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Programme theory and evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a realist study protocol

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ABSTRACT

Introduction: Smoke-free school hours (SFSH) entails a smoking ban during school hours and might be an effective intervention to reduce the high smoking prevalence in vocational schools. For SFSH to be effective, the policy must be adequately implemented and enforced; this challenge for schools constitutes a research gap. The 'Smoke-Free Vocational Schools' research and intervention project has been developed to facilitate schools' implementation of SFSH. It is scheduled to run from 2018–2022, with SFSH being implemented in 11 Danish vocational schools. This study protocol describes the intervention programme theory and study design.

Methods and analysis: The study's epistemological foundation is realistic evaluation, and it aims to develop an evidence-based model for implementing SFSH in vocational schools and similar settings. The project is developed in a collaboration between research and practice. Two public health NGOs are responsible for delivering the intervention activities in schools, while the research partner evaluates what works, for whom, and under what circumstances. The intervention lasts one year per school, targeting different socioecological levels. During the first six months, activities are delivered to stimulate organisational readiness to implement SFSH. Then, SFSH is established, and during the next six months, activities are delivered to stimulate the implementation of SFSH into routine practice. The evaluation focuses on both implementation (process evaluation) and outcomes. Process evaluation will determine the level of implementation and explore what hinders or enables SFSH becoming part of routine practice using both qualitative and quantitative methods. Outcomes evaluation will quantitively assess the intervention's effectiveness, with the primary outcome measure being changes in smoking during school hours.

Ethics and dissemination: Informed consent will be obtained from all study participants according to the GDPR and Danish data protection law. Study findings will be disseminated at national and international conferences and further published in open-access peer-reviewed journals.

Strengths and limitations:

- The study draws on realistic evaluation and aims to answer both research and practice needs by generating new application-oriented knowledge on how to implement smoke-free school hours in vocational schools and similar settings.
- The study includes both implementation/process evaluation and outcomes evaluation in a unified multi-methods study design.
- The intervention has been developed in a joint venture between research and practice that emphasises including practice-based experience and research evidence, which may generate high external validity and more sustainable implementation practices.
- The study seeks to assess outcomes in a pretest-posttest study design without using control schools, which is appropriate in realistic evaluation but limits internal validity in relation to determining the intervention's effectiveness.

INTRODUCTION

From August 2021, a school tobacco policy (STP) of smoke-free school hours (SFSH) is expected to be ratified in all Danish educational institutions with at least one student aged under 18. The policy basically stipulates a smoking ban for students during school hours – both inside and outside school grounds. An expanded definition of SFSH also bans smoking by school staff, managers and visitors (smoke-free work hours). Additionally, SFSH might include all tobacco-related products (e.g. cigarettes, vapers, and snuff). SFSH is an expansion of traditional STPs, which do not prohibit smoking outside school grounds.[1] The rationale is the same: restricting smoking behaviour as a means to prevent exposure to second-hand smoke, smoking initiation, and smoking continuation among adolescents and young adults.[2,3] Restricting smoking behaviour can further be linked to political denormalization strategies aiming to make the future smoke-free: a tobacco endgame.[4] Evidence about SFSH is sparse, but some researchers[5] suggest that it might be more effective than traditional STPs, which have been shown to relocate smoking to just outside school premises (e.g. at the school entrance), and therefore do not remove smoking visibility.[5,6] Additionally, traditional STPs can have adverse effects on students with lower socioeconomic status (SES), (lower odds of anti-smoking social believes)[7], which suggest that SFSH might be a more appropriate strategy in schools with low SES groups, such as vocational schools.

In Denmark, vocational education and training (VET) is a short, practical upper-secondary education for a specific service or industry, such as hairdresser, carpenter, office assistant, or chef. It is characterised by a combination of traditional in-school education and out-of-school apprenticeship in the future workplace. Danish vocational students have low SES backgrounds[8] and are overrepresented in smoking behaviour: 29% smoke daily, compared to 9% in general upper-secondary education.[9,10] The average vocational student age is 24, but as 14% of these students are aged 15–17,[11] the SFSH law will apply to Danish vocational schools. As such, the law has considerable health-promoting potential: it may not only reduce smoking within a vulnerable population group setting (vocational schools) but also contribute towards decreasing health inequality.[12] However, policies which are not well-implemented will not improve health.[13–16] We conceptualise the implementation of SFSH as a school organisational process with the end-goal of incorporating the policy into routine practice.[17] Staff and managers must enact and enforce the policy as part of their professional duties, and students must experience the policy as an accepted part of their everyday school life. Hence, enforcement is a significant task of organisational

implementation.[16,18–20] Despite legislation imposing STPs in many secondary schools across Europe, they are often poorly implemented and enforced.[21–24]

Three reviews have systematised decades of evidence related to STP implementation. The 2014 systematic review by Galanti et al.[15] identified implementation components that improve STPs' impact on student smoking behaviour (e.g. strict and consistent enforcement). However, the authors also showed that most studies do not measure implementation fidelity and that enforcement is inconsistently operationalised across studies.[15] Two realist reviews,[5,16] as part of the SILNE-R project (2015–2018),[25] yield prominent new insights into the functioning of STPs. The first shows how STPs' implementation and comprehensiveness affects students' beliefs and behaviour: for example, if smoking is not visible during school hours, students feel less pressure to conform to others' smoking behaviour.[5] The second shows that staff enforcement depends on whether they 1) believe that STP enforcement is their role and duty, 2) have confidence to deal with students' negative responses when enforcing the rules, and 3) experience enforcement having a positive impact on students.[16] Other recent studies[26–28] have explored which practices facilitate or hinder adopting SFSH; one key finding is that schools should develop a shared understanding about the policy being part of their jurisdiction prior to implementation).[26–28] Seen together, the studies point towards important elements for schools to consider when implementing SFSH, but do not provide knowledge about what activities and processes can stimulate better implementation. In other words, most studies focus on understanding existing STPs rather than generating new knowledge about how to facilitate implementation. The latter might only be possible using interventionist study designs. One intervention study provides an important measure of STP implementation fidelity.[29] To the best of our knowledge, however, no intervention studies have examined how to stimulate or measure the process of implementing SFSH into routine practice. As such, it remains unclear how to best support, stimulate, and measure the implementation of SFSH.

To address the identified research gap, we developed the 'Smoke-Free Vocational Schools' intervention project, which aims to facilitate implementing SFSH in vocational schools and to generate new knowledge about the implementation and effectiveness of SFSH. The intervention takes place in 11 Danish vocational schools from 2018–2022.

Realistic evaluation

Realistic evaluation (RE) is the epistemological foundation of the intervention project. Pawson and Tilley developed the RE approach, arguing that to generate application-oriented knowledge for policy

and practice, it is more useful to address 'what works, for whom and under what circumstances', rather than evaluating whether an intervention 'works'.[30] According to RE, interventions might generate different outcomes (O) in different contexts (C) by triggering underlying changes in reasoning and behaviour among participants – conceptualised as mechanisms (M).[31] As such, interventions may 'work' by enabling participants to make different choices, but the choices are always constrained by a context, such as the organisational norms, values, and discourses that operate in school settings. 'Complex intervention' is used to describe innovations within highly complex and emergent social systems,[32] such as schools.[33–34] It can be understood in relation to the RE notion of 'open systems', defined by Pawson and Tilley[30] as '[T]he acknowledgement that programs are implemented in a changing and permeable social world, and that program effectiveness may thus be subverted or enhanced through the unanticipated intrusion of new contexts' (p. 218). Hence, the overall RE methodology is to examine C + M = O relations in complex interventions, known as CMO configurations.[30]

Study aim

In reporting complex interventions, the intervention and evaluation design must be clearly described to enable replication and synthesis of evidence,[35,36] yet many RE studies inadequately report their methodological practices.[37–39] Therefore, the aim of this study protocol is two-fold: 1) to describe the Smoke-Free Vocational Schools intervention, and 2) to present how the intervention is evaluated, including the study design, specific methods, and theoretical assumptions.

METHODS AND ANALYSIS

The overall objective of the Smoke-Free Vocational Schools intervention project is to develop an evidence-based model for implementing SFSH in Danish vocational schools and comparable settings. To accomplish the objective, the study examines what works, for whom, and under what circumstances. RE starts with the development of an initial programme theory (IPT).[39] Programme theory is theory incarnate, explicitly explaining which context-mechanisms should be triggered among different actors to produce desired outcomes.[40,41] In relation to the Smoke-Free Vocational Schools intervention, the IPT represents a hypothesis on how and why to implement SFSH and the study design is developed to test the hypothesis. We have structured the study protocol following the steps of the realist research cycle,[39,42] as shown in figure 1.

Figure 1 Realist research cycle of the Smoke-Free Vocational Schools intervention project.

Step 1: Programme theory

The intervention project is a collaboration between research and practice. Two Danish public health NGOs – the Danish Heart Foundation and the Danish Cancer Society – are practice partners, while Steno Diabetes Centre Copenhagen is the research partner. The practice partners are responsible for delivering the intervention activities in schools; the research partner is responsible for conducting a formative evaluation of the implementation processes and outcomes. The research and practice partners together developed the IPT, and it is part of our method to continually discuss and apply preliminary research findings as part of the formative evaluation. As such, we follow the proposal of RE[37] by iteratively testing and developing the programme theory in parallel to new empirical learnings.

The IPT was developed through a co-creation workshop. The practice partners contributed their extensive first-hand experience of implementing tobacco preventive efforts in different school contexts: for example, the Danish Cancer Society has tailored a motivational interviewing course to support smoking cessation by upper-secondary school students. The translation of practice-based experience and ideas into the intervention might increase the sustainability of implementation practices and improve external validity.[43] The research partner contributed with evidence on effective tobacco preventive methods in vocational schools, based on recent research and the results from a qualitative study on facilitators and barriers for implementing SFSH.[28] At the workshop, we developed a graphic representation of the intervention,[44] including the short- and long-term outputs, outcomes, and impact expected of different intervention activities targeting actors within and outside the school. The co-creation process also served as a learning and management tool, as the research and practice partners developed a shared understanding on how the intervention is expected to produce change, which is crucial in public health interventions.[45]

The Smoke-Free Vocational Schools intervention

The intervention is delivered in two phases, each lasting approximately six months (as shown in figure 2). During phase 1, activities are delivered to stimulate organisational readiness[46] to implement SFSH: these include preparing staff and managers for their new professional tasks, and establishing new school-break facilities for students as alternatives to social smoking. At the beginning of phase 2, SFSH is established. During phase 2, activities are delivered to stimulate the gradual implementation of SFSH into routine practice by supporting schools in addressing emergent challenges, such as nicotine dependence or enforcement. Table 1 describes all the intervention activities.

Figure 2 Graphic representation of the initial programme theory of the Smoke-Free Vocational Schools intervention. SFSH: Smoke-free school hours. The intervention activities delivered by practice partners are shown in purple. The activities or processes managed by schools but facilitated by practice partners are shown in green.

The activities are expected to produce short-term outputs, which are operationalised in four sets according to ecological levels[47]: 1) individual guidance, e.g. smoking cessation assistance for students (individual); 2) organisational development, e.g. development of professional skills and confidence to enforce SFSH (interpersonal); 3) physical environment changes, e.g. new school-break activities (structural/organisational); and 4) capacity building between school and community, e.g. increased cooperation between the school and the local municipality (community).

Table 1 Description of intervention activities in the Smoke-Free Vocational Schools intervention.

Activity	Description	Purpose	Participants
		Phase 1	
First meeting	An initial meeting between the schools and practice partners, where the SFSH implementation plan is discussed.	To ensure that the schools have a clear implementation plan and know how the intervention activities can support them. To clarify role distributions between different stakeholders.	Practice partners. School principal and other management representatives. School project coordinator. Local municipality representative.
Developing the SFSH policy	The schools develop their SFSH policy, including rules and responsibilities for sanctioning and enforcement. The practice partners provide inspirational material, e.g. other schools' policies.	To ensure the schools develop a clear SFSH policy, which aligns with the schools' rules of conduct.	Decided locally in schools. Practice partners recommend that schools establish a working group including both management and staff representatives.
Developing the SFSH communication strategy	The schools develop their internal and external SFSH communication strategy. The practice partners provide inspirational material and financial support to smoke-free signing.	To ensure that all organisational members (e.g. students and staff) and relevant external stakeholders (e.g. neighbours and apprenticeship workplaces) know what SFSH entails.	Decided locally in schools.
Workshop 1 on SFSH implementation	A joint meeting at the schools for all school staff and managers, facilitated by the practice partners.	To stimulate a joint vision and understanding of why the school is implementing SFSH. To ensure that all organisational members feel confident to enforce SFSH. To address school-specific challenges and issues, e.g. resistance.	Practice partners. All school staff and managers. Local municipality representative.
Motivational interviewing course	A selected group of school staff and managers attend a two-day course delivered by the practice partners.	To provide new knowledge and skills for the selected staff and managers, who are supposed to become key drivers of the implementation in school. To help nicotine-addicted students to cope with not smoking during school hours.	Practice partners. Selected school staff and managers including the school project coordinator. Local municipality representative.
Smoking cessation assistance	Offered to students and staff in collaboration with the local municipality. The type of assistance varies between municipalities, depending	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.

	on local resources and availabilities.		
Student workshop	A participatory student workshop on how to improve the social environment, delivered in schools by the practice partners. The schools are given financial support (averaging 15,000 € per school) to establish some of the best school-break activities.	To create alternatives to smoking communities at school. To ensure that the new school-break activities are relevant for the students.	Practice partners. Selected group of students. Local municipality representative. The school management and school project coordinator approve the new school-break activities.
Removal of smoking facilities	The schools remove smoking facilities, e.g. ashtrays.	To signal that the school is smoke-free.	Decided locally in schools.
Phase 2			
The school tobacco policy of SFSH	The SFSH policy is established in schools. The schools must enact and enforce the policy.	To prevent exposure to second-hand smoke. To prevent smoking initiation and continuation.	Decided locally in schools. Practice partners recommend that all school staff and managers play a role in enforcement.
Continued smoking cessation assistance	Smoking cessation assistance is offered to students and staff in collaboration with the local municipality. The type of smoking cessation assistance varies between municipalities, depending on local resources and availabilities.	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.
Network activities for intervention schools	A network for intervention schools is established by the practice partners. Two larger network activities for all schools are delivered during 2018–2020.	To facilitate schools exchanging experiences of implementing SFSH and learning from one another.	School principal and school project coordinator are invited. Participation in network activities will be decided locally in schools.
Schools' own initiatives	Supportive actions which ease the implementation of SFSH.	Decided locally by schools.	Decided locally by schools.
Workshop 2	A joint meeting at the schools for all staff and managers, facilitated by the practice partners.	To address school-specific challenges in relation to implementing SFSH.	Practice partners. All school staff and managers. Local municipality representative.
Final meeting	A final meeting between the schools and practice partners to discuss the SFSH maintenance plan.	To ensure the schools have a clear maintenance plan and know how the municipality and practice partners can support them after the intervention period.	Practice partners. School principal. School project coordinator. Local municipality representative.

SFSH: Smoke-free school hours.

The activities and outputs are together expected to produce 'mechanisms of change', which are the underlying changes in reasoning and behaviour among participants, triggered by the intervention and the intervention context. We expect that the central context-mechanisms allowing SFSH to become part of routine practice will be found at the organisational level, where school staff and managers take responsibility for SFSH, feel confident to enforce SFSH, and feel motivated by positive student responses.[16] At the student level, we expect context-mechanisms to be triggered by: 1) staff and managers enforcing SFSH, resulting in decreased smoking visibility and, in turn, students becoming less prone to conform to others' smoking behaviour;[5] and 2) the new school-break activities resulting

in new practices and social norms at school.[48] As such, we expect SFSH to become a natural and accepted part of students' everyday school life.

The mechanisms of change are expected to result in outcomes related to students' smoking behaviour. Our primary outcome measure is 'changes in smoking during school hours', while the secondary outcome measure is 'changes in the number of cigarettes smoked per day'; both are proximal outcomes. The intermediate outcome measures are 'changes in intention to quit' and 'changes in smoking status'. The long-term impact of the intervention will not be evaluated as part of this study.

Step 2: Study design

The study is designed to test the IPT through focusing on both implementation/process evaluation and outcomes evaluation. As considered most appropriate in RE,[30,37] we use a multi-methods design, which allows us to quantify some elements of CMO configurations (e.g. changes in smoking behaviour) and qualitatively explore the change mechanisms and context.[49] The process evaluation investigates to what extent the intervention activities have been delivered and are implemented according to the programme theory, and seeks to explore the mechanisms that hinder or enable SFSH becoming part of routine practice. The outcomes evaluation assesses the intervention's outcomes in terms of students' smoking behaviour, using a one-group pretest-posttest study design, with sub-group analysis further determining for whom the intervention is most effective.

The intervention is delivered at 11 schools during 2018–2020, seven of which are included in the evaluation. The remaining four are considered 'pilot schools', where the intervention activities and evaluation methods (e.g. questionnaires) are tested and adjusted. The practice partners recruited schools that wanted to implement the expanded version of SFSH, banning all tobacco-related products (e.g. cigarettes, vapers, and snuff) during school and work hours for students, staff, and visitors. The sample of seven vocational schools accounts for 10% of all Danish vocational schools; represents all four main educational areas (Technical, Business, Agriculture and food services, and Social and health services); and covers three (out of five) geographical regions. As such, the study sample includes a broad variety of vocational school contexts across the country and is, thus, considered representative of all Danish vocational schools.

Process evaluation

The process evaluation comprises two mutually informing parts based on the RE-compatible[50] Medical Research Councils guidelines for Process Evaluation of Complex Interventions.[35] Our operationalisation of the framework in the study is shown in figure 3.

Figure 3 Process evaluation of the Smoke-Free Vocational Schools intervention, based on the Medical Research Councils guidelines for process evaluation of complex interventions.

The 'Implementation degree' study quantitively measures implementation levels for each of the four sets of outputs and for the SFSH policy based on fidelity, adaptions, dose, quality of delivery, participant responsiveness, and reach. Hence, the study seeks to occupy a middle position in the fidelity vs. adaptions debate[50] with an emphasis on measuring both central intervention implementation (e.g. extent of enforcement) and the schools' contextual initiatives and tailoring (e.g. means and methods of enforcement). The 'Mechanisms of change' study explores the implementation processes using both qualitative and quantitative methods. Normalisation process theory[17] proposes that implementation processes are shaped and motivated by four generative mechanisms – coherence, cognitive participation, collective action, and reflexive monitoring. This will be the guiding theory in the investigation of processes that hinder or enable SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation assesses the effectiveness of the intervention in terms of the primary and secondary outcomes, measured before SFSH (T1), six months after the establishment of SFSH (T2), and twelve months after the establishment of SFSH (T3), as shown in figure 4. The primary outcome measure is changes in 1) smoking during school hours (dichotomous – y/n); the secondary outcome measures are changes in 2a) the number of cigarettes smoked per day (continuous), 2b) intention to quit (nominal), and 2c) smoking status (nominal). Further, to elaborate on CMO configurations, sub-group analyses are performed to investigate for whom the intervention is most effective and to explore relations between findings from the process evaluation, that is, the SFSH implementation fidelity measure and quantitative indicators of implementation processes. The study thus seeks to elaborate on outcomes within the programme and/or in different localities and subgroups within the population without using control schools, which is considered appropriate for RE.[37,51,52]

Figure 4 Outcomes evaluation for the Smoke-Free Vocational Schools intervention.

Step 3: Data collection

The evaluation lasts approximately 1.5 years per school and covers intervention phase 1 (six months) and intervention phase 2 (six months), with the final follow-up conducted six months after the intervention has ended. During this time period, qualitative and quantitative data will be collected from students, staff, and managers to increase the validity of findings.[53] Table 2 presents an overview of all data collection measures and procedures, including estimates of eligible participants and expected response rates. The different data collection measures provide cross-cutting insights for the process and outcomes evaluations. A preliminary operationalisation of how the data contribute to each is presented in Supplementary File 1.

Student surveys

Electronic student surveys are conducted during school hours at three different time points. Students self-report smoking behaviour[54] and intention to quit,[55] smoking-related rules and practices and social norms at school,[56–61] self-efficacy,[62–64], well-being,[65,66] educational information, and demographics. Validated questions have been used when possible and the questionnaire has been pilot-tested in two vocational school classes (n=30 participants) to ensure face validity.[67] Due to the VET school structure, combining in-school education and apprenticeships, individual follow-up is rarely possible. Instead, both paired data from the same individuals and cross-sectional data will be collected. To maximise response rates, data collection is organised by the research partners in each school and conducted during school hours. The students are given time to complete the questionnaire and ask questions. The survey takes approximately 30 minutes per school class. Based on experience with the procedure,[9] we expect that 95% of students will participate in the study.

Sample size calculation

The outcome measure used to determine sample size is change in the number of cigarettes smoked during school hours per day, per student, based on individual follow-up data. We assume that 30% are daily smokers who averagely smoke 18 cigarettes per day, including 8 during school hours.[68] We assume that the intervention will reduce smoking intensity during school hours by 50%, meaning a reduction of 4 cigarettes smoked per school day (with a standard deviation of 4 and 3 and correlation = 0.3). To avoid type-I errors and type-II errors, we respectively chose a 5% significance level and power at 80%. Assuming that the data are normally distributed, we will need to conduct individual follow-up on 11 daily smokers per school. We expect a 30% reduction in participants from baseline to follow-up. Accounting for this, the sample size must include 14.3 daily smokers per school. Thus, if the smoking prevalence is 30%, 24.4 students per school must participate in the prospective study.

As seven schools are participating, the sample size for the prospective study must include (at least) 171 students.

Staff and project coordinator surveys

Staff and project coordinator surveys are electronically distributed to all school organisational members – i.e. managers, teaching staff, counsellors, administrative and kitchen staff, etc. – at three different time points to follow the gradual implementation of SFSH. It is important to include all organisational members as all are expected to be affected by SFSH. The surveys include questions to investigate the implementation degree (e.g. fidelity, dose) and the validated NoMAD scale[69,70] to grasp the implementation processes. The project coordinator surveys include additional questions about the implementation work (e.g. collaboration with the local municipality and contextual tailoring). The surveys have been pilot-tested among staff, managers, and project coordinators at the four pilot schools (n=23 participants) to ensure face validity.[67]

Structured observations

Structured observations on school grounds are carried out by the researchers at the same time points as the student surveys. Inspired by other studies,[71,72] the structured observations will include observations on smoking visibility (e.g. who, where, and how many smokers are visible during school hours) and physical environment changes (e.g. smoke-free signing and removal of smoking facilities). Data will be registered as field notes.

Interviews and focus groups with principal manager, project coordinator, and teachers

Semi-structured individual interviews and focus groups with school principals, project coordinators, and teachers are carried out to explore the implementation processes in terms of intervention modalities, change mechanisms, and context features.[73] It is important to gather interview material from the different respondent groups as they provide different perspectives, challenges, and opportunities in relation to implementing SFSH. Specifically, school principals have decision-making power on SFSH and knowledge about school strategic-political processes; project coordinators have in-depth knowledge and experience of all actions for implementing SFSH; and teachers have direct contact with students and are expected to play a large role in enforcing SFSH.

Table 2 Overview of data in the Smoke-Free Vocational Schools intervention project, including eligible participants (n), expected response rates (n), and data collection procedures.

Data collection	When	N (eligible)	N (expected)	Procedure

Student survey 1	Before SFSH	3,000	2,000	Baseline measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	Before SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 1	Before SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about SFSH preparation (email).
Project coordinator survey 1	Before SFSH	7	7	In-depth electronic questionnaire concerning SFSH preparation (email).
Principal manager interview	Before SFSH	7	7	Semi-structured interview focusing on SFSH preparation, including motivation and past experiences (in school or via Skype).
Student survey 2	6 months after SFSH	3,000	2,000	Follow-up 1 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	6 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 2	6 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Project coordinator survey 2	6 months after SFSH	7	7	In-depth electronic questionnaire about the gradual SFSH implementation (email).
Staff focus group	6–8 months after SFSH	21–42	21–42	Focus groups with teaching staff, counsellors, and/or others assigned a special role in relation to SFSH. Focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Project coordinator interview	6–8 months after SFSH	7	7	Semi-structured interview focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Student survey 3	12 months after SFSH	3,000	2,000	Follow-up 2 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	12 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 3	12 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Facilitator survey (NGOs)	Before and after SFSH	NA	NA	Electronic questionnaire distributed to the practice partners in relation to different intervention activities, i.e. student and staff workshops and courses.

SFSH: Smoke-free school hours.

Step 4: Data analysis

Process evaluation

Implementation levels are assessed using confirmatory factor analysis.[74] Inspired by Bast et al.,[29] data are used to develop indexes of low and high implementation degree, while associations between the outputs and the overall SFSH implementation fidelity model are analysed using regression analysis. This allows us to investigate to what extent the intervention activities predict the implementation

degree of SFSH. Mechanisms of change are explored by combining qualitative and quantitative data and by using the generative mechanisms proposed by normalisation process theory (coherence, cognitive participation, collective action, and reflexive monitoring) to structure the analysis. Qualitative data will be coded using an abductive approach, whereas quantitative data will be analysed using descriptive techniques to further explain, supplement, or challenge the qualitative analyses of what enables or hinders SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation uses multi-level linear or logistic regression, depending on the outcome measures.[75] The primary analysis will be a two-level model, with students (level 1) nested in schools (level 2). In secondary analysis, we will investigate effects according to pre-defined subgroups, such as sex, age, and SES. To further elaborate on CMO configurations, we will test the associations between quantitative measures of implementation degree and implementation processes from the process evaluation, using descriptive analysis, logistic regression, and/or factor analysis.[76,77]

Step 5: Synthesis

Empirical and theoretical knowledge about the implementation and outcomes of the intervention will be synthesised into recommendations on how to implement SFSH. RE advocates using retroduction and abduction in iterative processes to test and refine IPT.[37,73,78] Retroduction is a form of inference that seeks to identify and verify the mechanisms theorised to have generated the phenomena under study,[73,78] whereas abduction is the process of describing empirical data using theoretical concepts,[73] with emphasis on analysing data that fall outside an initial theoretical frame or premise.[78,79] Regarding the Smoke-Free Vocational Schools intervention project, our goal is to integrate qualitative and quantitative findings from the process and outcomes evaluations to re-analyse the IPT in terms of what works, for whom, and under what circumstances, using a retroductive-abductive approach. Based on the refined programme theory, we will be able to develop model recommendations for implementing SFSH in vocational schools and similar settings.

ETHICS AND DISSEMINATION

In public health interventions it is important to examine and clarify possible negative reverse effects, so as to avoid further interventions generating the same negative effects.[80] Therefore, unexpected consequences of the intervention will be explored and reported to minimise and avoid participants feeling stigmatised in this study and similar future studies.

The study has been reported to the Capital Region of Denmark's legal centre for personal data handling (journal number: VD-2018-485). Informed consent will be obtained from all study participants according to the General Data Protection Regulation and Danish data protection law. Study findings will be disseminated at international and national conferences and further published in open-access peer-reviewed journals. Also, the study findings will be used by the practice partners in their further work supporting schools implementing SFSH, as well as by other stakeholders (e.g. schools).

Declarations

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Authors contributions

The authors contributions to different aspects of this work were as follows: Conceiving and designing the study: AVH, TBC, MS, KHR and CDK; Refining the study design and obtaining ethical approval: AVH, CP, TTT, CDK; Writing and revising this manuscript (fully or in part): AVH, TBC, MS, KHR, CP, TTT, CDK.

Patient and public partnership

The research and intervention project is a collaboration between research and practice: Two Danish public health NGOs (the Danish Heart Foundation and the Danish Cancer Society) are practice partners, whereas Steno Diabetes Center Copenhagen is research partner. The intervention has been cocreated through a participatory process, with an emphasis on including both evidence and practice experience. Further, the practice partners involved in the design and conduct of the study, the choice of outcome measures and recruitment to the study.

Competing interests

The authors declare that they have no competing interests.

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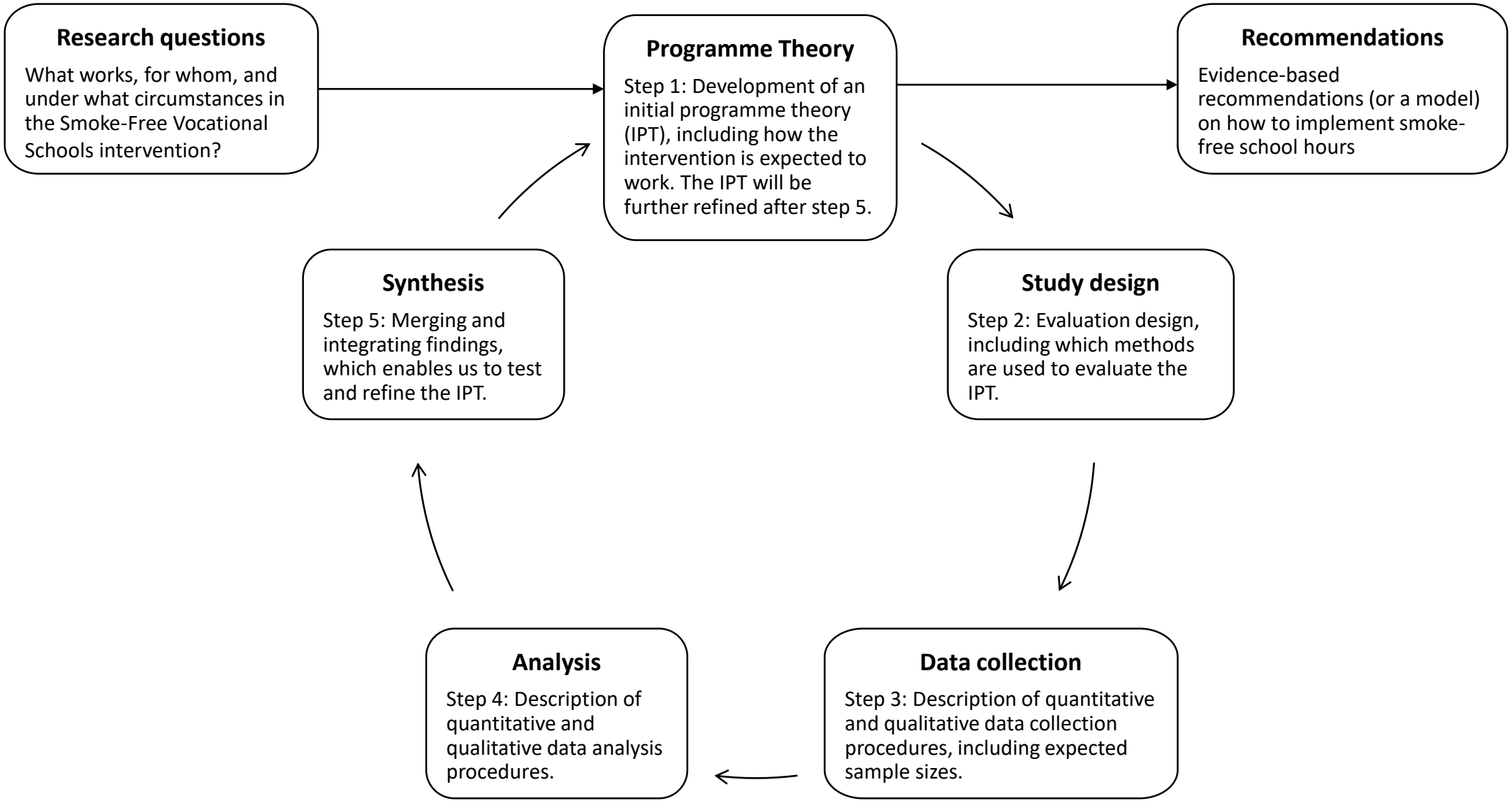
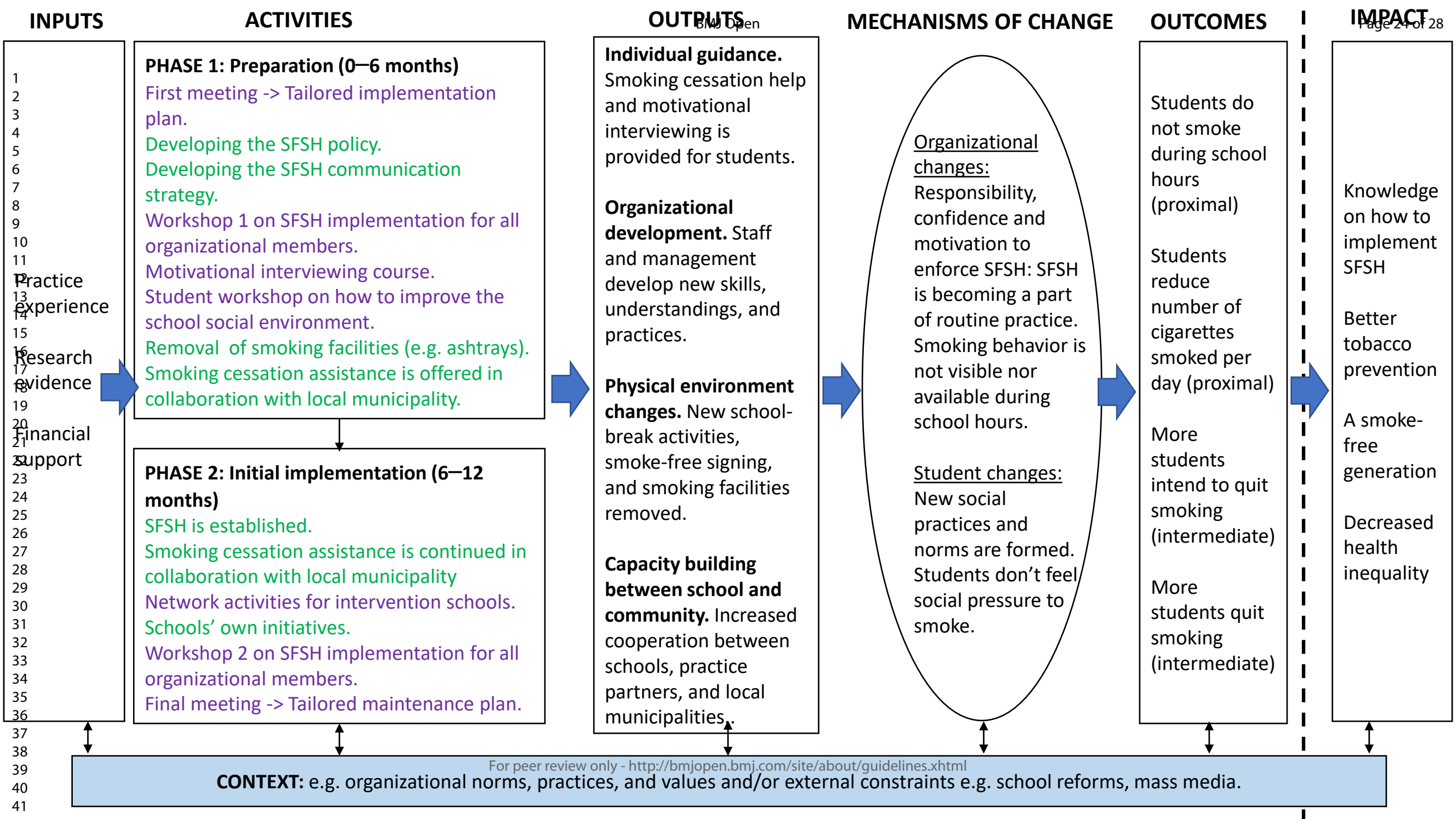
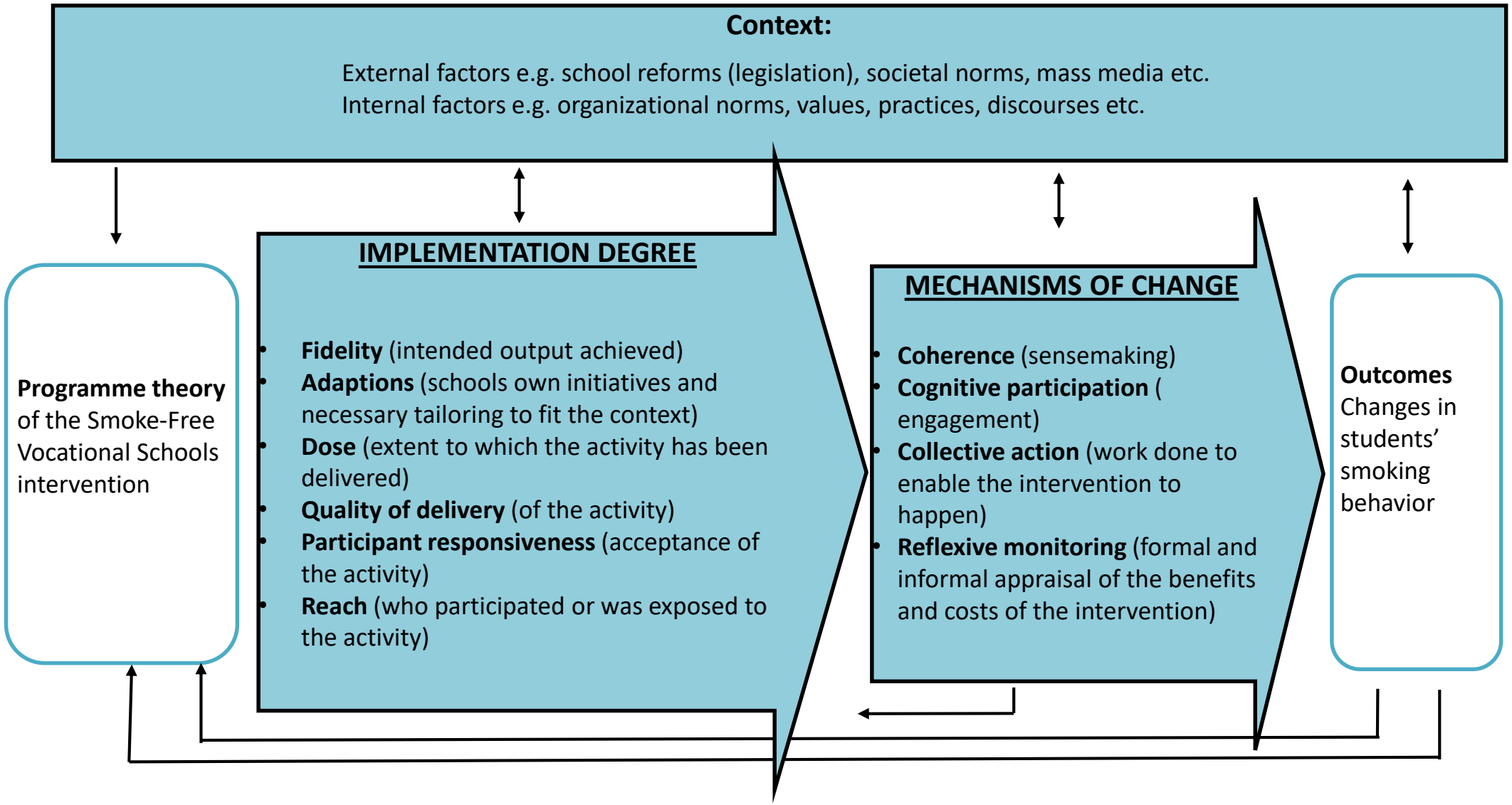
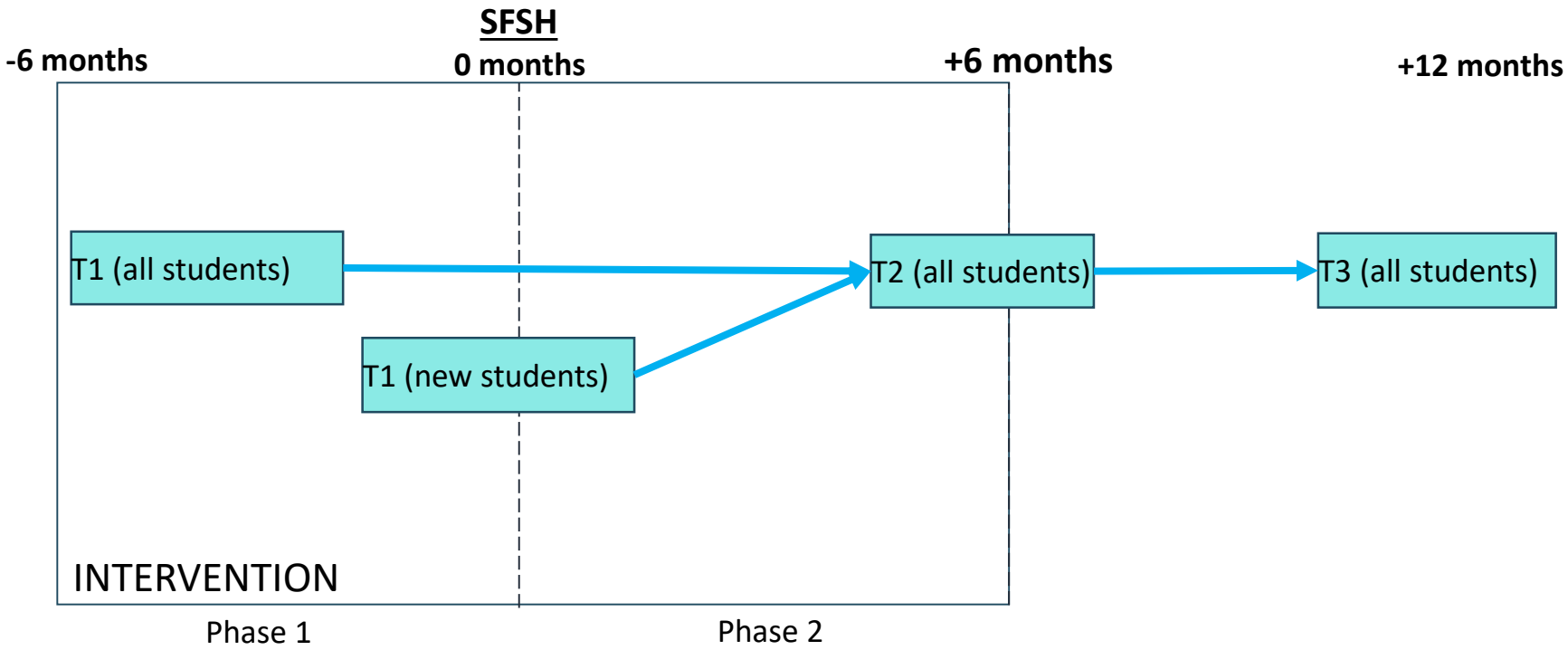

Research questions
What works, for whom, and under what circumstances in the Smoke-Free Vocational Schools intervention?
Programme Theory
Step 1: Development of an initial programme theory (IPT), including how the intervention is expected to work. The IPT will be further refined after step 5.
Recommendations
Evidence-based recommendations (or a model) on how to implement smoke-free school hours
Synthesis
Step 5: Merging and integrating findings, which enables us to test and refine the IPT.
Study design
Step 2: Evaluation design, including which methods are used to evaluate the IPT.
Analysis
Step 4: Description of quantitative and qualitative data analysis procedures.
Data collection
Step 3: Description of quantitative and qualitative data collection procedures, including expected sample sizes.




Context:
External factors e.g. school reforms (legislation), societal norms, mass media etc.
Internal factors e.g. organizational norms, values, practices, discourses etc.
Programme theory of the Smoke-Free Vocational Schools intervention
IMPLEMENTATION DEGREE
Fidelity (intended output achieved)
Adaptions (schools own initiatives and necessary tailoring to fit the context)
Dose (extent to which the activity has been delivered)
Quality of delivery (of the activity)
Participant responsiveness (acceptance of the activity)
Reach (who participated or was exposed to the activity)
MECHANISMS OF CHANGE
Coherence (sensemaking)
Cognitive participation (engagement)
Collective action (work done to enable the intervention to happen)
Reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention)
Outcomes
Changes in students' smoking behavior


SFSH
-6 months
0 months
+6 months
+12 months
T1 (all students)
T1 (new students)
T2 (all students)
T3 (all students)
INTERVENTION
Phase 1
Phase 2

Supplementary File 1: Operationalization of data collection in the process evaluation (implementation degree and mechanisms of change) and the outcomes evaluation

	Concept	Operationalization	Data collection
Implementation degree			
Organizational development	Fidelity	If the workshops and course has resulted in a shared smoke-free school hours understanding and new skills to support students dealing with not smoking during school hours	Staff survey 1; Staff survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2: Facilitator questionnaire (NGOs)
	Dose	Extent to which new learnings from workshops and skills from course are being used at school	Staff survey 1; Staff survey 2
	Quality of delivery	Organization of new learnings and skills at school	Staff survey 1; Staff survey 2
	Participant responsiveness	Attitudes towards workshops and course	Staff survey 1; Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Staff survey 1; Staff survey 2
Physical environment changes	Fidelity	If new school-break activities and smoke-free-signing has been established, and smoking facilities removed	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; structured observations on school grounds; Project coordinator interviews
	Dose	Extent to which school-break activities and smoke-free signing is known to students	Student survey 2
	Quality of delivery	Extent to which new school-break activities are being used by students and smoke-free signing has a prominent position	Student survey 2; structured observations on school grounds
	Participant responsiveness	Attitudes towards workshops new school-break activities and smoke-free-signing	Student survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Individual guidance	Fidelity	If the school offers smoking cessation help or other help for students to cope with smoke-free school hours	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 1; Project coordinator survey 2; Project coordinator interview
	Dose	Number of smoking cessation courses delivered and number of students attending the courses	Project coordinator survey 1; Project coordinator survey 2
	Quality of delivery	Extent to which students know which support to cope with smoke-free school hours is provided	Student survey 2
	Participant responsiveness	Attitudes towards help to cope with smoke-free school hours and attitudes towards attending smoking cessation courses	Student survey 2

	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Capacity building between the school and community	Fidelity	If the relationship between school and NGOs, and school and municipality has been strengthened	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; Project coordinator interview
	Dose	Extent to which the school has discussed smoke-free school hours implementation with NGOs and local municipality	Project coordinator survey 2
	Quality of delivery	Extent to which the schools has experienced support from the NGOs and local municipality	Project coordinator survey 2
	Participant responsiveness	Attitudes towards integrating external resources in smoke-free school hours implementation	Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Facilitator questionnaire (NGOs)
Smoke-free school hours implementation	Fidelity	If smoking is allowed during school hours and extent to which students experience smoking during school-hours	Staff survey 2; Staff survey 3; Student survey 2
	Adaptions	Context-specific adjustments in sanctioning and enforcement procedures and practice	Staff survey 2; Staff survey 3; Project coordinator interview
	Dose	Extent to which students know the policy and extent of smoking visibility	Student survey 2, Staff survey 2; Staff survey 3; Structured observations on school grounds
	Quality of delivery	Frequency and manner/method of enforcement	Staff survey 2; Staff survey 3
	Participant responsiveness	Attitudes towards the policy and whether staff experience the policy as a normal part of their work	Student survey 2; Staff survey 2; Staff survey 3
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2; Staff survey 2; Staff survey 3
Mechanisms of change			
Interactions between the intervention and context-mechanisms i.e. reasoning and behavior among participants, constrained by e.g. organizational norms, values and discourses	Coherence	If and why smoke-free school hours makes sense given the situation the school currently face. Extant to which there's a shared understanding about the policy and the organizational members see the potential value of smoke-free school hours.	Management interview; Project coordinator interview; Teacher focus groups; Staff survey 2; Staff survey 3
	Cognitive participation	If and how there's been established a community of practice around smoke-free school hours, if there's key people driving the implementation forward or the contrary and who. If it is seen as a legitimate part of the schoolwork and if there's been established new practices. Extent to which the organizational members are open to change their daily routines to work with smoke-free school hours.	
	Collective action	If and how smoke-free school hours in enacted as part of routine practice including management practices e.g. how is the work organized and which resources are in place to support the implementation. To what extent the work can be integrated into the everyday school practices and whether people involved has sufficient skills and confidence in work with smoke-free school hours.	
	Reflexive monitoring	If and how smoke-free school hours affect the everyday school life. Formel and informal appraisal procedures and reconfiguration.	

Sub-study 3: Outcomes			
Baseline	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 1
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 1	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 2
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 2	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 3
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	

BMJ Open

Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol

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Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol

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ABSTRACT

Introduction: Smoke-free school hours (SFSH) entails a smoking ban during school hours and might be an effective intervention to reduce the high smoking prevalence in vocational schools. For SFSH to be effective, the policy must be adequately implemented and enforced; this challenge for schools constitutes a research gap. The 'Smoke-Free Vocational Schools' research and intervention project has been developed to facilitate schools' implementation of SFSH. It is scheduled to run from 2018–2022, with SFSH being implemented in 11 Danish vocational schools. This study protocol describes the intervention project and evaluation design research and intervention project.

Methods and analysis: The intervention project aims to develop an evidence-based model for implementing SFSH in vocational schools and similar settings. The project is developed in a collaboration between research and practice. Two public health NGOs are responsible for delivering the intervention activities in schools, while the research partner evaluates what works, for whom, and under what circumstances. The intervention lasts one year per school, targeting different socioecological levels. During the first six months, activities are delivered to stimulate organisational readiness to implement SFSH. Then, SFSH is established, and during the next six months, activities are delivered to stimulate implementation of SFSH into routine practice. The epistemological foundation is realistic evaluation. The evaluation focuses on both implementation and outcomes. Process evaluation will determine the level of implementation and explore what hinders or enables SFSH becoming part of routine practice using qualitative and quantitative methods. Outcomes evaluation will quantitively assess the intervention's effectiveness, with the primary outcome measure being changes in smoking during school-hours.

Ethics and dissemination: Informed consent will be obtained from study participants according to the GDPR and Danish data protection law. The study adheres to Danish ethics procedures. Study findings will be disseminated at conferences and further published in open-access peer-reviewed journals.

Strengths and limitations:

- The study draws on realistic evaluation and aims to answer both research and practice needs by generating new application-oriented knowledge on how to implement smoke-free school hours in vocational schools and similar settings.
- The study includes both implementation/process evaluation and outcomes evaluation in a unified multi-methods study design.
- The intervention has been developed in a joint venture between research and practice that emphasises including practice-based experience and research evidence, which may generate high external validity and more sustainable implementation practices.
- The study seeks to assess outcomes in a pretest-posttest study design without using control schools, which is appropriate in realistic evaluation but limits internal validity in relation to determining the intervention's effectiveness.

INTRODUCTION

From August 2021, a school tobacco policy (STP) of smoke-free school hours (SFSH) is expected to be ratified in all Danish educational institutions with at least one student aged under 18. The policy basically stipulates a smoking ban for students during school hours – both inside and outside school

grounds. An expanded definition of SFSH also bans smoking by school staff, managers and visitors (smoke-free work hours). Additionally, SFSH might include all tobacco-related products (e.g. cigarettes, vapers, and snuff). SFSH is an expansion of traditional STPs, which do not prohibit smoking outside school grounds.[1] The rationale is the same: restricting smoking behaviour as a means to prevent exposure to second-hand smoke, smoking initiation, and smoking continuation among adolescents and young adults.[2,3] Restricting smoking behaviour can further be linked to political denormalization strategies aiming to make the future smoke-free: a tobacco endgame.[4] Evidence about SFSH is sparse, but some researchers[5] suggest that it might be more effective than traditional STPs, which have been shown to relocate smoking to just outside school premises (e.g. at the school entrance), and therefore do not remove smoking visibility.[5,6] Additionally, traditional STPs can have adverse effects on students with lower socioeconomic status (SES), (lower odds of anti-smoking social believes)[7], which suggest that SFSH might be a more appropriate strategy in schools with low SES groups, such as vocational schools.

In Denmark, vocational education and training (VET) is a short, practical upper-secondary education for a specific service or industry, such as hairdresser, carpenter, office assistant, or chef. It is characterised by a combination of traditional in-school education and out-of-school apprenticeship in the future workplace. Danish vocational students have low SES backgrounds[8] and are overrepresented in smoking behaviour: 29% smoke daily, compared to 9% in general upper-secondary education.[9,10] The average vocational student age is 24, but as 14% of these students are aged 15–17,[11] the SFSH law will apply to Danish vocational schools. As such, the law has considerable health-promoting potential: it may not only reduce smoking within a vulnerable population group setting (vocational schools) but also contribute towards decreasing health inequality.[12] However, policies which are not well-implemented will not improve health.[13–16] We conceptualise the implementation of SFSH as a school organisational process with the end-goal of incorporating the policy into routine practice.[17] Staff and managers must enact and enforce the policy as part of their professional duties, and students must experience the policy as an accepted part of their everyday school life. Hence, enforcement is a significant task of organisational implementation.[16,18–20] Despite legislation imposing STPs in many secondary schools across Europe, they are often poorly implemented and enforced.[21–24]

Three reviews have systematised decades of evidence related to STP implementation. The 2014 systematic review by Galanti et al.[15] identified implementation components that improve STPs'

impact on student smoking behaviour (e.g. strict and consistent enforcement). However, the authors also showed that most studies do not measure implementation fidelity and that enforcement is inconsistently operationalised across studies.[15] Two realist reviews,[5,16] as part of the SILNE-R project (2015–2018),[25] yield prominent new insights into the functioning of STPs. The first shows how STPs' implementation and comprehensiveness affects students' beliefs and behaviour: for example, if smoking is not visible during school hours, students feel less pressure to conform to others' smoking behaviour.[5] The second shows that staff enforcement depends on whether they 1) believe that STP enforcement is their role and duty, 2) have confidence to deal with students' negative responses when enforcing the rules, and 3) experience enforcement having a positive impact on students.[16] Other recent studies[26–28] have explored which practices facilitate or hinder adopting SFSH; one key finding is that schools should develop a shared understanding about the policy being part of their jurisdiction prior to implementation).[26–28] Seen together, the studies point towards important elements for schools to consider when implementing SFSH, but do not provide knowledge about what activities and processes can stimulate better implementation. In other words, most studies focus on understanding existing STPs rather than generating new knowledge about how to facilitate implementation. The latter might only be possible using interventionist study designs. One intervention study provides an important measure of STP implementation fidelity.[29] To the best of our knowledge, however, no intervention studies have examined how to stimulate or measure the process of implementing SFSH into routine practice. As such, it remains unclear how to best support, stimulate, and measure the implementation of SFSH.

To address the identified research gap, we developed the 'Smoke-Free Vocational Schools' intervention project, which aims to facilitate implementing SFSH in vocational schools and to generate new knowledge about the implementation and effectiveness of SFSH. The intervention takes place in 11 Danish vocational schools from 2018–2022.

Realistic evaluation

Realistic evaluation (RE) is the epistemological foundation of the evaluation. Pawson and Tilley developed the RE approach, arguing that to generate application-oriented knowledge for policy and practice, it is more useful to address 'what works, for whom and under what circumstances', rather than evaluating whether an intervention 'works'.[30] According to RE, interventions might generate different outcomes (O) in different contexts (C) by triggering underlying changes in reasoning and behaviour among participants – conceptualised as mechanisms (M).[31] As such, interventions may

'work' by enabling participants to make different choices, but the choices are always constrained by a context, such as the organisational norms, values, and discourses that operate in school settings. 'Complex intervention' is used to describe innovations within highly complex and emergent social systems,[32] such as schools.[33–34] It can be understood in relation to the RE notion of 'open systems', defined by Pawson and Tilley[30] as '[T]he acknowledgement that programs are implemented in a changing and permeable social world, and that program effectiveness may thus be subverted or enhanced through the unanticipated intrusion of new contexts' (p. 218). Hence, the overall RE methodology is to examine C + M = O relations in complex interventions, known as CMO configurations.[30]

Study aim

In reporting complex interventions, the intervention and evaluation design must be clearly described to enable replication and synthesis of evidence,[35,36] yet many RE studies inadequately report their methodological practices.[37–39] Therefore, the aim of this study protocol is two-fold: 1) to describe the Smoke-Free Vocational Schools intervention, and 2) to present how the intervention is evaluated, including the study design, specific methods, and theoretical assumptions.

METHODS AND ANALYSIS

The overall objective of the Smoke-Free Vocational Schools intervention project is to develop an evidence-based model for implementing SFSH in Danish vocational schools and comparable settings. To accomplish the objective, the study examines what works, for whom, and under what circumstances. RE starts with the development of an initial programme theory (IPT).[39] Programme theory is theory incarnate, explicitly explaining which context-mechanisms should be triggered among different actors to produce desired outcomes.[40,41] In relation to the Smoke-Free Vocational Schools intervention, the IPT represents a hypothesis on how and why to implement SFSH and the study design is developed to test the hypothesis. We have structured this study protocol following the steps of the realist research cycle,[39,42] as shown in figure 1. The content was further informed by the SPIRIT (Standard Protocol Items for Randomized Trials) statement.

>> Insert Figure 1 here <<

Step 1: Programme theory

The intervention project is a collaboration between research and practice. Two Danish public health NGOs – the Danish Heart Foundation and the Danish Cancer Society – are practice partners, while Steno Diabetes Centre Copenhagen is the research partner. The practice partners are responsible for

delivering the intervention activities in schools; the research partner is responsible for conducting a formative evaluation of the implementation processes and outcomes. The research and practice partners together developed the IPT, and it is part of our method to continually discuss and apply preliminary research findings as part of the formative evaluation. As such, we follow the proposal of RE[37] by iteratively testing and developing the programme theory in parallel to new empirical learnings.

The IPT was developed through a workshop where research and practice worked collaboratively. The practice partners contributed their extensive first-hand experience of implementing tobacco preventive efforts in different school contexts: for example, the Danish Cancer Society has tailored a motivational interviewing course to support smoking cessation by upper-secondary school students. The translation of practice-based experience and ideas into the intervention might increase the sustainability of implementation practices and improve external validity.[43] The research partner contributed with evidence on effective tobacco preventive methods in vocational schools, based on recent research and the results from a qualitative study on facilitators and barriers for implementing SFSH.[28] At the workshop, we developed a graphic representation of the intervention,[44] including the short- and long-term outputs, outcomes, and impact expected of different intervention activities targeting actors within and outside the school. The workshop process also served as a learning and management tool, as the research and practice partners developed a shared understanding on how the intervention is expected to produce change, which is crucial in public health interventions.[45]

The Smoke-Free Vocational Schools intervention

The intervention is delivered in two phases, each lasting approximately six months (as shown in figure 2). During phase 1, activities are delivered to stimulate organisational readiness[46] to implement SFSH: these include preparing staff and managers for their new professional tasks, and establishing new school-break facilities for students as alternatives to social smoking. At the beginning of phase 2, SFSH is established. During phase 2, activities are delivered to stimulate the gradual implementation of SFSH into routine practice by supporting schools in addressing emergent challenges, such as nicotine dependence or enforcement. Table 1 describes all the intervention activities.

>> Insert Figure 2 here <<

The activities are expected to produce short-term outputs, which are operationalised in four sets according to ecological levels[47]: 1) individual guidance, e.g. smoking cessation assistance for students (individual); 2) organisational development, e.g. development of professional skills and confidence

to enforce SFSH (interpersonal); 3) physical environment changes, e.g. new school-break activities (structural/organisational); and 4) capacity building between school and community, e.g. increased cooperation between the school and the local municipality (community).

Table 1 Description of intervention activities in the Smoke-Free Vocational Schools intervention.

Activity	Description	Purpose	Participants
		Phase 1	
First meeting	An initial meeting between the schools and practice partners, where the SFSH implementation plan is discussed.	To ensure that the schools have a clear implementation plan and know how the intervention activities can support them. To clarify role distributions between different stakeholders.	Practice partners. School principal and other management representatives. School project coordinator. Local municipality representative.
Developing the SFSH policy	The schools develop their SFSH policy, including rules and responsibilities for sanctioning and enforcement. The practice partners provide inspirational material, e.g. other schools' policies.	To ensure the schools develop a clear SFSH policy, which aligns with the schools' rules of conduct.	Decided locally in schools. Practice partners recommend that schools establish a working group including both management and staff representatives.
Developing the SFSH communication strategy	The schools develop their internal and external SFSH communication strategy. The practice partners provide inspirational material and financial support to smoke-free signing.	To ensure that all organisational members (e.g. students and staff) and relevant external stakeholders (e.g. neighbours and apprenticeship workplaces) know what SFSH entails.	Decided locally in schools.
Workshop 1 on SFSH implementation	A joint meeting at the schools for all school staff and managers, facilitated by the practice partners.	To stimulate a joint vision and understanding of why the school is implementing SFSH. To ensure that all organisational members feel confident to enforce SFSH. To address school-specific challenges and issues, e.g. resistance.	Practice partners. All school staff and managers. Local municipality representative.
Motivational interviewing course	A selected group of school staff and managers attend a two-day course delivered by the practice partners.	To provide new knowledge and skills for the selected staff and managers, who are supposed to become key drivers of the implementation in school. To help nicotine-addicted students to cope with not smoking during school hours.	Practice partners. Selected school staff and managers including the school project coordinator. Local municipality representative.
Smoking cessation assistance	Offered to students and staff in collaboration with the local municipality. The type of assistance varies between municipalities, depending on local resources and availabilities.	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.
Student workshop	A participatory student workshop on how to improve the social environment, delivered in schools by the practice partners. The schools are given financial support (averaging 15,000 € per school) to	To create alternatives to smoking communities at school. To ensure that the new school-break activities are relevant for the students.	Practice partners. Selected group of students. Local municipality representative. The school management and school project coordinator approve the new school-break activities.

	establish some of the best school-break activities.		
Removal of smoking facilities	The schools remove smoking facilities, e.g. ashtrays.	To signal that the school is smoke-free.	Decided locally in schools.
Phase 2			
The school tobacco policy of SFSH	The SFSH policy is established in schools. The schools must enact and enforce the policy.	To prevent exposure to second-hand smoke. To prevent smoking initiation and continuation.	Decided locally in schools. Practice partners recommend that all school staff and managers play a role in enforcement.
Continued smoking cessation assistance	Smoking cessation assistance is offered to students and staff in collaboration with the local municipality. The type of smoking cessation assistance varies between municipalities, depending on local resources and availabilities.	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.
Network activities for intervention schools	A network for intervention schools is established by the practice partners. Two larger network activities for all schools are delivered during 2018–2020.	To facilitate schools exchanging experiences of implementing SFSH and learning from one another.	School principal and school project coordinator are invited. Participation in network activities will be decided locally in schools.
Schools' own initiatives	Supportive actions which ease the implementation of SFSH.	Decided locally by schools.	Decided locally by schools.
Workshop 2	A joint meeting at the schools for all staff and managers, facilitated by the practice partners.	To address school-specific challenges in relation to implementing SFSH.	Practice partners. All school staff and managers. Local municipality representative.
Final meeting	A final meeting between the schools and practice partners to discuss the SFSH maintenance plan.	To ensure the schools have a clear maintenance plan and know how the municipality and practice partners can support them after the intervention period.	Practice partners. School principal. School project coordinator. Local municipality representative.

SFSH: Smoke-free school hours.

The activities and outputs are together expected to produce 'mechanisms of change', which are the underlying changes in reasoning and behaviour among participants, triggered by the intervention and the intervention context. We expect that the central context-mechanisms allowing SFSH to become part of routine practice will be found at the organisational level, where school staff and managers take responsibility for SFSH, feel confident to enforce SFSH, and feel motivated by positive student responses.[16] At the student level, we expect context-mechanisms to be triggered by: 1) staff and managers enforcing SFSH, resulting in decreased smoking visibility and, in turn, students becoming less prone to conform to others' smoking behaviour;[5] and 2) the new school-break activities resulting in new practices and social norms at school.[48] As such, we expect SFSH to become a natural and accepted part of students' everyday school life.

The mechanisms of change are expected to result in outcomes related to students' smoking behaviour. Our primary outcome measure is 'changes in smoking during school hours', while the secondary

outcome measure is 'changes in the number of cigarettes smoked per day'; both are proximal outcomes. The intermediate outcome measures are 'changes in intention to quit' and 'changes in smoking status'. The long-term impact of the intervention will not be evaluated as part of this study.

Step 2: Study design

The study is designed to test the IPT through focusing on both implementation/process evaluation and outcomes evaluation. As considered most appropriate in RE,[30,37] we use a multi-methods design, which allows us to quantify some elements of CMO configurations (e.g. changes in smoking behaviour) and qualitatively explore the change mechanisms and context.[49] The process evaluation investigates to what extent the intervention activities have been delivered and are implemented according to the programme theory, and seeks to explore the mechanisms that hinder or enable SFSH becoming part of routine practice. The outcomes evaluation assesses the intervention's outcomes in terms of students' smoking behaviour, using a one-group pretest-posttest study design, with sub-group analysis further determining for whom the intervention is most effective.

The intervention is delivered at 11 schools during 2018–2020, seven of which are included in the evaluation. The remaining four are considered 'pilot schools', where the intervention activities and evaluation methods (e.g. questionnaires) are tested and adjusted. The practice partners recruited schools that wanted to implement the expanded version of SFSH, banning all tobacco-related products (e.g. cigarettes, vapers, and snuff) during school and work hours for students, staff, and visitors. The sample of seven vocational schools accounts for 10% of all Danish vocational schools; represents all four main educational areas (Technical, Business, Agriculture and food services, and Social and health services); and covers three (out of five) geographical regions. As such, the study sample includes a broad variety of vocational school contexts across the country and is, thus, considered representative of all Danish vocational schools.

Process evaluation

The process evaluation comprises two mutually informing parts based on the RE-compatible[50] Medical Research Councils guidelines for Process Evaluation of Complex Interventions.[35] Our operationalisation of the framework in the study is shown in figure 3.

>> Insert Figure 3 here <<

The 'Implementation degree' study quantitively measures implementation levels for each of the four sets of outputs and for the SFSH policy based on fidelity, adaptions, dose, quality of delivery,

participant responsiveness, and reach. Hence, the study seeks to occupy a middle position in the fidelity vs. adaptions debate[50] with an emphasis on measuring both central intervention implementation (e.g. extent of enforcement) and the schools' contextual initiatives and tailoring (e.g. means and methods of enforcement). The 'Mechanisms of change' study explores the implementation processes using both qualitative and quantitative methods. Normalisation process theory[17] proposes that implementation processes are shaped and motivated by four generative mechanisms – coherence, cognitive participation, collective action, and reflexive monitoring. This will be the guiding theory in the investigation of processes that hinder or enable SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation assesses the effectiveness of the intervention in terms of the primary and secondary outcomes, measured before SFSH (Time 1, T1), six months after the establishment of SFSH (Tine 2, T2), and twelve months after the establishment of SFSH (Time 3, T3), as shown in figure 4. The primary outcome measure is changes in 1) smoking during school hours (dichotomous variable (yes/no)); the secondary outcome measures are changes in 2a) the number of cigarettes smoked per day (continuous variable), 2b) intention to quit (nominal variable), and 2c) smoking status (nominal variable). Further, to elaborate on CMO configurations, sub-group analyses are performed to investigate for whom the intervention is most effective and to explore relations between findings from the process evaluation, that is, the SFSH implementation fidelity measure and quantitative indicators of implementation processes. The study thus seeks to elaborate on outcomes across the programme but also considers outcomes for different subgroups within the population without using control schools, which is considered appropriate for RE.[37,51,52]

>> Insert Figure 4 here <<

Step 3: Data collection

The evaluation lasts approximately 1.5 years per school and covers intervention phase 1 (six months) and intervention phase 2 (six months), with the final follow-up conducted six months after the intervention has ended. During this time period, qualitative and quantitative data will be collected from students, staff, and managers to increase the validity of findings.[53] Table 2 presents an overview of all data collection measures and procedures, including estimates of eligible participants and expected response rates. The different data collection measures provide cross-cutting insights for the process and outcomes evaluations. A preliminary operationalisation of how the data contribute to each is presented in Supplementary File 1.

Student surveys

Electronic student surveys are conducted during school hours at three different time points. Students self-report smoking behaviour[54] and intention to quit,[55] smoking-related rules and practices and social norms at school,[56–61] self-efficacy,[62–64], well-being,[65,66] educational information, and demographics. Validated questions have been used when possible and the questionnaire has been pilot-tested in two vocational school classes (n=30 participants) to ensure face validity.[67] Due to the VET school structure, combining in-school education and apprenticeships, individual follow-up is rarely possible. Instead, both paired data from the same individuals and cross-sectional data will be collected. To maximise response rates, data collection is organised by the research partners in each school and conducted during school hours. The students are given time to complete the questionnaire and ask questions. The survey takes approximately 30 minutes per school class. Based on experience with the procedure,[9] we expect that 95% of students will participate in the study.

Sample size calculation

The outcome measure used to determine sample size is change in the number of cigarettes smoked during school hours per day, per student, based on individual follow-up data. We assume that 30% are daily smokers who averagely smoke 18 cigarettes per day, including 8 during school hours.[68] We assume that the intervention will reduce smoking intensity during school hours by 50%, meaning a reduction of 4 cigarettes smoked per school day (with a standard deviation of 4 and 3 and correlation = 0.3). To avoid type-I errors and type-II errors, we respectively chose a 5% significance level and power at 80%. Assuming that the data are normally distributed, we will need to conduct individual follow-up on 11 daily smokers per school. We expect a 30% reduction in participants from baseline to follow-up. Accounting for this, the sample size must include 14.3 daily smokers per school. Thus, if the smoking prevalence is 30%, 24.4 students per school must participate in the prospective study. As seven schools are participating, the sample size for the prospective study must include (at least) 171 students.

Staff and project coordinator surveys

Staff and project coordinator surveys are electronically distributed to all school organisational members – i.e. managers, teaching staff, counsellors, administrative and kitchen staff, etc. – at three different time points to follow the gradual implementation of SFSH. It is important to include all organisational members as all are expected to be affected by SFSH. The surveys include questions to investigate the implementation degree (e.g. fidelity, dose) and the validated NoMAD scale[69,70] to grasp the implementation processes. The project coordinator surveys include additional questions

about the implementation work (e.g. collaboration with the NGO partners, local municipality and contextual tailoring). The surveys have been pilot-tested among staff, managers, and project coordinators at the four pilot schools (n=23 participants) to ensure face validity.[67] Surveys distributed to NGOs partners both before and after SFSH explore their role in facilitating meetings.

Structured observations

Structured observations on school grounds are carried out by the researchers at the same time points as the student surveys. Inspired by other studies,[71,72] the structured observations will include observations on smoking visibility (e.g. who, where, and how many smokers are visible during school hours) and physical environment changes (e.g. smoke-free signing and removal of smoking facilities). Data will be registered as field notes.

Interviews and focus groups with principal manager, project coordinator, and teachers

Semi-structured individual interviews and focus groups with school principals, project coordinators, and teachers are carried out to explore the implementation processes in terms of intervention modalities, change mechanisms, and context features.[73] It is important to gather interview material from the different respondent groups as they provide different perspectives, challenges, and opportunities in relation to implementing SFSH. Specifically, school principals have decision-making power on SFSH and knowledge about school strategic-political processes; project coordinators have in-depth knowledge and experience of all actions for implementing SFSH; and teachers have direct contact with students and are expected to play a large role in enforcing SFSH. During interviews the role of the NGO partners is also explored.

Table 2 Overview of data in the Smoke-Free Vocational Schools intervention project, including eligible participants (n), expected response rates (n), and data collection procedures.

Data collection	When	N (eligible)	N (expected)	Procedure
Student survey 1	Before SFSH	3,000	2,000	Baseline measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	Before SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 1	Before SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about SFSH preparation (email).
Project coordinator survey 1	Before SFSH	7	7	In-depth electronic questionnaire concerning SFSH preparation (email).
Principal manager interview	Before SFSH	7	7	Semi-structured interview focusing on SFSH preparation, including motivation and past experiences (in school or via Skype).
Student survey 2	6 months after SFSH	3,000	2,000	Follow-up 1 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).

Structured observations on school grounds	6 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 2	6 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Project coordinator survey 2	6 months after SFSH	7	7	In-depth electronic questionnaire about the gradual SFSH implementation (email).
Staff focus group	6–8 months after SFSH	21–42	21–42	Focus groups with teaching staff, counsellors, and/or others assigned a special role in relation to SFSH. Focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Project coordinator interview	6–8 months after SFSH	7	7	Semi-structured interview focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Student survey 3	12 months after SFSH	3,000	2,000	Follow-up 2 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	12 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 3	12 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Facilitator survey (NGOs)	Before and after SFSH	NA	NA	Electronic questionnaire distributed to the practice partners in relation to different intervention activities, i.e. student and staff workshops and courses.

SFSH: Smoke-free school hours.

Step 4: Data analysis

Process evaluation

Implementation levels are assessed using confirmatory factor analysis.[74] Inspired by Bast et al.,[29] data are used to develop indexes of low and high implementation degree, while associations between the outputs and the overall SFSH implementation fidelity model are analysed using regression analysis. This allows us to investigate to what extent the intervention activities predict the implementation degree of SFSH. Mechanisms of change are explored by combining qualitative and quantitative data and by using the generative mechanisms proposed by normalisation process theory (coherence, cognitive participation, collective action, and reflexive monitoring) to structure the analysis. Qualitative data will be coded using an abductive approach, whereas quantitative data will be analysed using descriptive techniques to further explain, supplement, or challenge the qualitative analyses of what enables or hinders SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation uses multi-level linear or logistic regression, depending on the outcome measures.[75] The primary analysis will be a two-level model, with students (level 1) nested in schools

(level 2). In secondary analysis, we will investigate effects according to pre-defined subgroups, such as sex, age, and SES. To further elaborate on CMO configurations, we will test the associations between quantitative measures of implementation degree and implementation processes from the process evaluation, using descriptive analysis, logistic regression, and/or factor analysis.[76,77]

Step 5: Synthesis

Empirical and theoretical knowledge about the implementation and outcomes of the intervention will be synthesised into recommendations on how to implement SFSH. RE advocates using retroduction and abduction in iterative processes to test and refine IPT.[37,73,78] Retroduction is a form of inference that seeks to identify and verify the mechanisms theorised to have generated the phenomena under study,[73,78] whereas abduction is the process of describing empirical data using theoretical concepts,[73] with emphasis on analysing data that fall outside an initial theoretical frame or premise.[78,79] Regarding the Smoke-Free Vocational Schools intervention project, our goal is to integrate qualitative and quantitative findings from the process and outcomes evaluations to re-analyse the IPT in terms of what works, for whom, and under what circumstances, using a retroductive-abductive approach. Based on the refined programme theory, we will be able to develop model recommendations for implementing SFSH in vocational schools and similar settings.

Patient and Public Involvement

This study protocol describes a health promotion intervention and no patients have been involved. Public involvement, defined as collaboration with public health partners with knowledge on the VET school setting, has been extensive. The partnering NGO organizations and research institution have worked closely together and collaborated and agreed on the design of the intervention and evaluation. The NGO partners have been involved in the development of the research questions and on choosing the outcome measures and are co-authoring this study protocol. The NGO partners recruited the VET schools and supported the schools in the implementation of SFSH. The evaluation results will be disseminated to NGO partners, VET schools and students through SoMe news and a short 2-page publication in layman language.

ETHICS AND DISSEMINATION

In public health interventions it is important to examine and clarify possible negative reverse effects, so as to avoid further interventions generating the same negative effects.[80] Therefore, unexpected consequences of the intervention will be explored and reported to minimise and avoid participants feeling stigmatised in this study and similar future studies.

The study has been reported to the Capital Region of Denmark's legal centre for personal data handling (journal number: VD-2018-485). Informed consent will be obtained from all study participants according to the General Data Protection Regulation and Danish data protection law. The study adheres to the ethics procedures in Denmark. Study findings will be disseminated at international and national conferences and further published in open-access peer-reviewed journals. Also, the study findings will be used by the practice partners in their further work supporting schools implementing SFSH, as well as by other stakeholders (e.g. schools).

Declarations

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Authors contributions

The authors contributions to different aspects of this work were as follows: Conceiving and designing the study: AVH, TBC, MS, KHR and CDK; Refining the study design and obtaining ethical approval: AVH, CP, TTT, CDK; Writing and revising this manuscript (fully or in part): AVH, TBC, MS, KHR, CP, TTT, CDK.

Patient and public partnership

The research and intervention project is a collaboration between research and practice: Two Danish public health NGOs (the Danish Heart Foundation and the Danish Cancer Society) are practice partners, whereas Steno Diabetes Center Copenhagen is research partner. The intervention has been cocreated through a participatory process, with an emphasis on including both evidence and practice experience. Further, the practice partners involved in the design and conduct of the study, the choice of outcome measures and recruitment to the study.

Competing interests

The authors declare that they have no competing interests.

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Figure Legends

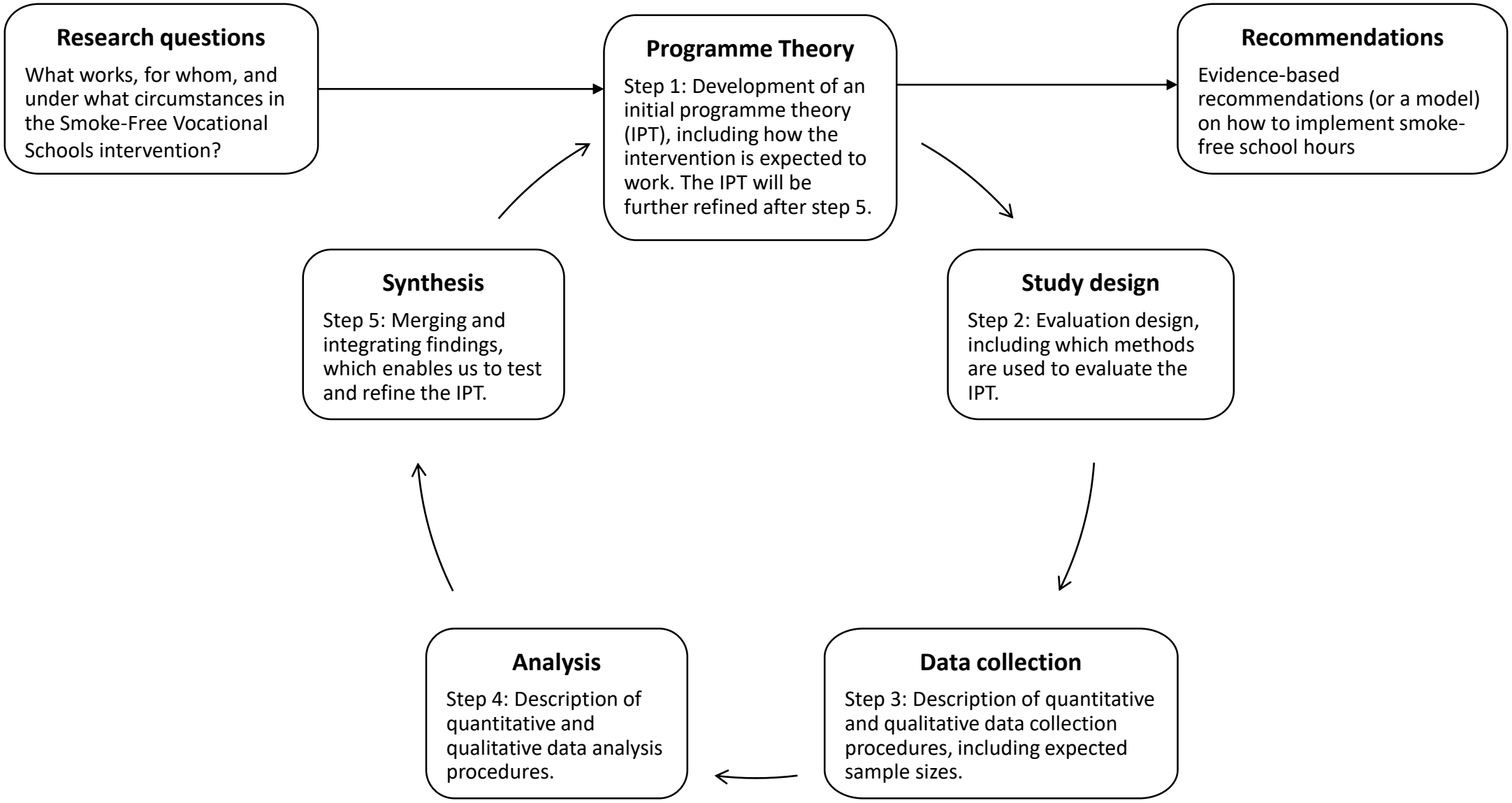
Figure 1 Realist research cycle of the Smoke-Free Vocational Schools intervention project.

Figure 2 Graphic representation of the initial programme theory of the Smoke-Free Vocational Schools intervention. SFSH: Smoke-free school hours. The intervention activities delivered by practice partners are shown in purple. The activities or processes managed by schools but facilitated by practice partners are shown in green.

Figure 3 Process evaluation of the Smoke-Free Vocational Schools intervention, based on the Medical Research Councils guidelines for process evaluation of complex interventions.

Figure 4 Timeline and outcomes evaluation for the Smoke-Free Vocational Schools intervention.

Figure 1 Realist research cycle of the Smoke-Free Vocational Schools intervention project.



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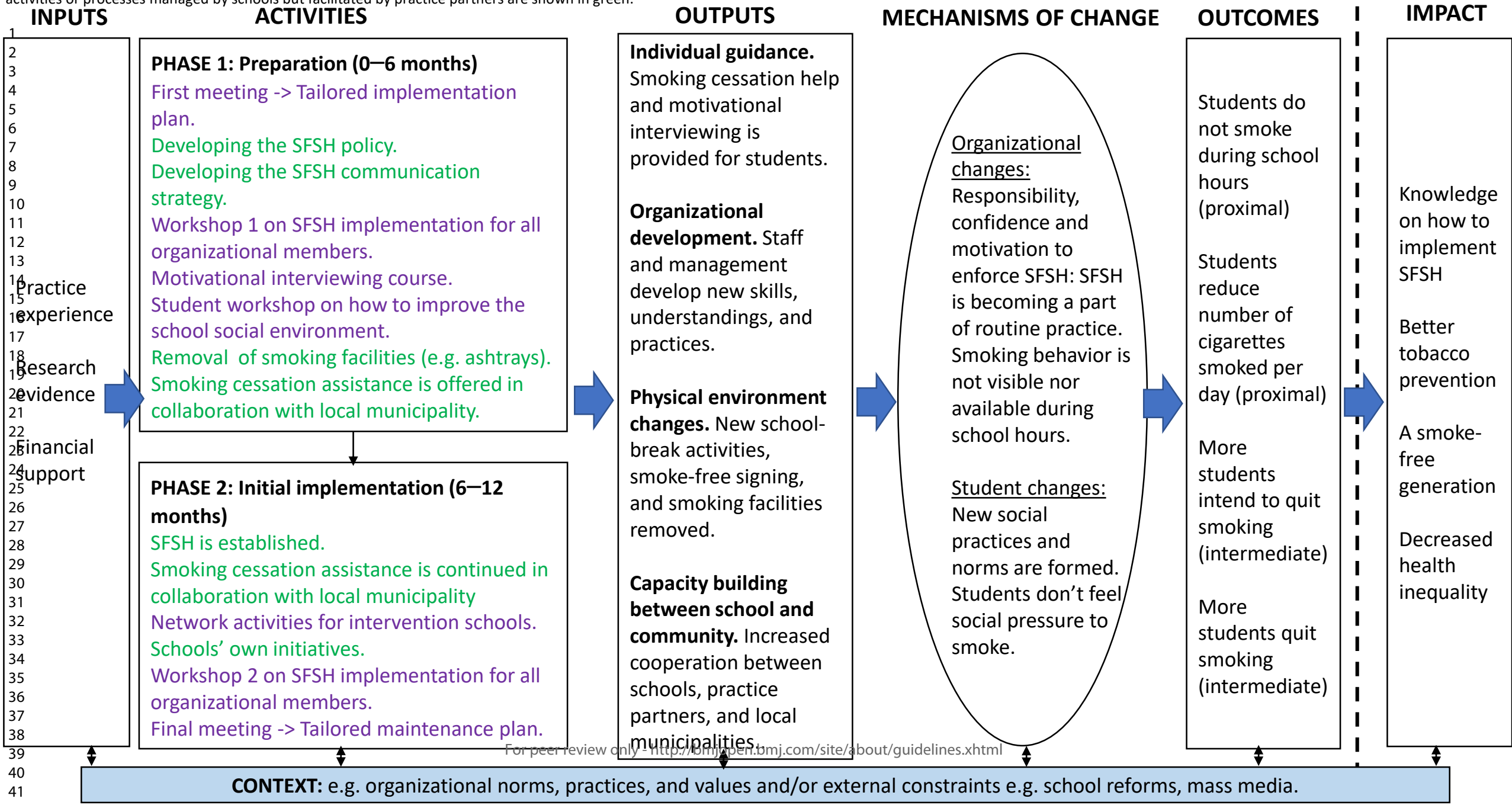

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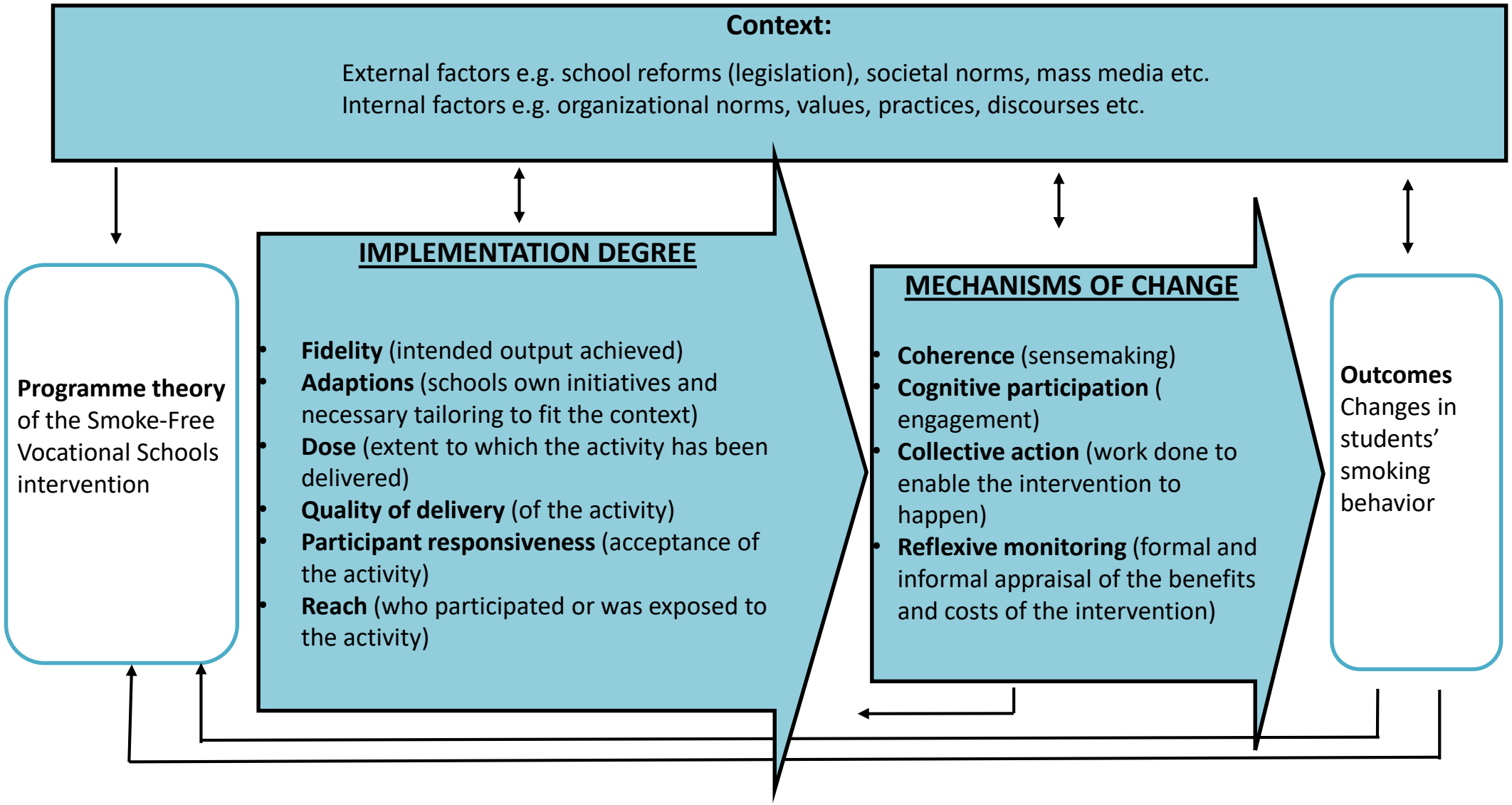
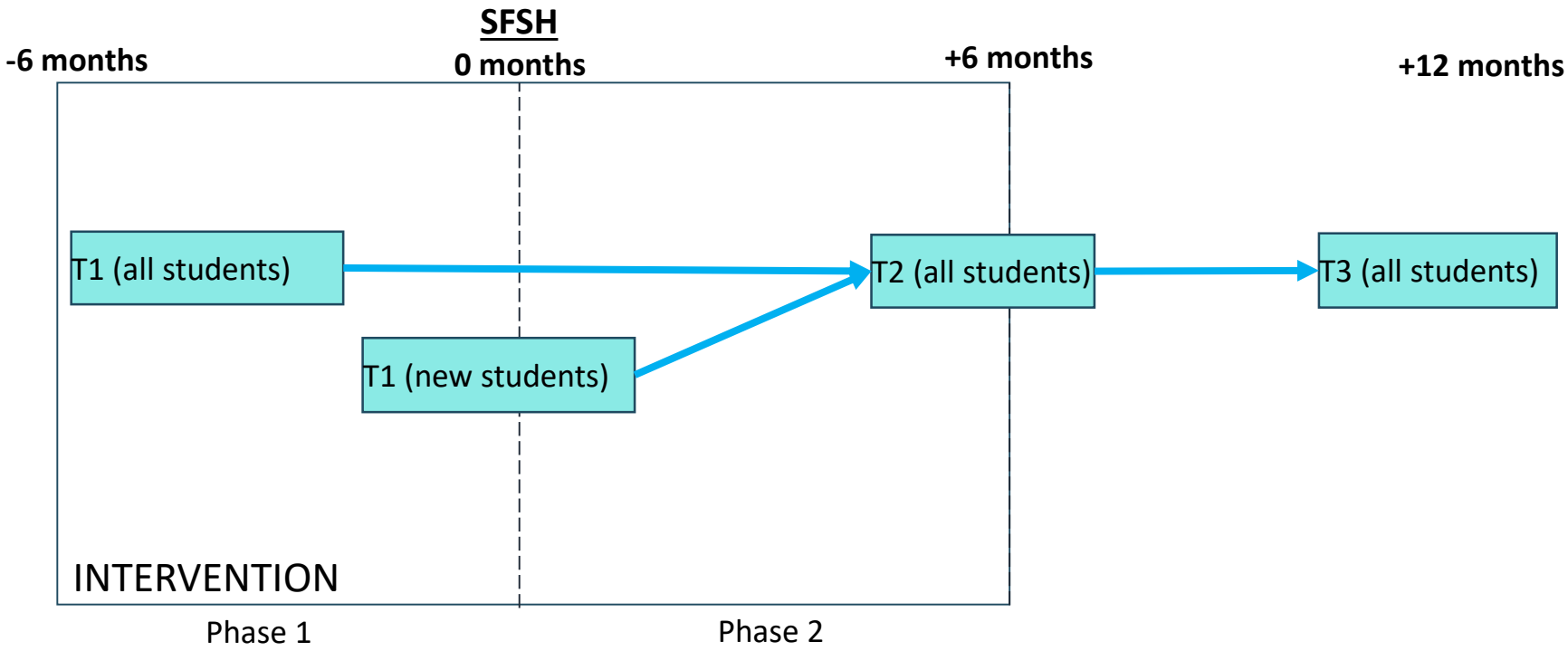


Figure 4 Timeline and outcomes evaluation for the Smoke-Free Vocational Schools intervention.



Supplementary File 1: Operationalization of data collection in the process evaluation (implementation degree and mechanisms of change) and the outcomes evaluation

	Concept	Operationalization	Data collection
Implementation degree			
Organizational development	Fidelity	If the workshops and course has resulted in a shared smoke-free school hours understanding and new skills to support students dealing with not smoking during school hours	Staff survey 1; Staff survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2: Facilitator questionnaire (NGOs)
	Dose	Extent to which new learnings from workshops and skills from course are being used at school	Staff survey 1; Staff survey 2
	Quality of delivery	Organization of new learnings and skills at school	Staff survey 1; Staff survey 2
	Participant responsiveness	Attitudes towards workshops and course	Staff survey 1; Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Staff survey 1; Staff survey 2
Physical environment changes	Fidelity	If new school-break activities and smoke-free-signing has been established, and smoking facilities removed	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; structured observations on school grounds; Project coordinator interviews
	Dose	Extent to which school-break activities and smoke-free signing is known to students	Student survey 2
	Quality of delivery	Extent to which new school-break activities are being used by students and smoke-free signing has a prominent position	Student survey 2; structured observations on school grounds
	Participant responsiveness	Attitudes towards workshops new school-break activities and smoke-free-signing	Student survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Individual guidance	Fidelity	If the school offers smoking cessation help or other help for students to cope with smoke-free school hours	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 1; Project coordinator survey 2; Project coordinator interview
	Dose	Number of smoking cessation courses delivered and number of students attending the courses	Project coordinator survey 1; Project coordinator survey 2
	Quality of delivery	Extent to which students know which support to cope with smoke-free school hours is provided	Student survey 2
	Participant responsiveness	Attitudes towards help to cope with smoke-free school hours and attitudes towards attending smoking cessation courses	Student survey 2

	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Capacity building between the school and community	Fidelity	If the relationship between school and NGOs, and school and municipality has been strengthened	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; Project coordinator interview
	Dose	Extent to which the school has discussed smoke-free school hours implementation with NGOs and local municipality	Project coordinator survey 2
	Quality of delivery	Extent to which the schools has experienced support from the NGOs and local municipality	Project coordinator survey 2
	Participant responsiveness	Attitudes towards integrating external resources in smoke-free school hours implementation	Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Facilitator questionnaire (NGOs)
Smoke-free school hours implementation	Fidelity	If smoking is allowed during school hours and extent to which students experience smoking during school-hours	Staff survey 2; Staff survey 3; Student survey 2
	Adaptions	Context-specific adjustments in sanctioning and enforcement procedures and practice	Staff survey 2; Staff survey 3; Project coordinator interview
	Dose	Extent to which students know the policy and extent of smoking visibility	Student survey 2, Staff survey 2; Staff survey 3; Structured observations on school grounds
	Quality of delivery	Frequency and manner/method of enforcement	Staff survey 2; Staff survey 3
	Participant responsiveness	Attitudes towards the policy and whether staff experience the policy as a normal part of their work	Student survey 2; Staff survey 2; Staff survey 3
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2; Staff survey 2; Staff survey 3
Mechanisms of change			
Interactions between the intervention and context-mechanisms i.e. reasoning and behavior among participants, constrained by e.g. organizational norms, values and discourses	Coherence	If and why smoke-free school hours makes sense given the situation the school currently face. Extant to which there's a shared understanding about the policy and the organizational members see the potential value of smoke-free school hours.	Management interview; Project coordinator interview; Teacher focus groups; Staff survey 2; Staff survey 3
	Cognitive participation	If and how there's been established a community of practice around smoke-free school hours, if there's key people driving the implementation forward or the contrary and who. If it is seen as a legitimate part of the schoolwork and if there's been established new practices. Extent to which the organizational members are open to change their daily routines to work with smoke-free school hours.	
	Collective action	If and how smoke-free school hours in enacted as part of routine practice including management practices e.g. how is the work organized and which resources are in place to support the implementation. To what extent the work can be integrated into the everyday school practices and whether people involved has sufficient skills and confidence in work with smoke-free school hours.	
	Reflexive monitoring	If and how smoke-free school hours affect the everyday school life. Formel and informal appraisal procedures and reconfiguration.	

Sub-study 3: Outcomes			
Baseline	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 1
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 1	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 2
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 2	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 3
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	

BMJ Open

Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol

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Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol

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ABSTRACT

Introduction: Smoke-free school hours (SFSH) entails a smoking ban during school hours and might be an effective intervention to reduce the high smoking prevalence in vocational schools. For SFSH to be effective, the policy must be adequately implemented and enforced; this challenge for schools constitutes a research gap. The 'Smoke-Free Vocational Schools' research and intervention project has been developed to facilitate schools' implementation of SFSH. It is scheduled to run from 2018–2022, with SFSH being implemented in 11 Danish vocational schools. This study protocol describes the intervention project and evaluation design research and intervention project.

Methods and analysis: The intervention project aims to develop an evidence-based model for implementing SFSH in vocational schools and similar settings. The project is developed in a collaboration between research and practice. Two public health NGOs are responsible for delivering the intervention activities in schools, while the research partner evaluates what works, for whom, and under what circumstances. The intervention lasts one year per school, targeting different socioecological levels. During the first six months, activities are delivered to stimulate organisational readiness to implement SFSH. Then, SFSH is established, and during the next six months, activities are delivered to stimulate implementation of SFSH into routine practice. The epistemological foundation is realistic evaluation. The evaluation focuses on both implementation and outcomes. Process evaluation will determine the level of implementation and explore what hinders or enables SFSH becoming part of routine practice using qualitative and quantitative methods. Outcomes evaluation will quantitively assess the intervention's effectiveness, with the primary outcome measure being changes in smoking during school-hours.

Ethics and dissemination: Informed consent will be obtained from study participants according to the GDPR and Danish data protection law. The study adheres to Danish ethics procedures. Study findings will be disseminated at conferences and further published in open-access peer-reviewed journals.

Strengths and limitations:

- The study draws on realistic evaluation and aims to answer both research and practice needs by generating new application-oriented knowledge on how to implement smoke-free school hours in vocational schools and similar settings.
- The study includes both implementation/process evaluation and outcomes evaluation in a unified multi-methods study design.
- The intervention has been developed in a joint venture between research and practice that emphasises including practice-based experience and research evidence, which may generate high external validity and more sustainable implementation practices.
- It is a limitation to the internal validity, that the study seeks to assess outcomes without the use of control schools. However, the practice is considered appropriate in realistic evaluation.
- The study seeks to integrate both qualitative and quantitative methods, which is a methodological challenge, as the methods represent different epistemological paradigms.

INTRODUCTION

From August 2021, a school tobacco policy (STP) of smoke-free school hours (SFSH) is expected to be ratified in all Danish educational institutions with at least one student aged under 18. The policy basically stipulates a smoking ban for students during school hours – both inside and outside school grounds. An expanded definition of SFSH also bans smoking by school staff, managers and visitors (smoke-free work hours). Additionally, SFSH might include all tobacco-related products (e.g. cigarettes, vapers, and snuff). SFSH is an expansion of traditional STPs, which do not prohibit smoking outside school grounds.[1] The rationale is the same: restricting smoking behaviour as a means to prevent exposure to second-hand smoke, smoking initiation, and smoking continuation among adolescents and young adults.[2,3] Restricting smoking behaviour can further be linked to political denormalization strategies aiming to make the future smoke-free: a tobacco endgame.[4] Evidence about SFSH is sparse, but some researchers[5] suggest that it might be more effective than traditional STPs, which have been shown to relocate smoking to just outside school premises (e.g. at the school entrance), and therefore do not remove smoking visibility.[5,6] Additionally, traditional STPs can have adverse effects on students with lower socioeconomic status (SES), (lower odds of anti-smoking social believes)[7], which suggest that SFSH might be a more appropriate strategy in schools with low SES groups, such as vocational schools.

In Denmark, vocational education and training (VET) is a short, practical upper-secondary education for a specific service or industry, such as hairdresser, carpenter, office assistant, or chef. It is characterised by a combination of traditional in-school education and out-of-school apprenticeship in the future workplace. Danish vocational students have low SES backgrounds[8] and are overrepresented in smoking behaviour: 29% smoke daily, compared to 9% in general upper-secondary education.[9,10] The average vocational student age is 24, but as 14% of these students are aged 15–17,[11] the SFSH law will apply to Danish vocational schools. As such, the law has considerable health-promoting potential: it may not only reduce smoking within a vulnerable population group setting (vocational schools) but also contribute towards decreasing health inequality.[12] However, policies which are not well-implemented will not improve health.[13–16] We conceptualise the implementation of SFSH as a school organisational process with the end-goal of incorporating the policy into routine practice.[17] Staff and managers must enact and enforce the policy as part of their professional duties, and students must experience the policy as an accepted part of their everyday school life. Hence, enforcement is a significant task of organisational

implementation.[16,18–20] Despite legislation imposing STPs in many secondary schools across Europe, they are often poorly implemented and enforced.[21–24]

Three reviews have systematised decades of evidence related to STP implementation. The 2014 systematic review by Galanti et al.[15] identified implementation components that improve STPs' impact on student smoking behaviour (e.g. strict and consistent enforcement). However, the authors also showed that most studies do not measure implementation fidelity and that enforcement is inconsistently operationalised across studies.[15] Two realist reviews,[5,16] as part of the SILNE-R project (2015–2018),[25] yield prominent new insights into the functioning of STPs. The first shows how STPs' implementation and comprehensiveness affects students' beliefs and behaviour: for example, if smoking is not visible during school hours, students feel less pressure to conform to others' smoking behaviour.[5] The second shows that staff enforcement depends on whether they 1) believe that STP enforcement is their role and duty, 2) have confidence to deal with students' negative responses when enforcing the rules, and 3) experience enforcement having a positive impact on students.[16] Other recent studies[26–28] have explored which practices facilitate or hinder adopting SFSH; one key finding is that schools should develop a shared understanding about the policy being part of their jurisdiction prior to implementation).[26–28] Seen together, the studies point towards important elements for schools to consider when implementing SFSH, but do not provide knowledge about what activities and processes can stimulate better implementation. In other words, most studies focus on understanding existing STPs rather than generating new knowledge about how to facilitate implementation. The latter might only be possible using interventionist study designs. One intervention study provides an important measure of STP implementation fidelity.[29] To the best of our knowledge, however, no intervention studies have examined how to stimulate or measure the process of implementing SFSH into routine practice. As such, it remains unclear how to best support, stimulate, and measure the implementation of SFSH.

To address the identified research gap, we developed the 'Smoke-Free Vocational Schools' intervention project, which aims to facilitate implementing SFSH in vocational schools and to generate new knowledge about the implementation and effectiveness of SFSH. The intervention takes place in 11 Danish vocational schools from 2018–2022.

Realistic evaluation

Realistic evaluation (RE) is the epistemological foundation of the evaluation. Pawson and Tilley developed the RE approach, arguing that to generate application-oriented knowledge for policy and

practice, it is more useful to address 'what works, for whom and under what circumstances', rather than evaluating whether an intervention 'works'.[30] According to RE, interventions might generate different outcomes (O) in different contexts (C) by triggering underlying changes in reasoning and behaviour among participants – conceptualised as mechanisms (M).[31] As such, interventions may 'work' by enabling participants to make different choices, but the choices are always constrained by a context, such as the organisational norms, values, and discourses that operate in school settings. 'Complex intervention' is used to describe innovations within highly complex and emergent social systems,[32] such as schools.[33–34] It can be understood in relation to the RE notion of 'open systems', defined by Pawson and Tilley[30] as '[T]he acknowledgement that programs are implemented in a changing and permeable social world, and that program effectiveness may thus be subverted or enhanced through the unanticipated intrusion of new contexts' (p. 218). Hence, the overall RE methodology is to examine C + M = O relations in complex interventions, known as CMO configurations.[30]

Study aim

In reporting complex interventions, the intervention and evaluation design must be clearly described to enable replication and synthesis of evidence,[35,36] yet many RE studies inadequately report their methodological practices.[37–39] Therefore, the aim of this study protocol is two-fold: 1) to describe the Smoke-Free Vocational Schools intervention, and 2) to present how the intervention is evaluated, including the study design, specific methods, and theoretical assumptions.

METHODS AND ANALYSIS

The overall objective of the Smoke-Free Vocational Schools intervention project is to develop an evidence-based model for implementing SFSH in Danish vocational schools and comparable settings. To accomplish the objective, the study examines what works, for whom, and under what circumstances. RE starts with the development of an initial programme theory (IPT).[39] Programme theory is theory incarnate, explicitly explaining which context-mechanisms should be triggered among different actors to produce desired outcomes.[40,41] In relation to the Smoke-Free Vocational Schools intervention, the IPT represents a hypothesis on how and why to implement SFSH and the study design is developed to test the hypothesis. We have structured this study protocol following the steps of the realist research cycle,[39,42] as shown in figure 1. The content was further informed by the SPIRIT (Standard Protocol Items for Randomized Trials) statement.

>> Insert Figure 1 here <<

Step 1: Programme theory

The intervention project is a collaboration between research and practice. Two Danish public health NGOs – the Danish Heart Foundation and the Danish Cancer Society – are practice partners, while Steno Diabetes Centre Copenhagen is the research partner. The practice partners are responsible for delivering the intervention activities in schools; the research partner is responsible for conducting a formative evaluation of the implementation processes and outcomes. The research and practice partners together developed the IPT, and it is part of our method to continually discuss and apply preliminary research findings as part of the formative evaluation. As such, we follow the proposal of RE[37] by iteratively testing and developing the programme theory in parallel to new empirical learnings.

The IPT was developed through a workshop where research and practice worked collaboratively. The practice partners contributed their extensive first-hand experience of implementing tobacco preventive efforts in different school contexts: for example, the Danish Cancer Society has tailored a motivational interviewing course to support smoking cessation by upper-secondary school students. The translation of practice-based experience and ideas into the intervention might increase the sustainability of implementation practices and improve external validity.[43] The research partner contributed with evidence on effective tobacco preventive methods in vocational schools, based on recent research and the results from a qualitative study on facilitators and barriers for implementing SFSH.[28] At the workshop, we developed a graphic representation of the intervention,[44] including the short- and long-term outputs, outcomes, and impact expected of different intervention activities targeting actors within and outside the school. The workshop process also served as a learning and management tool, as the research and practice partners developed a shared understanding on how the intervention is expected to produce change, which is crucial in public health interventions.[45]

The Smoke-Free Vocational Schools intervention

The intervention is delivered in two phases, each lasting approximately six months (as shown in figure 2). During phase 1, activities are delivered to stimulate organisational readiness[46] to implement SFSH: these include preparing staff and managers for their new professional tasks, and establishing new school-break facilities for students as alternatives to social smoking. At the beginning of phase 2, SFSH is established. During phase 2, activities are delivered to stimulate the gradual implementation of SFSH into routine practice by supporting schools in addressing emergent challenges, such as nicotine dependence or enforcement. Table 1 describes all the intervention activities.

>> Insert Figure 2 here <<

The activities are expected to produce short-term outputs, which are operationalised in four sets according to ecological levels[47]: 1) individual guidance, e.g. smoking cessation assistance for students (individual); 2) organisational development, e.g. development of professional skills and confidence to enforce SFSH (interpersonal); 3) physical environment changes, e.g. new school-break activities (structural/organisational); and 4) capacity building between school and community, e.g. increased cooperation between the school and the local municipality (community).

Table 1 Description of intervention activities in the Smoke-Free Vocational Schools intervention.

Activity	Description	Purpose	Participants
		Phase 1	
First meeting	An initial meeting between the schools and practice partners, where the SFSH implementation plan is discussed.	To ensure that the schools have a clear implementation plan and know how the intervention activities can support them. To clarify role distributions between different stakeholders.	Practice partners. School principal and other management representatives. School project coordinator. Local municipality representative.
Developing the SFSH policy	The schools develop their SFSH policy, including rules and responsibilities for sanctioning and enforcement. The practice partners provide inspirational material, e.g. other schools' policies.	To ensure the schools develop a clear SFSH policy, which aligns with the schools' rules of conduct.	Decided locally in schools. Practice partners recommend that schools establish a working group including both management and staff representatives.
Developing the SFSH communication strategy	The schools develop their internal and external SFSH communication strategy. The practice partners provide inspirational material and financial support to smoke-free signing.	To ensure that all organisational members (e.g. students and staff) and relevant external stakeholders (e.g. neighbours and apprenticeship workplaces) know what SFSH entails.	Decided locally in schools.
Workshop 1 on SFSH implementation	A joint meeting at the schools for all school staff and managers, facilitated by the practice partners.	To stimulate a joint vision and understanding of why the school is implementing SFSH. To ensure that all organisational members feel confident to enforce SFSH. To address school-specific challenges and issues, e.g. resistance.	Practice partners. All school staff and managers. Local municipality representative.
Motivational interviewing course	A selected group of school staff and managers attend a two-day course delivered by the practice partners.	To provide new knowledge and skills for the selected staff and managers, who are supposed to become key drivers of the implementation in school. To help nicotine-addicted students to cope with not smoking during school hours.	Practice partners. Selected school staff and managers including the school project coordinator. Local municipality representative.
Smoking cessation assistance	Offered to students and staff in collaboration with the local municipality. The type of assistance varies between municipalities, depending on local resources and availabilities.	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.

Student workshop	A participatory student workshop on how to improve the social environment, delivered in schools by the practice partners. The schools are given financial support (averaging 15,000 € per school) to establish some of the best school-break activities.	To create alternatives to smoking communities at school. To ensure that the new school-break activities are relevant for the students.	Practice partners. Selected group of students. Local municipality representative. The school management and school project coordinator approve the new school-break activities.
Removal of smoking facilities	The schools remove smoking facilities, e.g. ashtrays.	To signal that the school is smoke-free.	Decided locally in schools.
Phase 2			
The school tobacco policy of SFSH	The SFSH policy is established in schools. The schools must enact and enforce the policy.	To prevent exposure to second-hand smoke. To prevent smoking initiation and continuation.	Decided locally in schools. Practice partners recommend that all school staff and managers play a role in enforcement.
Continued smoking cessation assistance	Smoking cessation assistance is offered to students and staff in collaboration with the local municipality. The type of smoking cessation assistance varies between municipalities, depending on local resources and availabilities.	To help motivated staff and students quit smoking.	Students and staff. Local municipality representative.
Network activities for intervention schools	A network for intervention schools is established by the practice partners. Two larger network activities for all schools are delivered during 2018–2020.	To facilitate schools exchanging experiences of implementing SFSH and learning from one another.	School principal and school project coordinator are invited. Participation in network activities will be decided locally in schools.
Schools' own initiatives	Supportive actions which ease the implementation of SFSH.	Decided locally by schools.	Decided locally by schools.
Workshop 2	A joint meeting at the schools for all staff and managers, facilitated by the practice partners.	To address school-specific challenges in relation to implementing SFSH.	Practice partners. All school staff and managers. Local municipality representative.
Final meeting	A final meeting between the schools and practice partners to discuss the SFSH maintenance plan.	To ensure the schools have a clear maintenance plan and know how the municipality and practice partners can support them after the intervention period.	Practice partners. School principal. School project coordinator. Local municipality representative.

SFSH: Smoke-free school hours.

The activities and outputs are together expected to produce 'mechanisms of change', which are the underlying changes in reasoning and behaviour among participants, triggered by the intervention and the intervention context. We expect that the central context-mechanisms allowing SFSH to become part of routine practice will be found at the organisational level, where school staff and managers take responsibility for SFSH, feel confident to enforce SFSH, and feel motivated by positive student responses.[16] At the student level, we expect context-mechanisms to be triggered by: 1) staff and managers enforcing SFSH, resulting in decreased smoking visibility and, in turn, students becoming less prone to conform to others' smoking behaviour;[5] and 2) the new school-break activities resulting

in new practices and social norms at school.[48] As such, we expect SFSH to become a natural and accepted part of students' everyday school life.

The mechanisms of change are expected to result in outcomes related to students' smoking behaviour. Our primary outcome measure is 'changes in smoking during school hours', while the secondary outcome measure is 'changes in the number of cigarettes smoked per day'; both are proximal outcomes. The intermediate outcome measures are 'changes in intention to quit' and 'changes in smoking status'. The long-term impact of the intervention will not be evaluated as part of this study.

Step 2: Study design

The study is designed to test the IPT through focusing on both implementation/process evaluation and outcomes evaluation. As considered most appropriate in RE,[30,37] we use a multi-methods design, which allows us to quantify some elements of CMO configurations (e.g. changes in smoking behaviour) and qualitatively explore the change mechanisms and context.[49] The process evaluation investigates to what extent the intervention activities have been delivered and are implemented according to the programme theory, and seeks to explore the mechanisms that hinder or enable SFSH becoming part of routine practice. The outcomes evaluation assesses the intervention's outcomes in terms of students' smoking behaviour, using a one-group pretest-posttest study design, with sub-group analysis further determining for whom the intervention is most effective.

The intervention is delivered at 11 schools during 2018–2020, seven of which are included in the evaluation. The remaining four are considered 'pilot schools', where the intervention activities and evaluation methods (e.g. questionnaires) are tested and adjusted. The practice partners recruited schools that wanted to implement the expanded version of SFSH, banning all tobacco-related products (e.g. cigarettes, vapers, and snuff) during school and work hours for students, staff, and visitors. The sample of seven vocational schools accounts for 10% of all Danish vocational schools; represents all four main educational areas (Technical, Business, Agriculture and food services, and Social and health services); and covers three (out of five) geographical regions. As such, the study sample includes a broad variety of vocational school contexts across the country and is, thus, considered representative of all Danish vocational schools.

Process evaluation

The process evaluation comprises two mutually informing parts based on the RE-compatible[50] Medical Research Councils guidelines for Process Evaluation of Complex Interventions.[35] Our operationalisation of the framework in the study is shown in figure 3.

>> Insert Figure 3 here <<

The 'Implementation degree' study quantitively measures implementation levels for each of the four sets of outputs and for the SFSH policy based on fidelity, adaptions, dose, quality of delivery, participant responsiveness, and reach. Hence, the study seeks to occupy a middle position in the fidelity vs. adaptions debate[50] with an emphasis on measuring both central intervention implementation (e.g. extent of enforcement) and the schools' contextual initiatives and tailoring (e.g. means and methods of enforcement). The 'Mechanisms of change' study explores the implementation processes using both qualitative and quantitative methods. Normalisation process theory[17] proposes that implementation processes are shaped and motivated by four generative mechanisms – coherence, cognitive participation, collective action, and reflexive monitoring. This will be the guiding theory in the investigation of processes that hinder or enable SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation assesses the effectiveness of the intervention in terms of the primary and secondary outcomes, measured before SFSH (Time 1, T1), six months after the establishment of SFSH (Tine 2, T2), and twelve months after the establishment of SFSH (Time 3, T3), as shown in figure 4. The primary outcome measure is changes in 1) smoking during school hours (dichotomous variable (yes/no)); the secondary outcome measures are changes in 2a) the number of cigarettes smoked per day (continuous variable), 2b) intention to quit (nominal variable), and 2c) smoking status (nominal variable). Further, to elaborate on CMO configurations, sub-group analyses are performed to investigate for whom the intervention is most effective and to explore relations between findings from the process evaluation, that is, the SFSH implementation fidelity measure and quantitative indicators of implementation processes. The study thus seeks to elaborate on outcomes across the programme but also considers outcomes for different subgroups within the population without using control schools, which is considered appropriate for RE.[37,51,52]

>> Insert Figure 4 here <<

Step 3: Data collection

The evaluation lasts approximately 1.5 years per school and covers intervention phase 1 (six months) and intervention phase 2 (six months), with the final follow-up conducted six months after the

intervention has ended. During this time period, qualitative and quantitative data will be collected from students, staff, and managers to increase the validity of findings.[53] Table 2 presents an overview of all data collection measures and procedures, including estimates of eligible participants and expected response rates. The different data collection measures provide cross-cutting insights for the process and outcomes evaluations. A preliminary operationalisation of how the data contribute to each is presented in Supplementary File 1.

Student surveys

Electronic student surveys are conducted during school hours at three different time points. Students self-report smoking behaviour[54] and intention to quit,[55] smoking-related rules and practices and social norms at school,[56–61] self-efficacy,[62–64], well-being,[65,66] educational information, and demographics. Validated questions have been used when possible and the questionnaire has been pilot-tested in two vocational school classes (n=30 participants) to ensure face validity.[67] Due to the VET school structure, combining in-school education and apprenticeships, individual follow-up is rarely possible. Instead, both paired data from the same individuals and cross-sectional data will be collected. To maximise response rates, data collection is organised by the research partners in each school and conducted during school hours. The students are given time to complete the questionnaire and ask questions. The survey takes approximately 30 minutes per school class. Based on experience with the procedure,[9] we expect that 95% of students will participate in the study.

Sample size calculation

The outcome measure used to determine sample size is change in the number of cigarettes smoked during school hours per day, per student, based on individual follow-up data. We assume that 30% are daily smokers who averagely smoke 18 cigarettes per day, including 8 during school hours.[68] We assume that the intervention will reduce smoking intensity during school hours by 50%, meaning a reduction of 4 cigarettes smoked per school day (with a standard deviation of 4 and 3 and correlation = 0.3). To avoid type-I errors and type-II errors, we respectively chose a 5% significance level and power at 80%. Assuming that the data are normally distributed, we will need to conduct individual follow-up on 11 daily smokers per school. We expect a 30% reduction in participants from baseline to follow-up. Accounting for this, the sample size must include 14.3 daily smokers per school. Thus, if the smoking prevalence is 30%, 24.4 students per school must participate in the prospective study. As seven schools are participating, the sample size for the prospective study must include (at least) 171 students.

Staff and project coordinator surveys

Staff and project coordinator surveys are electronically distributed to all school organisational members – i.e. managers, teaching staff, counsellors, administrative and kitchen staff, etc. – at three different time points to follow the gradual implementation of SFSH. It is important to include all organisational members as all are expected to be affected by SFSH. The surveys include questions to investigate the implementation degree (e.g. fidelity, dose) and the validated NoMAD scale[69,70] to grasp the implementation processes. The project coordinator surveys include additional questions about the implementation work (e.g. collaboration with the NGO partners, local municipality and contextual tailoring). The surveys have been pilot-tested among staff, managers, and project coordinators at the four pilot schools (n=23 participants) to ensure face validity.[67] Surveys distributed to NGOs partners both before and after SFSH explore their role in facilitating meetings.

Structured observations

Structured observations on school grounds are carried out by the researchers at the same time points as the student surveys. Inspired by other studies,[71,72] the structured observations will include observations on smoking visibility (e.g. who, where, and how many smokers are visible during school hours) and physical environment changes (e.g. smoke-free signing and removal of smoking facilities). Data will be registered as field notes.

Interviews and focus groups with principal manager, project coordinator, and teachers

Semi-structured individual interviews and focus groups with school principals, project coordinators, and teachers are carried out to explore the implementation processes in terms of intervention modalities, change mechanisms, and context features.[73] It is important to gather interview material from the different respondent groups as they provide different perspectives, challenges, and opportunities in relation to implementing SFSH. Specifically, school principals have decision-making power on SFSH and knowledge about school strategic-political processes; project coordinators have in-depth knowledge and experience of all actions for implementing SFSH; and teachers have direct contact with students and are expected to play a large role in enforcing SFSH. During interviews the role of the NGO partners is also explored.

Table 2 Overview of data in the Smoke-Free Vocational Schools intervention project, including eligible participants (n), expected response rates (n), and data collection procedures.

Data collection	When	N (eligible)	N (expected)	Procedure
Student survey 1	Before SFSH	3,000	2,000	Baseline measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).

Structured observations on school grounds	Before SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 1	Before SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about SFSH preparation (email).
Project coordinator survey 1	Before SFSH	7	7	In-depth electronic questionnaire concerning SFSH preparation (email).
Principal manager interview	Before SFSH	7	7	Semi-structured interview focusing on SFSH preparation, including motivation and past experiences (in school or via Skype).
Student survey 2	6 months after SFSH	3,000	2,000	Follow-up 1 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	6 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 2	6 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Project coordinator survey 2	6 months after SFSH	7	7	In-depth electronic questionnaire about the gradual SFSH implementation (email).
Staff focus group	6–8 months after SFSH	21–42	21–42	Focus groups with teaching staff, counsellors, and/or others assigned a special role in relation to SFSH. Focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Project coordinator interview	6–8 months after SFSH	7	7	Semi-structured interview focusing on daily practice, reasoning, and how/if the intervention has supported the gradual SFSH implementation (in school or via Skype).
Student survey 3	12 months after SFSH	3,000	2,000	Follow-up 2 measure focusing on smoking behaviour, etc. Electronic questionnaire distributed by the research team (in school).
Structured observations on school grounds	12 months after SFSH	NA	NA	Structured observations focusing on smoke-free signing, smoking facilities, and smoking visibility (in school).
Staff survey 3	12 months after SFSH	1,200	600	Electronic questionnaire distributed to all staff and managers about the gradual SFSH implementation (email).
Facilitator survey (NGOs)	Before and after SFSH	NA	NA	Electronic questionnaire distributed to the practice partners in relation to different intervention activities, i.e. student and staff workshops and courses.

SFSH: Smoke-free school hours.

Step 4: Data analysis

Process evaluation

Implementation levels are assessed using confirmatory factor analysis.[74] Inspired by Bast et al.,[29] data are used to develop indexes of low and high implementation degree, while associations between the outputs and the overall SFSH implementation fidelity model are analysed using regression analysis. This allows us to investigate to what extent the intervention activities predict the implementation degree of SFSH. Mechanisms of change are explored by combining qualitative and quantitative data and by using the generative mechanisms proposed by normalisation process theory (coherence,

cognitive participation, collective action, and reflexive monitoring) to structure the analysis. Qualitative data will be coded using an abductive approach, whereas quantitative data will be analysed using descriptive techniques to further explain, supplement, or challenge the qualitative analyses of what enables or hinders SFSH becoming part of routine practice.

Outcomes evaluation

The outcomes evaluation uses multi-level linear or logistic regression, depending on the outcome measures.[75] The primary analysis will be a two-level model, with students (level 1) nested in schools (level 2). In secondary analysis, we will investigate effects according to pre-defined subgroups, such as sex, age, and SES. To further elaborate on CMO configurations, we will test the associations between quantitative measures of implementation degree and implementation processes from the process evaluation, using descriptive analysis, logistic regression, and/or factor analysis.[76,77]

Step 5: Synthesis

Empirical and theoretical knowledge about the implementation and outcomes of the intervention will be synthesised into recommendations on how to implement SFSH. RE advocates using retroduction and abduction in iterative processes to test and refine IPT.[37,73,78] Retroduction is a form of inference that seeks to identify and verify the mechanisms theorised to have generated the phenomena under study,[73,78] whereas abduction is the process of describing empirical data using theoretical concepts,[73] with emphasis on analysing data that fall outside an initial theoretical frame or premise.[78,79] Regarding the Smoke-Free Vocational Schools intervention project, our goal is to integrate qualitative and quantitative findings from the process and outcomes evaluations to re-analyse the IPT in terms of what works, for whom, and under what circumstances, using a retroductive-abductive approach. Based on the refined programme theory, we will be able to develop model recommendations for implementing SFSH in vocational schools and similar settings.

Patient and Public Involvement

This study protocol describes a health promotion intervention and no patients have been involved. Public involvement, defined as collaboration with public health partners with knowledge on the VET school setting, has been extensive. The partnering NGO organizations and research institution have worked closely together and collaborated and agreed on the design of the intervention and evaluation. The NGO partners have been involved in the development of the research questions and on choosing the outcome measures and are co-authoring this study protocol. The NGO partners recruited the VET schools and supported the schools in the implementation of SFSH. The evaluation results will be disseminated to NGO partners, VET schools and students through SoMe news and a short 2-page publication in layman language.

ETHICS AND DISSEMINATION

In public health interventions it is important to examine and clarify possible negative reverse effects, so as to avoid further interventions generating the same negative effects.[80] Therefore, unexpected consequences of the intervention will be explored and reported to minimise and avoid participants feeling stigmatised in this study and similar future studies.

The study has been reported to the Capital Region of Denmark's legal centre for personal data handling (journal number: VD-2018-485). Informed consent will be obtained from all study participants according to the General Data Protection Regulation and Danish data protection law. The study adheres to the ethics procedures in Denmark. Study findings will be disseminated at international and national conferences and further published in open-access peer-reviewed journals. Also, the study findings will be used by the practice partners in their further work supporting schools implementing SFSH, as well as by other stakeholders (e.g. schools).

Declarations

Acknowledgements

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Authors contributions

The authors contributions to different aspects of this work were as follows: Conceiving and designing the study: AVH, TBC, MS, KHR and CDK; Refining the study design and obtaining ethical approval: AVH, CP, TTT, CDK; Writing and revising this manuscript (fully or in part): AVH, TBC, MS, KHR, CP, TTT, CDK.

Patient and public partnership

The research and intervention project is a collaboration between research and practice: Two Danish public health NGOs (the Danish Heart Foundation and the Danish Cancer Society) are practice partners, whereas Steno Diabetes Center Copenhagen is research partner. The intervention has been cocreated through a participatory process, with an emphasis on including both evidence and practice experience. Further, the practice partners involved in the design and conduct of the study, the choice of outcome measures and recruitment to the study.

Competing interests

The authors declare that they have no competing interests.

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Figure Legends

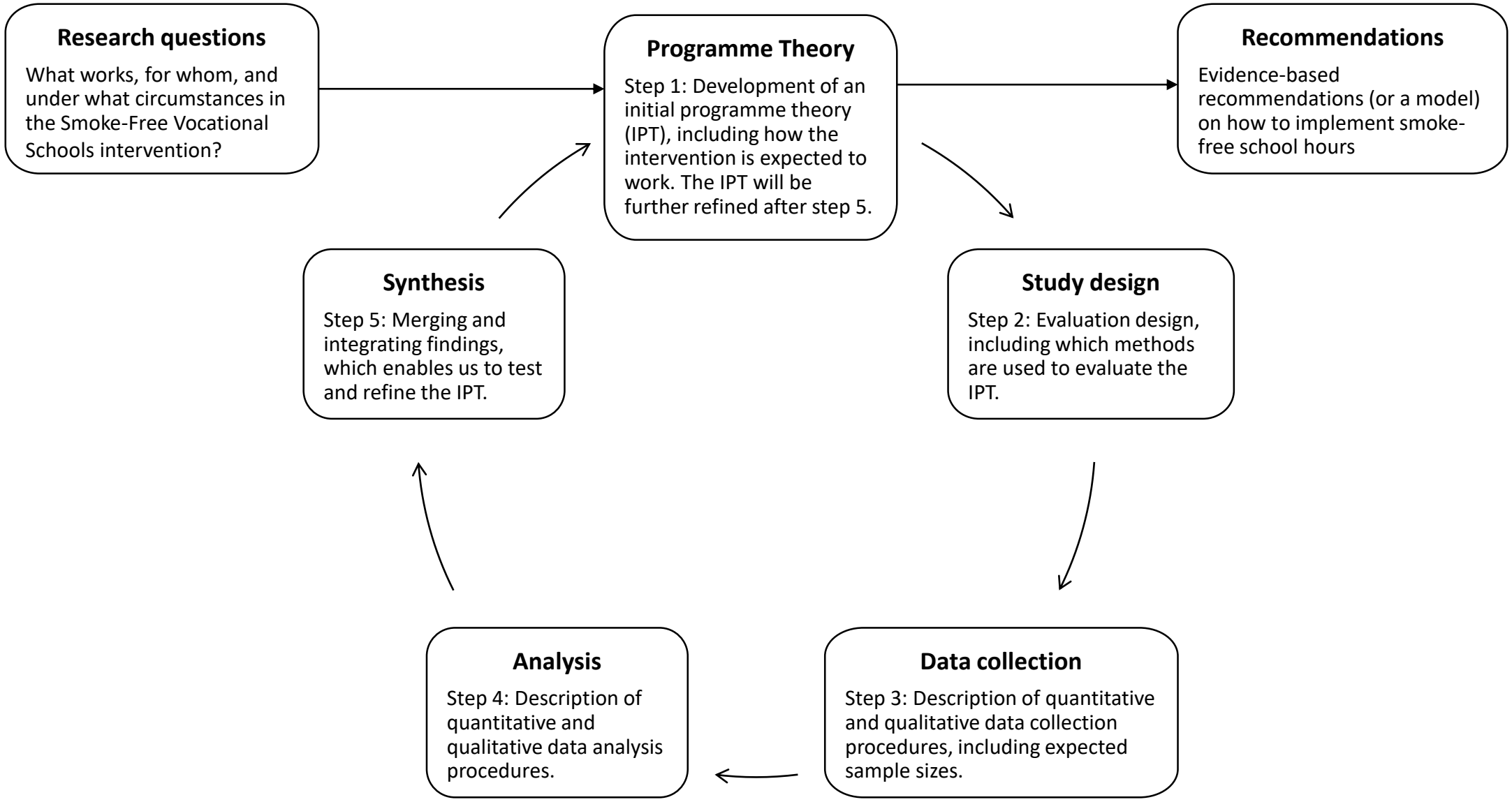
Figure 1 Realist research cycle of the Smoke-Free Vocational Schools intervention project.

Figure 2 Graphic representation of the initial programme theory of the Smoke-Free Vocational Schools intervention. SFSH: Smoke-free school hours. The intervention activities delivered by practice partners are shown in purple. The activities or processes managed by schools but facilitated by practice partners are shown in green.

Figure 3 Process evaluation of the Smoke-Free Vocational Schools intervention, based on the Medical Research Councils guidelines for process evaluation of complex interventions.

Figure 4 Timeline and outcomes evaluation for the Smoke-Free Vocational Schools intervention.

Figure 1 Realist research cycle of the Smoke-Free Vocational Schools intervention project.



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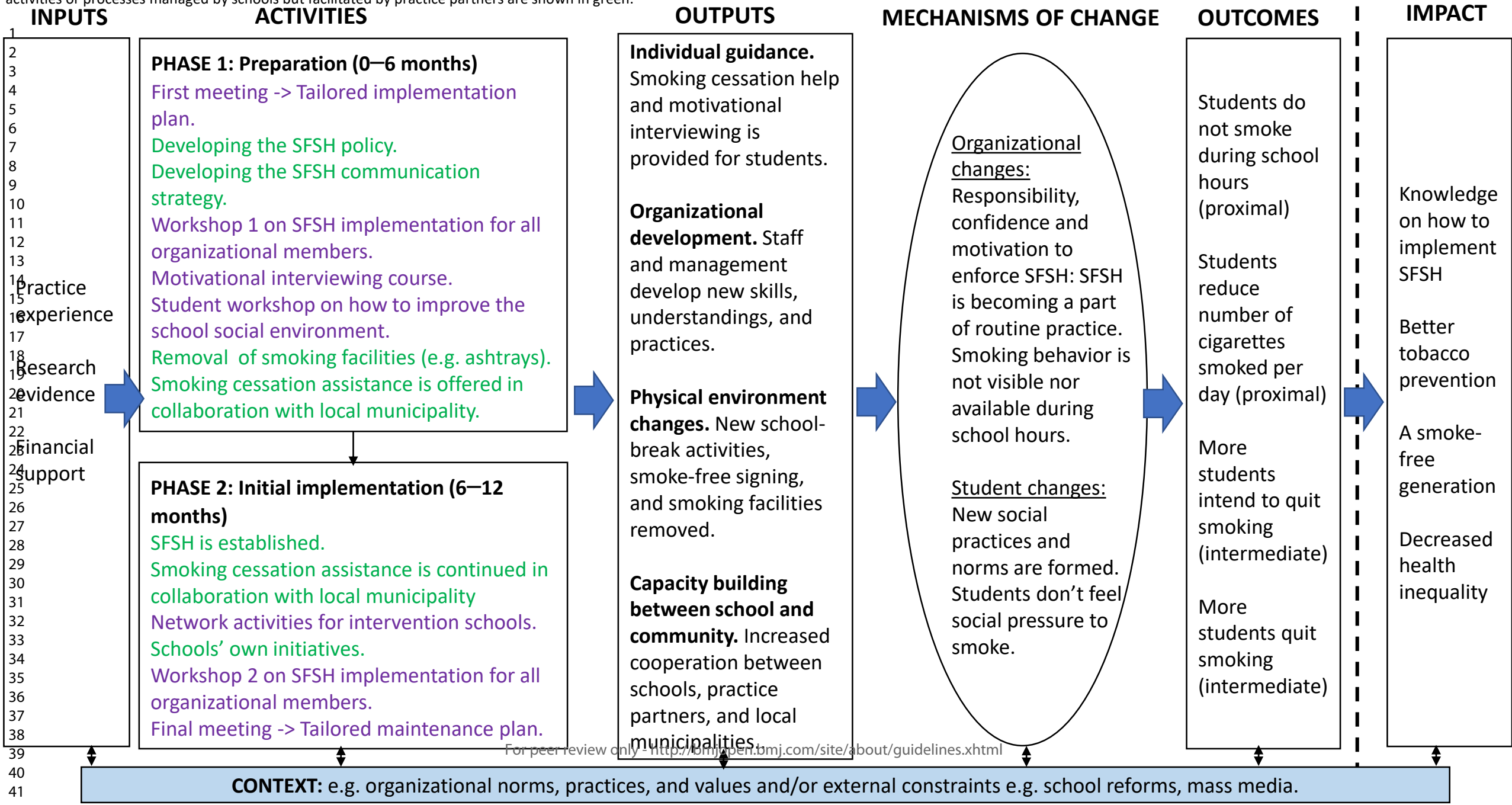

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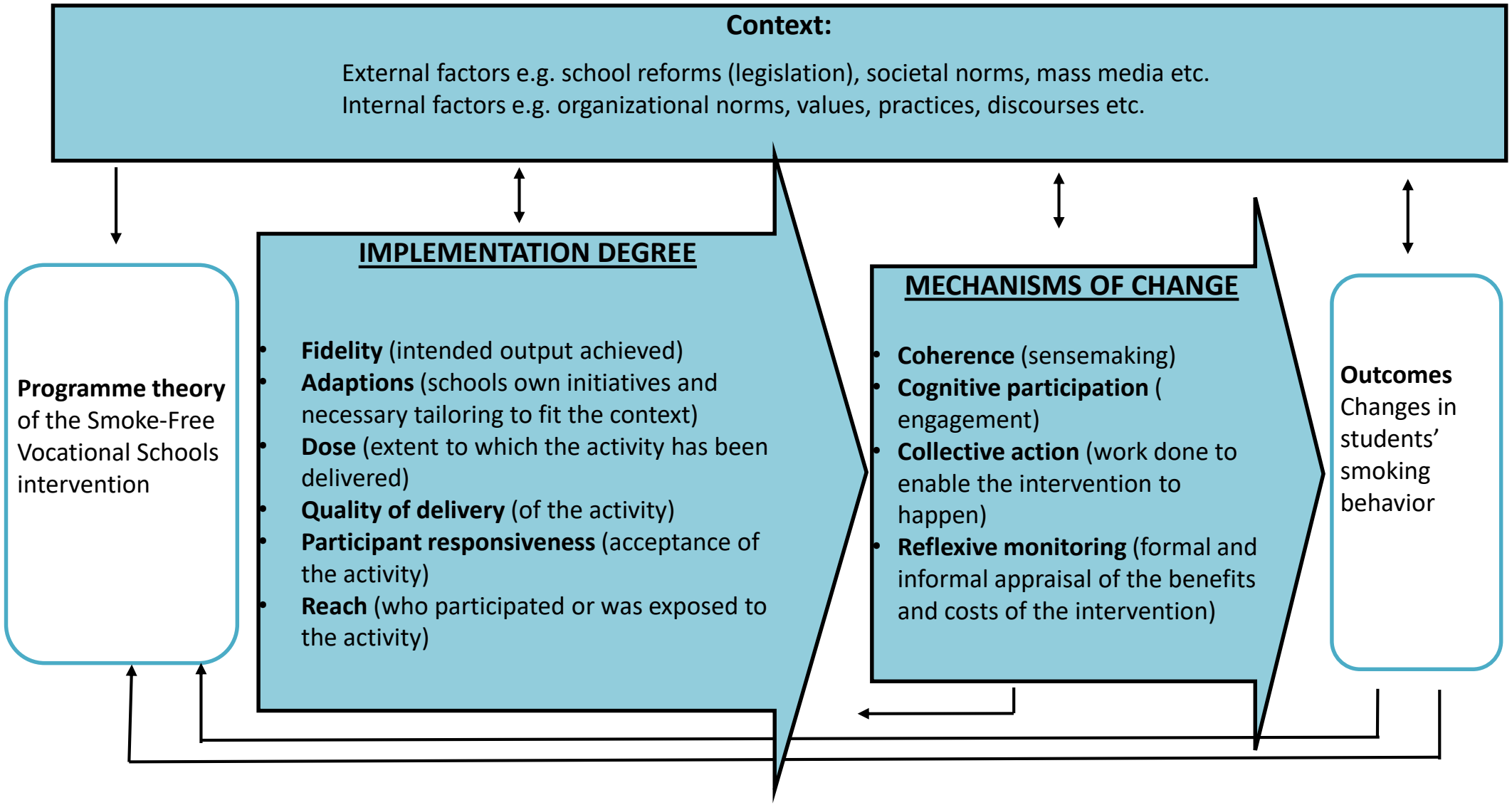

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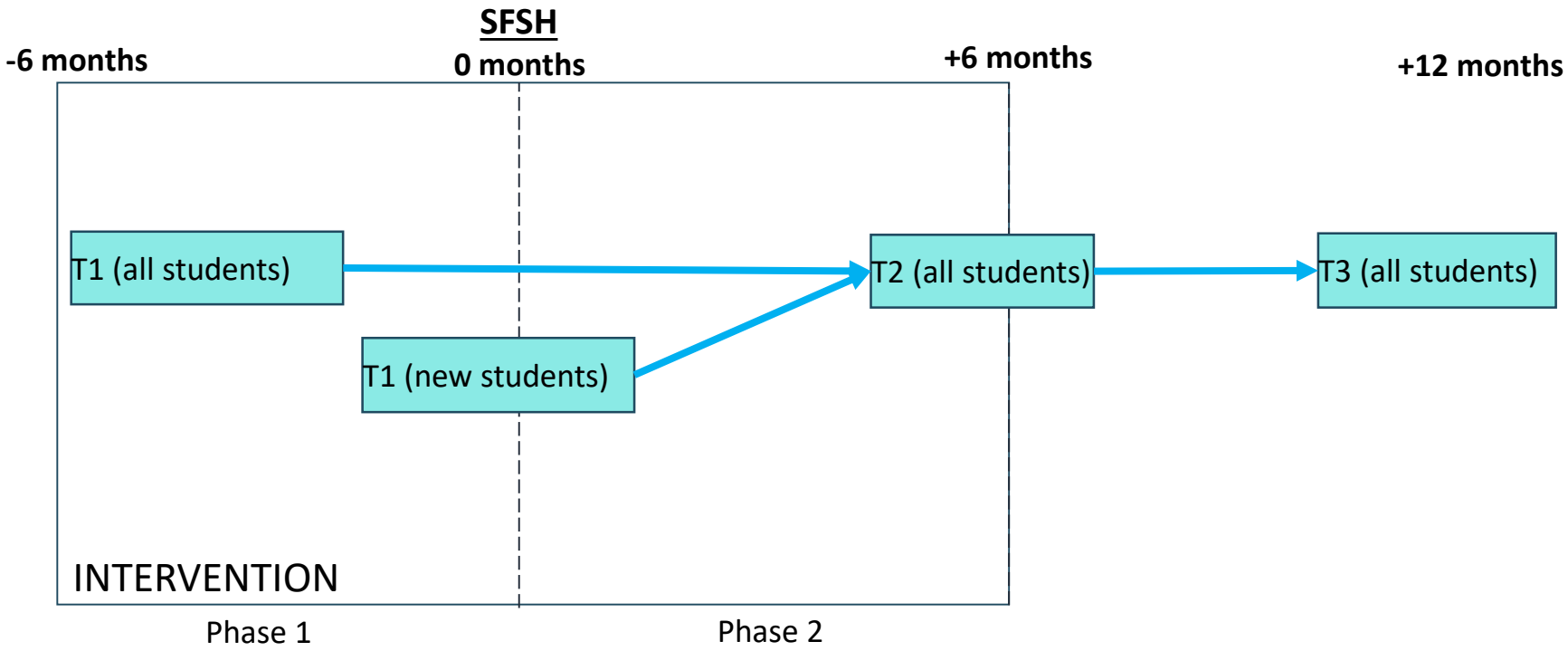

Supplementary File 1: Operationalization of data collection in the process evaluation (implementation degree and mechanisms of change) and the outcomes evaluation

	Concept	Operationalization	Data collection
Implementation degree			
Organizational development	Fidelity	If the workshops and course has resulted in a shared smoke-free school hours understanding and new skills to support students dealing with not smoking during school hours	Staff survey 1; Staff survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2: Facilitator questionnaire (NGOs)
	Dose	Extent to which new learnings from workshops and skills from course are being used at school	Staff survey 1; Staff survey 2
	Quality of delivery	Organization of new learnings and skills at school	Staff survey 1; Staff survey 2
	Participant responsiveness	Attitudes towards workshops and course	Staff survey 1; Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Staff survey 1; Staff survey 2
Physical environment changes	Fidelity	If new school-break activities and smoke-free-signing has been established, and smoking facilities removed	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; structured observations on school grounds; Project coordinator interviews
	Dose	Extent to which school-break activities and smoke-free signing is known to students	Student survey 2
	Quality of delivery	Extent to which new school-break activities are being used by students and smoke-free signing has a prominent position	Student survey 2; structured observations on school grounds
	Participant responsiveness	Attitudes towards workshops new school-break activities and smoke-free-signing	Student survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Individual guidance	Fidelity	If the school offers smoking cessation help or other help for students to cope with smoke-free school hours	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 1; Project coordinator survey 2; Project coordinator interview
	Dose	Number of smoking cessation courses delivered and number of students attending the courses	Project coordinator survey 1; Project coordinator survey 2
	Quality of delivery	Extent to which students know which support to cope with smoke-free school hours is provided	Student survey 2
	Participant responsiveness	Attitudes towards help to cope with smoke-free school hours and attitudes towards attending smoking cessation courses	Student survey 2

	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2
Capacity building between the school and community	Fidelity	If the relationship between school and NGOs, and school and municipality has been strengthened	Project coordinator survey 2
	Adaptions	Context-specific adjustments and initiatives	Project coordinator survey 2; Project coordinator interview
	Dose	Extent to which the school has discussed smoke-free school hours implementation with NGOs and local municipality	Project coordinator survey 2
	Quality of delivery	Extent to which the schools has experienced support from the NGOs and local municipality	Project coordinator survey 2
	Participant responsiveness	Attitudes towards integrating external resources in smoke-free school hours implementation	Staff survey 2
	Reach	For whom is the component implemented (sub-group analysis)	Facilitator questionnaire (NGOs)
Smoke-free school hours implementation	Fidelity	If smoking is allowed during school hours and extent to which students experience smoking during school-hours	Staff survey 2; Staff survey 3; Student survey 2
	Adaptions	Context-specific adjustments in sanctioning and enforcement procedures and practice	Staff survey 2; Staff survey 3; Project coordinator interview
	Dose	Extent to which students know the policy and extent of smoking visibility	Student survey 2, Staff survey 2; Staff survey 3; Structured observations on school grounds
	Quality of delivery	Frequency and manner/method of enforcement	Staff survey 2; Staff survey 3
	Participant responsiveness	Attitudes towards the policy and whether staff experience the policy as a normal part of their work	Student survey 2; Staff survey 2; Staff survey 3
	Reach	For whom is the component implemented (sub-group analysis)	Student survey 2; Staff survey 2; Staff survey 3
Mechanisms of change			
Interactions between the intervention and context-mechanisms i.e. reasoning and behavior among participants, constrained by e.g. organizational norms, values and discourses	Coherence	If and why smoke-free school hours makes sense given the situation the school currently face. Extant to which there's a shared understanding about the policy and the organizational members see the potential value of smoke-free school hours.	Management interview; Project coordinator interview; Teacher focus groups; Staff survey 2; Staff survey 3
	Cognitive participation	If and how there's been established a community of practice around smoke-free school hours, if there's key people driving the implementation forward or the contrary and who. If it is seen as a legitimate part of the schoolwork and if there's been established new practices. Extent to which the organizational members are open to change their daily routines to work with smoke-free school hours.	
	Collective action	If and how smoke-free school hours in enacted as part of routine practice including management practices e.g. how is the work organized and which resources are in place to support the implementation. To what extent the work can be integrated into the everyday school practices and whether people involved has sufficient skills and confidence in work with smoke-free school hours.	
	Reflexive monitoring	If and how smoke-free school hours affect the everyday school life. Formel and informal appraisal procedures and reconfiguration.	

Sub-study 3: Outcomes			
Baseline	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 1
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 1	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 2
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	
Follow-up 2	Primary outcome measure	Smoking during school hours (Y/N)	Student survey 3
	Secondary outcome measures	Number of cigarettes smoked per day, Intention to quit, Smoking status	
	Covariates	Age, gender, SES etc.	