

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol
AUTHORS	Hjort, Anneke; Christiansen, Tenna; Stage, Maria; Rasmussen, Kathrine; Pisinger, Charlotta; Tjørnhøj-Thomsen, Tine; Klinker, Charlotte

VERSION 1 – REVIEW

REVIEWER	Ruaraidh Dobson Institute for Social Marketing & Health University of Stirling Scotland, UK
REVIEW RETURNED	26-Aug-2020

GENERAL COMMENTS	<p>This is an interesting and well-developed study protocol describing a multicomponent-multilevel intervention to implement smoke-free school hours at vocational schools in Denmark. The development process is largely described well and the analysis plan is sound, including detailed information on statistical analysis. The results of this study will be of interest to researchers and practitioners working with young adults to promote smoking cessation, due to the complex nature of this setting (where many students are adults).</p> <p>Major points:</p> <ul style="list-style-type: none">• The manuscript describes “co-creation” of the intervention design through collaboration between the agencies developing this project. To my mind the process described was not true co-creation (which I have interpreted as similar to co-design or co-production), as it only involved the three agencies delivering the study, not the stakeholders themselves (the vocational schools as institutions, staff enforcing the policy and students at the schools). Please add further information on how the co-creation process differed from typical collaboration between charities, or remove references to co-creation from the manuscript.• The study is described as pre-post, with several schools used as “pilot” sites in concordance with the intervention development methodology used in the study. Was the use of control schools considered? I appreciate the small number of schools available (and that the methodology used doesn't require the use of controls) but given the large number of students the authors expect to recruit, could the study have been powered while leaving (for instance) two schools as controls? Will it be possible to compare results with schools not enrolled in the study (even on a basic level, e.g. smoking rates in one survey)
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	<p>Minor points:</p> <ul style="list-style-type: none"> • The language is generally good, but on page 12 (under “Outcomes evaluation”) it is quite convoluted and difficult to understand (e.g. “The study thus seeks to elaborate on outcomes within the programme and/or in different localities and subgroups”). Please simplify this section.
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REVIEWER	Sung-il Cho Seoul National University, Republic of Korea
REVIEW RETURNED	06-Sep-2020

GENERAL COMMENTS	<p>The paper reports a protocol for Smoke-Free Vocational Schools program. The protocol may be informative for the researchers to prepare for monitoring and evaluation, and in general for discussion on the approaches to tobacco use prevention and control among youths. However, there are some aspects that can be improved.</p> <p>1. Role of realist evaluation (RE) RE is somewhat open and semi-qualitative approach to evaluation and may be applied to evaluation in order to capture the planned or unplanned features and results of a program. However, it is not clear what is the role of RE in the planning stage or implementation stage. The part of RE in the introduction does not seem to connect to the need for the intervention protocol. The protocol should have been established clearly before implementation to achieve the goals of the program, not to conduct evaluation after the implementation. Even though the authors had to re-conceptualize the theory underlying the protocol at the evaluation stage, the paper first needs to describe the planned protocol that have lead to implementation of the program in the logical and actual order. Especially, since the Smoke-free Vocational Schools intervention has already started and still on-going, the motivation of any evaluation at this point needs to be described before mentioning RE methodology. e.g. What is the purpose of the evaluation if there is no outcome yet? Is it for process evaluation, or for monitoring implementation according to the plan? Just in case if there is any outcome already, how much is the data collected?</p> <p>2. Study aim It is confusing whether the "study protocol" means the protocol of the intervention study (Smoke-Free Vocational Schools project) or the paper the authors are writing. Maybe just deleting the word 'protocol' might reduce the confusion.</p> <p>3. Target outcomes of the intervention project The main target outcomes need to be described more specifically. Is the main target for the students prevention of smoking initiation, or smoking cessation, or just refraining from smoking within school campus or school hours? Or any combinations of them? Are the students still allowed to smoke within school premise?</p> <p>3. Intervention contents and mechanisms Although the authors appropriately comments on the mechanism, it is not clear what exactly is the mechanism assumed by the program theory and the contents of the intervention. For example, what are the known determinants of vocational school students' smoking, and which part of the intervention going</p>
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	to address these determinants? What determinants cannot be addressed by this intervention, limiting the effect of the program?
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REVIEWER	Ms. Hanna Ollila Finnish Institute for Health and Welfare, Finland
REVIEW RETURNED	22-Sep-2020

GENERAL COMMENTS	<p>The study protocol focuses on the development of the programme theory for the intervention, and the evaluation of the intervention. The intervention evaluation is likely to bring important information for preventing and reducing the socio-economic differences in smoking as it focuses on non-academically oriented schools where students have high smoking prevalence. The intervention is currently ongoing, in the middle of the study period of 2018–2022, which should enable more detailed description of the intervention contents and the timeline. The authors do not make a reference to the SPIRIT (Standard Protocol Items for Randomized Trials) statement, which the BMJ recommends for study protocols. Even when this intervention is not planned as a randomized trial or controlled trial – which would strengthen the evaluation aspect considerably – the authors would benefit from reviewing the manuscript against the SPIRIT recommendations. The intervention relies strongly on the activities of the NGO partners, who are external stakeholders to schools that should implement the actual policy, but the planned evaluation does not yet seem to provide information on how their potential impact and differences in the implementation fidelity will be taken into account in the outcomes. This applies both to collected data and measures, and to the planned analyses. There is also a large amount of financial support provided for participating schools to establish school-break activities, which could potentially impact the results. The financial support is currently only mentioned in the table 1 without further elaboration in terms of its impact on the implementation of the interventions, and to the evaluation. The information of the approval of an ethics committee for the intervention study seems to be missing, even though the data protection and informed consent aspects are described well. Overall, in order to meet the need of accurate description of the intervention and the planned evaluation, the study protocol would benefit of revision prior to new manuscript review.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
 Reviewer Name
 Ruaraidh Dobson

Institution and Country
 Institute for Social Marketing & Health
 University of Stirling
 Scotland, UK

Comments for the authors:
 This is an interesting and well-developed study protocol describing a multicomponent-multilevel intervention to implement smoke-free school hours at vocational schools in Denmark. The

development process is largely described well and the analysis plan is sound, including detailed information on statistical analysis. The results of this study will be of interest to researchers and practitioners working with young adults to promote smoking cessation, due to the complex nature of this setting (where many students are adults).

Major points:

The manuscript describes “co-creation” of the intervention design through collaboration between the agencies developing this project. To my mind the process described was not true co-creation (which I have interpreted as similar to co-design or co-production), as it only involved the three agencies delivering the study, not the stakeholders themselves (the vocational schools as institutions, staff enforcing the policy and students at the schools). Please add further information on how the co-creation process differed from typical collaboration between charities, or remove references to co-creation from the manuscript.

- Thank you for this comment. We agree that the term co-creation is not a precise term to use in this context and has therefore removed the term from the manuscript the two times it was mentioned
- page 8, line 22 has been changed to: The IPT was developed through a co-creation workshop where research and practice worked collaboratively.
- Page 8, line 39 has been changed to: The co-creation workshop process also served as a learning and management tool

The study is described as pre-post, with several schools used as “pilot” sites in concordance with the intervention development methodology used in the study. Was the use of control schools considered? I appreciate the small number of schools available (and that the methodology used doesn't require the use of controls) but given the large number of students the authors expect to recruit, could the study have been powered while leaving (for instance) two schools as controls? Will it be possible to compare results with schools not enrolled in the study (even on a basic level, e.g. smoking rates in one survey)

- Thank you for sharing these reflections with us. And yes, we have considered the use of control schools but have disregarded this due to mainly two reasons: 1) it is (in Denmark) almost impossible to recruit vocational schools to serve as controls, unless they are enrolled in a study using a waiting list design and this design was not possible in this study due to time-restraints from the funding body. 2) the schools vary a lot in terms of size, population, culture, subject etc. making it hard to find suitable control schools/control schools that are comparable to intervention schools. However, what we can and will do in the discussion and interpretation of our results, is to compare the smoking behavior at the national level with smoking behavior at the intervention schools as the research unit at SDCC recently have been responsible for conducting the first representative health and wellbeing profile among vocational school students, see e.g. Klinker CD, Aaby A, Ringgaard LW, Hjort AV, Hawkins M, Maindal HT. Health literacy is associated with health behaviors in students from vocational education and training schools: a Danish population-based survey. *Int J Environ Res Public Health*. 2020 Jan 20;17(2).

Minor points:

The language is generally good, but on page 12 (under “Outcomes evaluation”) it is quite convoluted and difficult to understand (e.g. “The study thus seeks to elaborate on outcomes within the programme and/or in different localities and subgroups”). Please simplify this section.

- We have revised this paragraph to make it more readable and better understandable, e.g. the above sentence now reads: The study thus seeks to elaborate on outcomes across the programme but also considers outcomes for different subgroups...

Reviewer: 2

Reviewer Name

Sung-il Cho

Institution and Country
Seoul National University, Republic of Korea

Comments for the authors:

The paper reports a protocol for Smoke-Free Vocational Schools program. The protocol may be informative for the researchers to prepare for monitoring and evaluation, and in general for discussion on the approaches to tobacco use prevention and control among youths. However, there are some aspects that can be improved.

1. Role of realist evaluation (RE)

RE is somewhat open and semi-qualitative approach to evaluation and may be applied to evaluation in order to capture the planned or unplanned features and results of a program.

However, it is not clear what is the role of RE in the planning stage or implementation stage. The part of RE in the introduction does not seem to connect to the need for the intervention protocol.

- Thank you for this comment, and we agree that the role of RE needed to be clarified. We believe that the ambiguity is partly due to the use of the term 'a realist study protocol' in the title, which we have now changed, so the title of the paper now reads: 'Programme theory and realist evaluation of the 'Smoke-Free Vocational Schools' research and intervention project: a study protocol ', to clarify that the paper is a study protocol, presenting our programme theory and that the realist aspects is mainly related to the evaluation of the project. To make this point more clear, minor changes have been made to the methods and analysis section in the abstract, and the Realistic Evaluation paragraph (page 6-7).

The protocol should have been established clearly before implementation to achieve the goals of the program, not to conduct evaluation after the implementation. Even though the authors had to re-conceptualize the theory underlying the protocol at the evaluation stage, the paper first needs to describe the planned protocol that have lead to implementation of the program in the logical and actual order.

- We are a bit unsure how to understand this comment, but we understand it as the reviewer is unsure about the order in which we have conducted the different steps in the realist research cycle and perhaps are unsure if we have already finished the project and are analyzing data. The protocol and evaluation methods has been developed before the implementation process began. The program has not yet reached the evaluation stage and therefore this paper describes the planned protocol end evaluation.

Especially, since the Smoke-free Vocational Schools intervention has already started and still on-going, the motivation of any evaluation at this point needs to be described before mentioning RE methodology. e.g. What is the purpose of the evaluation if there is no outcome yet? Is it for process evaluation, or for monitoring implementation according to the plan? Just in case if there is any outcome already, how much is the data collected?

- The aim (or purpose) of the intervention study is described in page 6, line 47-48 as 'to facilitate implementing SFSH in vocational schools and to generate new knowledge about the implementation and effectiveness of SFSH'. The purpose of the evaluation is to monitor these two aims.

- We investigate the study aim through a process evaluation (which focuses on implementation of the intervention) and an outcomes evaluation (which focuses on changes in smoking behavior among students). The primary outcome measure is changes in smoking behavior during school hours (See also reply to review comment 3 (Target outcomes of the intervention project) below).

2. Study aim

It is confusing whether the "study protocol" means the protocol of the intervention study (Smoke-Free Vocational Schools project) or the paper the authors are writing. Maybe just deleting the word

'protocol' might reduce the confusion.

- Thank you for this observation. The format of the paper is a study protocol for the intervention study, putting forth both the intervention programme project theory and study evaluation design. To avoid confusion we have now made an addition to the abstract to make it clear that “This study protocol describes the intervention programme project theory and study evaluation design for the ‘Smoke-Free Vocational Schools’ research and intervention project”. We have further made sure that each time we refer to the/this paper we use the term “this study protocol”.

3. Target outcomes of the intervention project The main target outcomes need to be described more specifically. Is the main target for the students prevention of smoking initiation, or smoking cessation, or just refraining from smoking within school campus or school hours? Or any combinations of them? Are the students still allowed to smoke within school premise?

- In the Methods and analysis section of the abstract, in the last paragraph of step 1, page 11 and in the Outcomes evaluation section it is stated that the primary outcome measure is changes in smoking during school hours. In the Outcomes evaluations’ secondary outcomes are also described. The definition of the implemented SFSH can be found on page 11, step 2, second paragraph, and is defined as: ...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. This means that neither students (or staff or visitors) are allowed to smoke during normal school hours, regardless of if there are on the school premises or not.

4. Intervention contents and mechanisms

Although the authors appropriately comments on the mechanism, it is not clear what exactly is the mechanism assumed by the program theory and the contents of the intervention.

- The content of the intervention is described as activities in the programme theory, figure 2. Table 1 further elaborate on the content of the activities. To not lengthen the paper, we prefer to not describe the content of the intervention in more detail.

- As we are working in a setting with very limited research available, we have chosen to put forth two guiding CMO-configurations (page 10, line 47...) elaborating on suggested mechanism of change and also use the initial programme theory as our starting point for displaying preliminary mechanisms, as shown in figure 2 and 3. When we start to analyze data more specific CMO-configurations will be developed.

For example, what are the known determinants of vocational school students' smoking, and which part of the intervention going to address these determinants? What determinants cannot be addressed by this intervention, limiting the effect of the program?

- The main active ingredient of our intervention is the implementation of SFSH, with all other activities supporting the implementation of the SFSH. Therefore, a focus on the main determinants of vocational school students' smoking is of less relevance in our study. However, we agree that other interventionist studies may be needed to address youth smoking behavior e.g. outside school hours.

Reviewer: 3

Reviewer Name

Ms. Hanna Ollila

Institution and Country

Finnish Institute for Health and Welfare, Finland

Comments for the authors:

The study protocol focuses on the development of the programme theory for the intervention, and the evaluation of the intervention. The intervention evaluation is likely to bring important information for preventing and reducing the socio-economic differences in smoking as it focuses on non-

academically oriented schools where students have high smoking prevalence. The intervention is currently ongoing, in the middle of the study period of 2018–2022, which should enable more detailed description of the intervention contents and the timeline

- The content of the intervention is described as activities in the programme theory, figure 2. Table 1 further elaborate on the content of the activities. To not lengthen the paper, we prefer to not describe the content of the intervention in more detail.
- The timeline for the intervention is shown in figure 4 but we acknowledge that this has not been clear as the legend does not show this. The title for the figure has been changed to: Timeline and outcomes evaluation for the Smoke-Free Vocational Schools Interventions

The authors do not make a reference to the SPIRIT (Standard Protocol Items for Randomized Trials) statement, which the BMJ recommends for study protocols. Even when this intervention is not planned as a randomized trial or controlled trial – which would strengthen the evaluation aspect considerably – the authors would benefit from reviewing the manuscript against the SPIRIT recommendations.

- Thank you for this comment and we are aware of this recommendation. In the development of our study protocol we have been informed by SPIRIT and other RE protocols protocol. This has now been added to the paper in the Methods and Analysis section: We have structured this study protocol following the steps of the realist research cycle, as shown in figure 1. The content was further informed by the SPIRIT (Standard Protocol Items for Randomized Trials) statement.
- As for the design of our study, initially we did consider if it was feasible to use control schools but have disregarded this due to mainly two reasons: 1) it is (in Denmark) almost impossible to recruit vocational schools to serve as controls, unless they are enrolled in a study using a waiting list design and this design was not possible in this study due to time-restraints from the funding body. 2) the schools vary a lot in terms of size, population, culture, subject etc. making it hard to find suitable control schools/control schools that are comparable to intervention schools. However, what we can and will do in the discussion and interpretation of our results, is to compare the smoking behavior at the national level with smoking behavior at the intervention schools as the research unit at SDCC recently have been responsible for conducting the first representative health and wellbeing profile among vocational school students, se e.g. Klinker CD, Aaby A, Ringgaard LW, Hjort AV, Hawkins M, Maindal HT. Health literacy is associated with health behaviors in students from vocational education and training schools: a Danish population-based survey. *Int J Environ Res Public Health*. 2020 Jan 20;17(2).

The intervention relies strongly on the activities of the NGO partners, who are external stakeholders to schools that should implement the actual policy, but the planned evaluation does not yet seem to provide information on how their potential impact and differences in the implementation fidelity will be taken into account in the outcomes. This applies both to collected data and measures, and to the planned analyses.

- Thank you for this observation, and we agree and are aware of that the NGO partners play an important part of the intervention, and we can see that this has not been clearly described.
- We have in the “Staff and project coordinator survey” section added that the project coordinator surveys also include questions on collaboration with the NGO partners. Further, we have added that we specifically collect data from the NGOs and their role and work through surveys to the NGO partners both before and after SFSH, as already displayed in table 2, bottom row.
- Further we have added to the section Interviews and focus groups with principal manager, project coordinator, and teachers that ‘During interviews the role of the NGO partners is also explored’.

There is also a large amount of financial support provided for participating schools to establish school-break activities, which could potentially impact the results. The financial support is currently only mentioned in the table 1 without further elaboration in terms of its impact on the implementation of the

interventions, and to the evaluation.

- All components of the intervention are considered active ingredients in the intervention and information to assess the importance of each component are an integral part of the process evaluation, as described on page 11, line 26-31. Components will be part of the final model, if this component seems to support the implementation of SFSH. As such, we do not from a starting point consider the financial support to e.g. be more important than other activities described in table 1.

The information of the approval of an ethics committee for the intervention study seems to be missing, even though the data protection and informed consent aspects are described well.

- Thank you for this observation. We have now added the following sentence to both the abstract and ethics section in the paper: The study adheres to the ethics procedures in Denmark.

Overall, in order to meet the need of accurate description of the intervention and the planned evaluation, the study protocol would benefit of revision prior to new manuscript review.

- With the above revision in mind, we believe our paper has improved substantially.

VERSION 2 – REVIEW

REVIEWER	Ruaraidh Dobson University of Stirling, Scotland
REVIEW RETURNED	02-Nov-2020

GENERAL COMMENTS	I thank the authors for their attention to my review.
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REVIEWER	Sung-il Cho Seoul National University Graduate School of Public Health, Republic of Korea
REVIEW RETURNED	12-Nov-2020

GENERAL COMMENTS	All issues are appropriately addressed. I have no further comments.
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REVIEWER	Hanna Ollila Finnish Institute for Health and Welfare, Finland
REVIEW RETURNED	27-Nov-2020

GENERAL COMMENTS	The authors have provided prompt and thorough responses to the reviewers. The current changes to the manuscript have improved the manuscript and addressed most of the issues, to which the reviewers have paid attention. The evaluation results will be highly interesting to many countries with similar school types and socioeconomic differences in youth tobacco use. However, the researchers would still need to clearly state in this manuscript whether the intervention study has got an approval from an ethics committee. If it has not been needed, it would be useful to explain to the reader why, since different countries can have slightly different requirements. The addition of the sentence "The study adheres to the ethics procedures in Denmark" does not yet answer the question of the approval of an ethics committee, which is generally required for intervention studies targeting youth.
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. Ruairaidh Dobson, University of Stirling Comments to the Author:

I thank the authors for their attention to my review.

Reviewer: 2

Prof. Sung-il Cho, Seoul National University Graduate School of Public Health Comments to the Author:

All issues are appropriately addressed. I have no further comments.

Reviewer: 3

Ms. Hanna Ollila , Finnish Institute for Health and Welfare Comments to the Author:

The authors have provided prompt and thorough responses to the reviewers. The current changes to the manuscript have improved the manuscript and addressed most of the issues, to which the reviewers have paid attention. The evaluation results will be highly interesting to many countries with similar school types and socioeconomic differences in youth tobacco use. However, the researchers would still need to clearly state in this manuscript whether the intervention study has got an approval from an ethics committee. If it has not been needed, it would be useful to explain to the reader why, since different countries can have slightly different requirements. The addition of the sentence "The study adheres to the ethics procedures in Denmark" does not yet answer the question of the approval of an ethics committee, which is generally required for intervention studies targeting youth.

- Thank you for the opportunity to provide clarity on this matter. According to Danish law, only research projects of biomedical character or projects that involve risks for participants need to have ethics reviewed by a Regional Ethics Board. All other research projects cannot apply for formal ethical approval.

- To not lengthen the Ethics Declaration, we have edited the section to the following: "The study has been reported to the Capital Region of Denmark's legal center for personal data handling (journal number: VD-2018-485), which is the ethics procedure in Denmark, as no patients are involved in this study"