanti AC, Niaura RS, Abrams DB, et al. Preventing Smoking Progression in Young Adults: the Concept of Preescalation. *Prev Sci* 2019;20(3):377-84.
33. Poole R, Carver H, Anagnostou D, et al. Tobacco use, smoking identities and pathways into and out of smoking among young adults: a meta-ethnography. *Substance Abuse Treatment, Prevention, and Policy* 2022;17(1):24.
34. Ministry of Children and Education. Produktionsskoler [Production schools]. 2020.
35. Aarkrog V. The standing and status of vocational education and training in Denmark. *Journal of Vocational Education & Training* 2020;72(2):170-88.
36. Michie S, Hyder N, Walia A, et al. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav* 2011;36(4):315-9.
37. Braveman P, Egerter S, Williams DR. The Social Determinants of Health: Coming of Age. *Annual Review of Public Health* 2011;32(1):381-98.
38. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000;55(1):68-78.
39. Gilbert C, Moss D. Biofeedback and biological monitoring. . In: Moss D, McGrady A, Davies T, et al., eds. *Handbook of Mind-Body Medicine for Primary Care*. Thousand Oaks, CA: Sage Publications 2003.
40. Hughes ME, Waite LJ, Hawkey LC, et al. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. *Res Aging* 2004;26(6):655-72.
41. Brown-Johnson CG, Cataldo JK, Orozco N, et al. Validity and reliability of the Internalized Stigma of Smoking Inventory: An exploration of shame, isolation, and discrimination in smokers with mental health diagnoses. *Am J Addict* 2015;24(5):410-8.
42. Christensen U, Krølner R, Nilsson CJ, et al. Addressing Social Inequality in Aging by the Danish Occupational Social Class Measurement. *Journal of Aging and Health* 2014;26(1):106-27.
43. Buhelt LP, Pisinger C, Andreasen AH. Smoking and stress in the general population in Denmark. *Tob Prev Cessat* 2021;7:27.
44. Jackson KJ, Muldoon PP, De Biasi M, et al. New mechanisms and perspectives in nicotine withdrawal. *Neuropharmacology* 2015;96(Pt B):223-34.
45. Hajek P, Taylor T, McRobbie H. The effect of stopping smoking on perceived stress levels. *Addiction* 2010;105(8):1466-71.
46. Aho H, Koivisto AM, Paavilainen E, et al. The relationship between peer relations, self-rated health and smoking behaviour in secondary vocational schools. *Nurs Open* 2019;6(3):754-64.
47. O'Connor RJ, Rees VW, Rivard C, et al. Internalized smoking stigma in relation to quit intentions, quit attempts, and current e-cigarette use. *Substance Abuse* 2017;38(3):330-36.
48. Kaftarian S, Robertson E, Compton W, et al. Blending prevention research and practice in schools: critical issues and suggestions. *Prev Sci* 2004;5(1):1-3.

UNINTENDED EFFECTS OF SMOKING PREVENTION

49. Mercken L, Moore L, Crone MR, et al. The effectiveness of school-based smoking prevention interventions among low- and high-SES European teenagers. *Health Educ Res* 2012;27(3):459-69.
50. Smith CE, Hill SE, Amos A. Impact of population tobacco control interventions on socioeconomic inequalities in smoking: a systematic review and appraisal of future research directions. *Tob Control* 2021;30(e2):e87-e95.
51. Andersen MB, Bast LS. § RØG-En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021 [§ SMOKE-A study of tobacco, behavior and regulations: selected tendencies 2021]. 2021
52. Petersen MT, Lund L, Bast LS. §RØG-En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021, rapport 3. [§SMOKE-A study of tobacco, behavior and regulations: Selected tendencies 2021, report 3]. 2022
53. Schreuders M, Klompmaker L, van den Putte B, et al. Adolescent Smoking in Secondary Schools that Have Implemented Smoke-Free Policies: In-Depth Exploration of Shared Smoking Patterns. *Int J Environ Res Public Health* 2019;16(12)
54. Suls JM, Luger TM, Curry SJ, et al. Efficacy of smoking-cessation interventions for young adults: a meta-analysis. *Am J Prev Med* 2012;42(6):655-62.

Table 2. Checklist of Items To Include When Reporting Harms in Randomized, Controlled Trials*

Standard CONSORT Checklist: Paper Section and Topic	Standard CONSORT Checklist: Item Number	Descriptor	Reported on Page Number
Title and abstract	1	If the study collected data on harms and benefits, the title or abstract should so state.	1,2
Introduction Background	2	If the trial addresses both harms and benefits, the introduction should so state.	3-5
Methods Participants Interventions Objectives Outcomes	3 4 5 6	List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardized and validated definitions, and description of new definitions). Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).	6-8
Sample size Randomization Sequence generation Allocation concealment Implementation Blinding (masking) Statistical methods	7 8 9 10 11 12	Describe plans for presenting and analyzing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses).	9
Results Participant flow	13	Describe for each arm the participant withdrawals that are due to harms and their experiences with the allocated treatment.	n/a
Recruitment Baseline data Numbers analyzed Outcomes and estimation Ancillary analyses Adverse events	14 15 16 17 18 19	Provide the denominators for analyses on harms. Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent.† Describe any subgroup analyses and exploratory analyses for harms.‡	9-13
Discussion Interpretation Generalizability Overall evidence	20 21 22	Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalizability, and other sources of information on harms.§	14-17

* This proposed extension for harms includes 10 recommendations that correspond to the original CONSORT checklist.

† Descriptors refer to items 17, 18, and 19.

‡ Descriptor refers to items 20, 21, and 22.

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CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3,4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	4,5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5 ^{1,2}
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		1
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	1
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication,	Whether interventions pertain to the cluster level, the individual participant level or both	6

		including how and when they were actually administered		
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	1,2
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		5 ^{1,2}
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5 ^{1,2}
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	5 ^{1,2}

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	1,2
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	1,2
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	18
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		n/a
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9
Results				

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	10 ²
Recruitment	14a	Dates defining the periods of recruitment and follow-up		5,6
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	11-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses		12-13

		and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	See CONSORT for harms
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant) 16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14,15
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	19
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

¹Jakobsen et al. (2021). Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. Tobacco Prevention and Cessation, 7, 1-12. <https://doi.org/10.18332/TPC/133934>

² Kjeld SG, Thygesen LC, Danielsen D, Jakobsen GS, Jensen MP, Holmberg T, Bast LS, Lund L, Pisinger C, Andersen S. Effectiveness of the multi-component intervention Focus on reducing smoking among students in the vocational education setting: A stratified cluster randomized controlled trial. Under review.

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

By Simone G. Kjeld^{1*}, Lau C. Thygesen¹, Dina Danielsen¹, Marie P. Jensen¹, Rikke F. Krølner¹, Charlotta Pisinger^{2,3,4}, and Susan Andersen¹

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¹National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark

²Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, The Capital Region of Denmark

³University of Copenhagen, Faculty of Health Sciences, Department of Public Health, Denmark

⁴Danish Heart Foundation, Copenhagen, Denmark

*Corresponding author:

Simone Gad Kjeld

National Institute of Public Health, University of Southern Denmark

Studiestræde 6, 1455 Copenhagen K

E-mail: simk@sdu.dk

Phone number: +45 65507768

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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 (VET) setting.

Design: Cluster-randomized controlled trial stratified by school type with five-months follow-up

Setting and participants: Across Denmark, eight schools were randomized 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 three-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 stigmatization 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, CI: 0.32;1.10) and experience stress (OR: 0.62, CI: 0.35;1.10), but more likely to report feeling stigmatized compared with the control group (OR: 1.55, CI: 0.71;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 stigmatization of smokers.

Trial registration: <https://www.isrctn.com/ISRCTN16455577>, date of registration 14/06/2018

Keywords: smoking, cigarettes, smoking prevention, intervention, vocational schools, cluster randomized controlled trial, unintended effects

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Strengths and limitations of this study

1. A program theory was developed with a priori specification of both intended and potential unintended effects of the intervention
2. The intervention was thoroughly designed with inclusion of the target group and other relevant actors to accommodate potential unintended effects
3. The intervention was evaluated in a cluster-randomized controlled trial
4. Since loss to follow-up could have resulted in attrition bias, multiple imputation of missing data was performed
5. Other unmeasured side-effects may have been produced as response to the intervention, e.g., 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 program theory is often developed in which a set of key components or activities are identified to enhance healthy behaviors or to prevent unhealthy behaviors, 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 behaviors. 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 multi-level and multi-component 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 individualized components [9,10]. The students enrolled in the vocational educational and training (VET) setting generally differ from those attending general high schools, e.g., students are often characterized 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 multi-level and multi-component

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intervention ‘Focus’ to reduce smoking among youth in the VET setting [16]. We evaluated the effect of the intervention in a cluster-randomized controlled trial (RCT) in which we found no overall effects of the intervention on smoking; however, at schools with full intervention, i.e., 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, i.e., girls and schools with healthcare programs, had higher benefits from the intervention compared to 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 interventions [18], 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]. Firstly, 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, i.e., 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]. Secondly, 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 stigmatization 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 stigmatization may lead to other unexpected

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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 (i) *direct harms* (substitution use) measured by alternative tobacco and nicotine product use as well as cannabis use, (ii) *psychological harms* measured by boredom in breaks and loneliness during school hours as well as stress levels, and (iii) *group and social harms* measured by perceived stigmatization. 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-randomized controlled trial (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 randomization

Schools offering basic course of vocational education and training (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 16-25 years old, and the intervention was targeted this age group. The randomization 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 three 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)=1,659), 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 five 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 details [16]). Baseline data was collected at semester start after the summer holiday. At the end of the semester (approximately five months after), the follow-up assessment was conducted.

The Focus intervention

The intervention was developed following the recommended stages within the Behavior 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 behavior (such as to stop smoking during school hours) requires that individuals make sense of the new behavior, develop the required skills for change, and internalize 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-judgmental 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

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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, e.g., 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 stigmatization. The included outcomes concerned with the unintended effects were developed and specified before the intervention start [16], and most were also pre-specified in the trial registration; however, specific outcomes (cannabis use, stress, boredom, and stigmatization) 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 five-months follow-up by asking students "Have you ever used the following...? 1)

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smokeless tobacco, 2) hookah, and 3) E-cigarettes.” Responses were categorized into regular use (daily and occasional) vs. no current use (used it a few times, had previously used, or never used).

Regular cannabis use was also assessed by dichotomizing students’ responses to use of cannabis into regular use vs. 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 dichotomized into boredom in breaks (often or very often) vs. 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? 3) left out?”. The items were summarized to a scale and categorized into low (3-4), moderate (5-6), and high (7-9) level of loneliness. In this study, loneliness during school hours were dichotomized into moderate to high level vs. 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 summarized to a scale and dichotomized into high level of stress (4-5) vs. low to moderate level of stress (0-3).

Group and social harms

Perceived stigmatization among smokers. Stigmatization related to smoking was measured at follow-up using the Internalized 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, 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

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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, 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, 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 dichotomized into experience with stigmatization (responding agree or completely agree to at least one item of the subscale) vs. no stigmatization.

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 categorized into 1) implementation of the school- 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 socioeconomic status (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 categorized into high (1-2), medium (3-4), and low (5-6).

Statistical analysis

All analyses were carried out 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 utilized 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 behavior 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 summarizing the imputed datasets.

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Multilevel logistic regression modeling was used to estimate intervention effects at five-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*-value below 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.

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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% was in the intervention group, and 46% was 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%).

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

	Total (N=491)	Intervention group (n=264, 54%)	Control group (n=227, 46%)
	n (%)	n (%)	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)

Note. Missing proportion of 0.6%.

Overall, no statistically significant differences between the intervention and control groups were found for any of the unintended outcomes at five-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;1.10) and experience high levels of stress (OR: 0.62, 95% CI: 0.35;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;4.20) and to report felt stigma (OR: 1.55, 95% CI: 0.71;3.40) compared with daily smokers in the control group.

Table 2. Logistic regression analyses of the associations between the intervention group (versus the control group) and unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

Unintended outcome at follow-up	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*	
	%	%	OR	95% CI
Alternative tobacco and nicotine product use				
Regular smokeless tobacco use	22.4	28.8	0.78	0.40;1.54
Regular hookah use	23.2	22.4	1.28	0.61;2.67
Regular e-cigarette use	37.2	34.1	1.17	0.65;2.10
Regular use of either smokeless tobacco, hookah, or e-cigarettes	56.1	57.2	1.10	0.64;1.88
Regular cannabis use	11.0	7.2	1.68	0.67;4.20
Well-being				
Boredom in breaks during school hours	22.6	32.2	0.59	0.32;1.10
Loneliness during school hours	18.1	16.8	1.15	0.53;2.50
High level of stress	66.6	75.1	0.62	0.35;1.10
Stigmatization				
Self-stigma	33.6	35.2	0.97	0.54;1.75
Felt stigma	12.0	9.5	1.55	0.71;3.40
Discrimination	1.8	1.9	-	-

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

Note. Due to low student representation in the discrimination subscale, regression analyses were not possible.

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;0.88) compared with daily smokers in the control 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;1.12) but more likely to report felt stigma (OR: 2.15, 95% CI: 0.84;5.53) compared with daily smokers in the control group.

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Table 3. Per-protocol analyses with control group as reference group with unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

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

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

Note. Due to low student representation in the discrimination subscale, regression analyses were not possible, leading to its exclusion from the table.

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;0.75).

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Table 4. Subgroup analyses stratified by school type of the associations between the intervention group (versus the control group) and unintended outcomes measured at five-months follow-up among daily smokers at baseline, using multiple imputation of missing data (N=40x491).

Outcome	Intervention group (n=40x264)	Control group (n=40x227)	Adjusted*	
	%	%	OR	95% CI
Alternative tobacco and nicotine product use				
Regular use of either smokeless tobacco, hookah, or e-cigarettes				
VET schools: Social and healthcare	49.0	47.0	1.16	0.43;3.09
VET schools: Technical and commercial	62.2	70.2	0.65	0.24;1.79
PBE schools	61.1	51.5	2.07	0.58;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;7.71
Well-being				
Boredom in breaks during school hours				
VET schools: Social and healthcare	21.0	19.5	1.05	0.36;3.11
VET schools: Technical and commercial	18.3	42.8	0.27	0.10;0.75
PBE schools	32.5	34.7	0.78	0.18;3.39
Loneliness during school hours				
VET schools: Social and healthcare	17.7	11.3	1.68	0.54;5.27
VET schools: Technical and commercial	17.8	18.3	1.12	0.33;3.83
PBE schools	18.4	23.3	0.75	0.18;3.13
High level of stress				
VET schools: Social and healthcare	75.2	77.3	0.82	0.37;1.81
VET schools: Technical and commercial	62.2	73.7	0.52	0.16;1.67
PBE schools	68.5	73.9	0.64	0.20;2.04
Stigmatization among smokers				
Self-stigma				
VET schools: Social and healthcare	35.1	32.8	1.14	0.46;2.85
VET schools: Technical and commercial	30.8	39.9	0.66	0.27;1.64
PBE schools	33.0	31.2	0.98	0.26;3.62
Felt stigma				
VET schools: Social and healthcare	9.9	10.4	0.87	0.27;2.76
VET schools: Technical and commercial	17.8	10.2	2.07	0.53;8.05
PBE schools	7.9	6.6	-	-

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

Note. 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.

Discussion

The multi-level and multi-component intervention, Focus, was developed to reduce smoking in the VET setting. The program 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 stigmatization in terms of felt stigma.

Previous studies have suggested strong connections between tobacco use and stress levels [25, 26]. Consequently, a hypothesized 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 e.g., 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 to non-smokers [43], and nicotine in cigarettes can intensify 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.

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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 (e.g., smoking as a means to build social relationships in school [46]), it was hypothesized 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].

Lastly, this study found a non-significant tendency towards students experiencing higher stigmatization from others in the intervention group compared with the control group – especially those students attending schools with full intervention. Little research has investigated stigmatization 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 stigmatization [27]. The potential stigmatization 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 hypothesized mechanism is that public stigma of smoking may lead to an internalized 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-stigmatization may negatively affect the mental health of individuals and help-seeking behaviors 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 program theory of Focus [16] and guided by a conceptual framework [18]. Two other types of harms are outlined in this framework, which were

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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 organizational level – and the Focus study draws from best-practice and previous research in reducing smoking among students using a multi-level 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 behaviors, which can guide and inform future interventions in this setting and may reveal potential for tailoring future interventions more effectively and carefully.

Secondly, *equity harms* concern the risk of interventions affecting students divergently according to various sociodemographic 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 high [48] – 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 individualized efforts in the school setting to equalize social inequalities in smoking. It is worth noting that – even within the context of this setting with lower SES students – the intervention may have benefitted 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 program 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 (e.g., the Danish Cancer Society) to ensure proper implementation and relevance among the students [16]. Further, the Focus intervention was evaluated in a cluster-randomized controlled trial, 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

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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 nonsignificant 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 program theory and measured in the surveys. Other side-effects may have been produced 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 prioritizing 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 emphasized 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 theorization of hypotheses about possible side-effects in the intervention development as well as involving e.g., 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 programs shows no long-term effects on smoking outcomes [52]; nevertheless it has not been investigated as add-on to implementing a strict school tobacco policy. The Focus study

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was implemented before national legislation prohibited smoking in youth educations. Hence, smoke-free school hours were implemented by law in Danish youth educations by July 31st, 2021. The law regulates students' smoking behavior, but school staff is still allowed to use tobacco products outside school grounds during school hours. Despite the new legislation, recent data shows 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 counseling 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, e.g., 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, i.e., students, teachers, and the organization 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 program theory.

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Data Availability Statement

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Data that support the findings of this study is available from the University of Southern Denmark (SDU). Data is available from the corresponding upon reasonable request and with permission from SDU. Requests to access research data should be directed to simk@sdu.dk.

Ethics Statement

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 behaviors, 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.

Author Contributions

All authors took part in the conceptualization or design of this study. Data collection was carried out by DD, MPJ, and SA. SGK, LCT, and SA carried out the main analyses, and SGK drafted the initial manuscript. LCT, DD, MPJ, CP, RFK, and SA critically reviewed and revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interests

The authors declare no conflicts of interests.

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References

1. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;374:n2061.
2. Funnell SC, Rogers PJ. Purposeful program theory: Effective use of theories of change and logic models: John Wiley & Sons 2011.
3. Oliver K, Lorenc T, Tinkler J, et al. Understanding the unintended consequences of public health policies: the views of policymakers and evaluators. *BMC Public Health* 2019;19(1):1057.
4. Schreuders M, Nuyts PAW, van den Putte B, et al. Understanding the impact of school tobacco policies on adolescent smoking behaviour: A realist review. *Soc Sci Med* 2017;183(Supplement C):19-27.
5. Bonell C, Fletcher A, Morton M, et al. Realist randomised controlled trials: A new approach to evaluating complex public health interventions. *Soc Sci Med* 2012;75(12):2299-306.
6. Bonell C, Jamal F, Melendez-Torres GJ, et al. 'Dark logic': theorising the harmful consequences of public health interventions. *J Epidemiol Community Health* 2015;69(1):95-98.
7. Jarlstrup NS, Juel K, Pisinger CH, et al. International Approaches to Tobacco Use Cessation Programs and Policy in Adolescents and Young Adults: Denmark. *Current Addiction Reports* 2018;5(1):42-53.
8. Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database of Systematic Reviews* 2013(4)
9. Galanti MR, Coppo A, Jonsson E, et al. Anti-tobacco policy in schools: upcoming preventive strategy or prevention myth? A review of 31 studies. *Tob Control* 2014;23(4):295-301.
10. Bast LS, Due P, Bendtsen P, et al. High impact of implementation on school-based smoking prevention: the X:IT study-a cluster-randomized smoking prevention trial. *Implement Sci* 2016;11(1):125.
11. Jarlstrup NS, Andersen MB, Kjeld SG, et al. § RØG-En undersøgelse af tobak, adfærd og regler: Basisrapport 2020 [§SMOKE-A study of tobacco, behavior and regulations: Basis report]. 2020
12. Chyderiotis S, Benmarhnia T, Spilka S, et al. Why do apprentices smoke much more than high school students? Understanding educational disparities in smoking with a Oaxaca-blinder decomposition analysis. *BMC Public Health* 2020;20(1):924.
13. Statistics Denmark. Erhvervsuddannelser i Danmark 2019 [Vocational schools in Denmark 2019]. 2019.
14. Andersen S, Pisinger V, Rod MH, et al. Associations of school tobacco policies and legislation with youth smoking: a cross-sectional study of Danish vocational high schools. *BMJ Open* 2019;9(7)
15. Andersen S, Rod MH, Ersbøll AK, et al. Effects of a settings-based intervention to promote student wellbeing and reduce smoking in vocational schools: A non-randomized controlled study. *Soc Sci Med* 2016;161:195-203.
16. Jakobsen GS, Danielsen D, Jensen MP, et al. Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. *Tob Prev Cessat* 2021;7:42.
17. Kjeld SG, Thygesen LC, Danielsen D, et al. Effectiveness of the multi-component intervention 'Focus' on reducing smoking among students in the vocational education setting: a cluster randomized controlled trial. *BMC Public Health* 2023;23(1):419.
18. Lorenc T, Oliver K. Adverse effects of public health interventions: a conceptual framework. *J Epidemiol Community Health* 2014;68(3):288-90.
19. Kjeld SG, Lund L, Andersen S, et al. Socioeconomic Differences in Cigarette Smoking and Alternative Tobacco Product Use Among Adolescents in a School-Based Smoking Preventive Intervention: Findings From the Second Year of the X:IT II Study. *Frontiers in Public Health* 2022;10
20. Mpousiou DP, Sakkas N, Soteriades ES, et al. Evaluation of a school-based, experiential-learning smoking prevention program in promoting attitude change in adolescents. *Tobacco Induced Diseases* 2021;19(June):1-10.
21. Kjeld SG, Glenstrup S, Bast LS. Gender and socioeconomic disparities in reasons for not smoking cigarettes among Danish adolescents. *BMC Research Notes* 2021;14(1):33.
22. Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA* 2019;322(21):2095-103.
23. Danielsen D, Jensen TS, Kjeld SG, et al. Context matters in smoking prevention: evaluating smoke-free school hours in Danish vocational schools. *Health Promot Int* 2023;38(2).

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24. Piko BF, Varga S, Wills TA. A Study of Motives for Tobacco and Alcohol Use Among High School Students in Hungary. *Journal of Community Health* 2015;40(4):744-49.
25. Lawless MH, Harrison KA, Grandits GA, et al. Perceived stress and smoking-related behaviors and symptomatology in male and female smokers. *Addictive Behaviors* 2015;51:80-83.
26. Kassel JD, Stroud LR, Paronis CA. Smoking, stress, and negative affect: correlation, causation, and context across stages of smoking. *Psychol Bull* 2003;129(2):270-304.
27. Robert P-O, Grard A, Mélard N, et al. The effect of school smoke-free policies on smoking stigmatization: A European comparison study among adolescents. *PLOS ONE* 2020;15(7):e0235772.
28. Burgess DJ, Fu SS, van Ryn M. Potential Unintended Consequences of Tobacco-Control Policies on Mothers Who Smoke: A Review of the Literature. *American Journal of Preventive Medicine* 2009;37(2, Supplement):S151-S58.
29. Evans-Polce RJ, Castaldelli-Maia JM, Schomerus G, et al. The downside of tobacco control? Smoking and self-stigma: A systematic review. *Social Science & Medicine* 2015;145:26-34.
30. Lozano P, Thrasher JF, Forthofer M, et al. Smoking-Related Stigma: A Public Health Tool or a Damaging Force? *Nicotine & Tobacco Research* 2018;22(1):96-103.
31. Helweg-Larsen M, Sorgen LJ, Pisinger C. Does it help smokers if we stigmatize them? A test of the stigma-induced identity threat model among U.S. and Danish smokers. *Soc Cogn* 2019;37(3):294-313.
32. Villanti AC, Niaura RS, Abrams DB, et al. Preventing Smoking Progression in Young Adults: the Concept of Preescalation. *Prev Sci* 2019;20(3):377-84.
33. Poole R, Carver H, Anagnostou D, et al. Tobacco use, smoking identities and pathways into and out of smoking among young adults: a meta-ethnography. *Substance Abuse Treatment, Prevention, and Policy* 2022;17(1):24.
34. Ministry of Children and Education. Produktionsskoler [Production schools]. 2020.
35. Aarkrog V. The standing and status of vocational education and training in Denmark. *Journal of Vocational Education & Training* 2020;72(2):170-88.
36. Michie S, Hyder N, Walia A, et al. Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation. *Addict Behav* 2011;36(4):315-9.
37. Braveman P, Egerter S, Williams DR. The Social Determinants of Health: Coming of Age. *Annual Review of Public Health* 2011;32(1):381-98.
38. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000;55(1):68-78.
39. Gilbert C, Moss D. Biofeedback and biological monitoring. . In: Moss D, McGrady A, Davies T, et al., eds. *Handbook of Mind-Body Medicine for Primary Care*. Thousand Oaks, CA: Sage Publications 2003.
40. Hughes ME, Waite LJ, Hawkey LC, et al. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. *Res Aging* 2004;26(6):655-72.
41. Brown-Johnson CG, Cataldo JK, Orozco N, et al. Validity and reliability of the Internalized Stigma of Smoking Inventory: An exploration of shame, isolation, and discrimination in smokers with mental health diagnoses. *Am J Addict* 2015;24(5):410-8.
42. Christensen U, Krølner R, Nilsson CJ, et al. Addressing Social Inequality in Aging by the Danish Occupational Social Class Measurement. *Journal of Aging and Health* 2014;26(1):106-27.
43. Buhelt LP, Pisinger C, Andreassen AH. Smoking and stress in the general population in Denmark. *Tob Prev Cessat* 2021;7:27.
44. Jackson KJ, Muldoon PP, De Biasi M, et al. New mechanisms and perspectives in nicotine withdrawal. *Neuropharmacology* 2015;96(Pt B):223-34.
45. Hajek P, Taylor T, McRobbie H. The effect of stopping smoking on perceived stress levels. *Addiction* 2010;105(8):1466-71.
46. Aho H, Koivisto AM, Paavilainen E, et al. The relationship between peer relations, self-rated health and smoking behaviour in secondary vocational schools. *Nurs Open* 2019;6(3):754-64.
47. O'Connor RJ, Rees VW, Rivard C, et al. Internalized smoking stigma in relation to quit intentions, quit attempts, and current e-cigarette use. *Substance Abuse* 2017;38(3):330-36.
48. Kaftarian S, Robertson E, Compton W, et al. Blending prevention research and practice in schools: critical issues and suggestions. *Prev Sci* 2004;5(1):1-3.

UNINTENDED EFFECTS OF SMOKING PREVENTION

49. Mercken L, Moore L, Crone MR, et al. The effectiveness of school-based smoking prevention interventions among low- and high-SES European teenagers. *Health Educ Res* 2012;27(3):459-69.
50. Smith CE, Hill SE, Amos A. Impact of population tobacco control interventions on socioeconomic inequalities in smoking: a systematic review and appraisal of future research directions. *Tob Control* 2021;30(e2):e87-e95.
51. Andersen S, Holt DH, Vinther JL, et al. Development and Feasibility Test of a Theory- and Evidence-Based Multicomponent Intervention to Reduce Student Smoking at Danish Vocational Schools. *Youth* 2023;3(2):715-36.
52. Etter J, Bouvier P. Some doubts about one of the largest smoking prevention programmes in Europe, the smokefree class competition. *J Epidemiol Community Health* 2006;60:757-9.
53. Andersen MB, Bast LS. § RØG-En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021 [§ SMOKE-A study of tobacco, behavior and regulations: selected tendencies 2021]. 2021
54. Petersen MT, Lund L, Bast LS. §RØG-En undersøgelse af tobak, adfærd og regler: Udvalgte tendenser 2021, rapport 3. [§SMOKE-A study of tobacco, behavior and regulations: Selected tendencies 2021, report 3]. 2022
55. Schreuders M, Klompmaker L, van den Putte B, et al. Adolescent Smoking in Secondary Schools that Have Implemented Smoke-Free Policies: In-Depth Exploration of Shared Smoking Patterns. *Int J Environ Res Public Health* 2019;16(12)
56. Suls JM, Luger TM, Curry SJ, et al. Efficacy of smoking-cessation interventions for young adults: a meta-analysis. *Am J Prev Med* 2012;42(6):655-62.

Table 2. Checklist of Items To Include When Reporting Harms in Randomized, Controlled Trials*

Standard CONSORT Checklist: Paper Section and Topic	Standard CONSORT Checklist: Item Number	Descriptor	Reported on Page Number
Title and abstract	1	If the study collected data on harms and benefits, the title or abstract should so state.	1,2
Introduction Background	2	If the trial addresses both harms and benefits, the introduction should so state.	3-5
Methods Participants Interventions Objectives Outcomes	3 4 5 6	List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardized and validated definitions, and description of new definitions). Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).	6-8
Sample size Randomization Sequence generation Allocation concealment Implementation Blinding (masking) Statistical methods	7 8 9 10 11 12	Describe plans for presenting and analyzing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses).	9
Results Participant flow	13	Describe for each arm the participant withdrawals that are due to harms and their experiences with the allocated treatment.	n/a
Recruitment Baseline data Numbers analyzed Outcomes and estimation Ancillary analyses Adverse events	14 15 16 17 18 19	Provide the denominators for analyses on harms. Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent.† Describe any subgroup analyses and exploratory analyses for harms.‡	9-13
Discussion Interpretation Generalizability Overall evidence	20 21 22	Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalizability, and other sources of information on harms.§	14-17

* This proposed extension for harms includes 10 recommendations that correspond to the original CONSORT checklist.

† Descriptors refer to items 17, 18, and 19.

‡ Descriptor refers to items 20, 21, and 22.

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CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3,4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	4,5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5 ^{1,2}
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		1
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	1
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication,	Whether interventions pertain to the cluster level, the individual participant level or both	6

		including how and when they were actually administered		
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	1,2
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		5 ^{1,2}
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5 ^{1,2}
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	5 ^{1,2}

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	1,2
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	1,2
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	18
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		n/a
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9
Results				

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	10 ²
Recruitment	14a	Dates defining the periods of recruitment and follow-up		5,6
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	11-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses		12-13

		and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	See CONSORT for harms
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant) 16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14,15
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	19
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

¹Jakobsen et al. (2021). Reducing smoking in youth by a smoke-free school environment: A stratified cluster randomized controlled trial of Focus, a multicomponent program for alternative high schools. Tobacco Prevention and Cessation, 7, 1-12. <https://doi.org/10.18332/TPC/133934>

² Kjeld SG, Thygesen LC, Danielsen D, Jakobsen GS, Jensen MP, Holmberg T, Bast LS, Lund L, Pisinger C, Andersen S. Effectiveness of the multi-component intervention Focus on reducing smoking among students in the vocational education setting: A stratified cluster randomized controlled trial. Under review.