PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The effectiveness of tobacco cessation interventions for different groups of tobacco users in Sweden: a study protocol for a national prospective cohort study
AUTHORS	Rasmussen, Mette; Larsson, Matz; Gilljam, Hans; Adami, Johanna; Wärjerstam, Sanne; Post, Ann; Björk-Eriksson, Thomas; Helgason, Asgeir; Tønnesen, Hanne

VERSION 1 – REVIEW

REVIEWER	Vogel, Erin Stanford Prevention Research Center, Department of Medicine, Stanford University, Medicine
REVIEW RETURNED	25-Jun-2021

GENERAL COMMENTS	This manuscript reports the protocol for an evaluation of existing tobacco cessation interventions in Sweden, with a focus on vulnerable populations. The idea behind this study is valuable and important. The protocol paper needs more detail and precision to improve its usefulness for readers. • Abstract: Does “abstinence at the end of the intervention” refer to 14-day point prevalence abstinence? • Abstract: “Effectiveness will be examined” is vague and does not state that smoking cessation outcomes will be compared between vulnerable and non-vulnerable individuals. • Introduction: The second sentence of the first paragraph (“This study includes smokers, users of snus, and e-cigarette users) seems misplaced. The first two paragraphs cover the harms of smoking combustible cigarettes. Other tobacco products are discussed later in the Introduction. • Introduction: Do the citations at the end of paragraph 3 (citations 8-11) refer to the entire paragraph? The first sentence needs a citation and it’s unclear whether citations 8-11 apply to it. • Introduction: After stating that “products such as cigarettes, snus, and e-cigarettes are often mixed,” it would be helpful to include a sentence or two about the harms of dual tobacco product use. • Introduction: Please briefly define “person-centered intervention” the first time the term is used. • Study aim: The manuscript states that the study will “focus on disadvantaged and vulnerable groups.” To be more specific, will their smoking cessation outcomes be compared with those of non-vulnerable groups? • Study aim: How were disadvantaged and vulnerable groups determined? Were priority groups determined by a national tobacco control strategy, or by the authors?

	• Research questions: Will smoking cessation outcomes only be measured among those who smoke daily? Research question 1 refers to “daily smokers.” • Research questions: In research question 2, which variables are considered predictors and which are confounders? Please give examples. Does this research question refer only to quitting cigarettes, or all tobacco products? • Setting: Please specify that the person-centered cessation programmes must be face-to-face. • Tobacco cessation interventions: This section says that face-to-face sessions can be conducted online, but also says that interventions must be in-person to be included. This seems contradictory. • Participants: Are all adult tobacco users eligible, or only those who use cigarettes, e-cigarettes, and/or snus? • Data collection: How will baseline questionnaires be administered? Will the participant complete the questions on a paper survey, or will the counsellor read the questions to the participant and record the participant’s responses? • Baseline: More detail is needed on the measures of baseline characteristics. For example, is “persons who has encouraged to quit” the number of people who have encouraged the participant to quit? Is “planned surgery” a yes/no question, or will more details be recorded? Most importantly, how is “tobacco use” measured? • Follow-up: Using consistent terminology would make the outcome measures clearer. Is “continuous successful quitting since planned quit date” the same as continuous abstinence? Which date will be used—the planned quit date or the end of the programme? The “Outcome” section only mentions recording abstinence from the planned quit date. • Outcome: Does continuous abstinence require abstinence from all tobacco products, or just the tobacco product(s) the person was using at the start of treatment? • Comparators: What additional data will be cross-linked from the Swedish National Patient Register? • Analytical strategy: What does MiReDif stand for? I’m not familiar with the acronym. • Statistical analyses: Which variables will be included based on common knowledge regardless of their univariable association with continuous abstinence? • Discussion: The first paragraph states that the study “will close a major knowledge gap” but does not state what the knowledge gap is. • Discussion: Intensity of cessation programmes is not addressed in the Introduction, Methods, or Results. It does not appear that programme intensity will be assessed in this study, so the discussion of intensity seems misplaced. It may help to state that all interventions evaluated in this study would be considered intensive.

REVIEWER	Jankowski, Mateusz Centrum Medyczne Ksztalcenia Podyplomowego, School of Public Health
REVIEW RETURNED	24-Jul-2021

GENERAL COMMENTS	This is a well-prepared study protocol. The Authors provided comprehensive information on an interesting prospective cohort study. There are two minor comments:

	1. Please clearly define the study aim. It will be more accurate to present a precise study aim in the first sentence, rather than the current version of line 47 that is focused on the novelty of the study. 2. The Authors will analyze three different groups of behaviors: smoking, use of snus and/or e-cigarettes. Line 31 We aim to recruit a total of 8,000 tobacco users". Thorugh the text, the authors referred to the e-cigarette uses as tobacco users. It would be more accurate to clearly define tobacco or e-cigarette users. Please consider changing this sentence (and other parts of the text) to specify. E-cigarettes are not tobacco products but nicotine-containing products, even if they are regulated in the same way as traditional tobacco. I would like to congratulate the Authors. The research topic is interesting and the findings of this study may have a significant contribution to the tobacco control research.

REVIEWER	Tateno, Hiroki Saitama City Hospital
REVIEW RETURNED	25-Jul-2021

GENERAL COMMENTS	This paper describes the protocol for an ongoing national level prospective cohort to evaluate the effectiveness of the Swedish smoking cessation intervention, focusing on disadvantaged and vulnerable tobacco users, including ten groups: without a job, with short or no education, without permanent housing, diagnosed with mental illness, diagnosed with COPD, undergoing surgery, adolescents, elderly, migrants, and pregnant women. This protocol describes recruitment of 8,000 participants and at least 200 contributing certified counsellors during 33 months study period. There are several notable strengths of the study: large and national level prospective cohort, focusing on disadvantaged and vulnerable population, which is needless to say important, including snus and/or e-cigarette users, long term abstinence (6 months), and an objective follow-up call by a project member. Overall, the authors have written the protocol for this study in a clear and concise way. I have a number of comments and concerns about the current proposal. 1. Introduction: a. What is the prevalence of snus and e-cigarettes use in Sweden? Is there any national survey or alternatives? b. What is the prevalence of snus and e-cigarettes among disadvantaged and vulnerable people in Sweden? Is the prevalence among those higher than that of other population? c. What kind of cessation intervention is usually provided for snus or e-cigarette users in Sweden? Is there a specific program for it? d. It is still not clear to me whether the cessation intervention provided by the certified counsellors could be considered generally unvarying, even if adjusting model for hierarchical clustering would be utilized. Is there a national guideline or protocol for smoking cessation in Sweden which should be followed by the counsellors? e. There is a growing interest in heated tobacco products (HTPs) worldwide, including IQOS and glo. Does tobacco described in the paper include HTPs, and what is the prevalence of HTPs users in Sweden, especially in the target population of the study?

	2. Study design: a. There is a lack of detailed information about confounders being analyzed. b. What king of pharmacotherapy can be included in the intervention? Will pharmacotherapy be one of the confounders to be controlled for? c. Although the paper describes "real life setting" several times, there are some concerns about it. c-1. The consented participants agree with answering additional questionnaires and being followed 6 months later. These processes of the consenting itself, whether it is intended or not, could affect participants' motivation to quit and cessation outcome. c-2. The contributing counsellors could have higher skills and motivations than the other usual counsellors. d. An estimated 6-month continuous abstinence rate of 35% in the control group looks high. Please show the current abstinence rate in Sweden as a reference.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Erin Vogel, Stanford Prevention Research Center, Department of Medicine, Stanford University
Comments to the Author:
This manuscript reports the protocol for an evaluation of existing tobacco cessation interventions in Sweden, with a focus on vulnerable populations. The idea behind this study is valuable and important. The protocol paper needs more detail and precision to improve its usefulness for readers.

Abstract:
• Abstract: Does “abstinence at the end of the intervention” refer to 14-day point prevalence abstinence?
The outcome at this point is not 14-days point prevalence, since all participants may not have been involved in an intensive intervention. We have changed the text:
“Secondary outcomes include abstinence at the end of the treatment programme, which could be from minutes over days to weeks, …”
• Abstract: “Effectiveness will be examined” is vague and does not state that smoking cessation outcomes will be compared between vulnerable and non-vulnerable individuals.
The paragraph has been changed to:
“Effectiveness of successful quitting will be examined by comparing vulnerable with non-vulnerable patients using a mixed-effect logistic regression model adjusting for potential prognostic factors and known confounders.”

Introduction:
• Introduction: The second sentence of the first paragraph (“This study includes smokers, users of snus, and e-cigarette users) seems misplaced. The first two paragraphs cover the harms of smoking combustible cigarettes. Other tobacco products are discussed later in the Introduction.
The sentence has been removed.
• Introduction: Do the citations at the end of paragraph 3 (citations 8-11) refer to the entire paragraph? The first sentence needs a citation and it’s unclear whether citations 8-11 apply to it.
Yes, the references refer to the entire sentence.
• Introduction: After stating that “products such as cigarettes, snus, and e-cigarettes are often mixed,” it would be helpful to include a sentence or two about the harms of dual tobacco product use.
We have added the following:

“In addition, products such as cigarettes, snus, and e-cigarettes are often mixed, and the negative impact would increase, accordingly.”

• Introduction: Please briefly define “person-centered intervention” the first time the term is used.

The following definition has been provided:

“Despite the fact that about a thousand counsellors have been trained in manual-based person-centred tobacco cessation interventions [21], following the general Swedish guidelines [12] (i.e. the intervention is tailored to the individual tobacco user, regarding tobacco profile, health profile, needs and preferences according to the clinical guideline, allowing for variations in length as well as in content) in Sweden [21], it is unknown how effective the interventions are.”

• Study aim: The manuscript states that the study will “focus on disadvantaged and vulnerable groups.” To be more specific, will their smoking cessation outcomes be compared with those of non-vulnerable groups?

Thank you for pointing this out, and yes they will be compared to non-vulnerable users. We have added the following at the end of the sentence:

“…compared with non-vulnerable users.”

• Study aim: How were disadvantaged and vulnerable groups determined? Were priority groups determined by a national tobacco control strategy, or by the authors?

We have added this information at the end of the Study Aim section:

“The groups prioritised were mainly defined by the National Board of Health and Welfare in Sweden and WHO (pregnant women, patients undergoing surgery, persons with severe mental illness, adolescents, migrants, and the elderly) [12]. The remaining groups were chosen by the authors based on needs described in clinical guidelines.”

• Research questions: Will smoking cessation outcomes only be measured among those who smoke daily? Research question 1 refers to “daily smokers.”

Yes, the main focus in the study is on daily smokers and other daily tobacco users. We have clarified this throughout the research questions (se next comment).

• Research questions: In research question 2, which variables are considered predictors and which are confounders? Please give examples. Does this research question refer only to quitting cigarettes, or all tobacco products?

We have refined the research questions to the following:

“ 1) Among daily smokers what is the effectiveness of in-person tobacco cessation interventions measured as successful quitting after 6 months, among disadvantaged and vulnerable groups compared to other smokers.

2) What are the most important predictors for successful/unsuccessful quitting smoking when using an adjusted model?

3) What are 1) and 2) for daily users of snus and/or users of e-cigarettes?”

Study Design:

• Setting: Please specify that the person-centered cessation programmes must be face-to-face.

This information has now been added:

“All the officially certified counsellors working with in-person person-centered cessation programmes…”

• Tobacco cessation interventions: This section says that face-to-face sessions can be conducted online, but also says that interventions must be in-person to be included. This seems contradictory.

To avoid misunderstandings we have added “online video calls” to the sentence:

“Face-to-face sessions can be conducted as online video calls as well as on-site meetings.”

• Participants: Are all adult tobacco users eligible, or only those who use cigarettes, e-cigarettes, and/or snus?

All adult smokers (not just cigarette smokers), snus users and e-cigarette are eligible.

• Data collection: How will baseline questionnaires be administered? Will the participant complete the questions on a paper survey, or will the counsellor read the questions to the participant and record the participant’s responses?

Thanks for drawing attention to this issue. We have clarified the procedure:
“After giving informed consent patients are included in the study and asked to fill in a questionnaire. The paper survey is filled in by the patient, with assistance from the counsellor. If necessary, the counsellor is allowed to read the questions to the patient and record the patient’s responses. All questions regarding tobacco use or quit attempts etc. are divided into three section a) Smoking, b) Use of snus, and c) Use of e-cigarettes. The baseline characteristics, include:”

• Baseline: More detail is needed on the measures of baseline characteristics. For example, is “persons who has encouraged to quit” the number of people who have encouraged the participant to quit? Is “planned surgery” a yes/no question, or will more details be recorded? Most importantly, how is “tobacco use” measured?

We have added more information on the baseline data collection:
“After giving informed consent patients are included in the study and asked to fill in a questionnaire. The paper survey is filled in by the patient, with assistance from the counsellor. If necessary, the counsellor is allowed to read the questions to the patient and record the patient’s responses. All questions regarding tobacco use or quit attempts etc. are divided into three section a) Smoking, b) Use of snus, and c) Use of e-cigarettes. The baseline characteristics, include:

- Years of smoking/snusing and using e-cigarettes; current daily tobacco use (No/Yes/Not on a daily basis); previous quit attempts (None/1-3/>3/Not using); cohabitating with a smoker (Yes/No); health care personnel who has encouraged the quitting (e.g. GP, hospital doctor, midwife, dentist); housing (e.g. own house, rental, without permanent housing).
- Social security number; level of education; employment; pregnancy (Yes/No); planned surgery (Yes/No); place of birth (Sweden, The Nordic countries, Europe, not Europe); mother tongue (Swedish, Nordic, European, not European).”

• Follow-up: Using consistent terminology would make the outcome measures clearer. Is “continuous successful quitting since planned quit date” the same as continuous abstinence? Which date will be used—the planned quit date or the end of the programme? The “Outcome” section only mentions recording abstinence from the planned quit date.

Thanks for bring the issue with consistent terminology to our attention. We have changed the terminology from continuous abstinence to continuous successful quitting, throughout the manuscript. Regarding the use of the planned quit day vs the last treatment day we have clarified the following in the outcome section:
“The primary outcome is self-reported continuous successful quitting after 6 months, measured from the planned quit day (or last day of the treatment if a specific quit date is not planned during the intervention) to the day of follow-up 6 months later.”

• Outcome: Does continuous abstinence require abstinence from all tobacco products, or just the tobacco product(s) the person was using at the start of treatment?

We will be looking at abstinence from all of the included tobacco products, and we have added the following after the primary outcome:
“We will be monitoring smoking, use of snus, and use of e-cigarettes, as successfully quitting one of the above, may lead to an increased use of one or more of the others.”

• Comparators: What additional data will be cross-linked from the Swedish National Patient Register?

We have clarified the use:
“… and all patients will be cross-linked with additional data from the Swedish National Patient Register to extract relevant diagnoses to uncover e.g. chronic obstructive pulmonary disease (COPD), severe mental illness, or recently giving birth [30].”

• Analytical strategy: What does MiReDif stand for? I’m not familiar with the acronym.

We have added the following:
“Based on a minimal relevant difference (MiReDif) on 10% and 5% each group …”

• Statistical analyses: Which variables will be included based on common knowledge regardless of their univariable association with continuous abstinence?

Based on common knowledge we will include sex, age, and geographical region. We have refined the list of variables that will be investigated:

“The final multivariable logistic regression model will be fitted, based on initial univariable tests, and common knowledge, to include relevant variables. Potential predictors including confounders concerning patients, intervention and tobacco cessation clinic will be included, and as a minimum the following will be examined:

- Patients: Sex, age, compliance with the intervention, tobacco/e-cigarette history, level of nicotine dependency, previous quit attempts, living with a smoker, level of education, job situation, and belonging to more than one vulnerable group.
- Intervention: Intensity, individual or group sessions, and treatment method.
- Clinic: Setting, and geographic location.”

Discussion:

• Discussion: The first paragraph states that the study “will close a major knowledge gap” but does not state what the knowledge gap is.

The following has been added:

“The present study will close a major knowledge gap regarding which programmes that work best for different groups of users in different settings, clinics and regions in Sweden.”

• Discussion: Intensity of cessation programmes is not addressed in the Introduction, Methods, or Results. It does not appear that programme intensity will be assessed in this study, so the discussion of intensity seems misplaced. It may help to state that all interventions evaluated in this study would be considered intensive.

Thanks a lot for pointing this out, as it definitely needs to be clarified in the methods section. We have no requirements to the intensity of the interventions used in this study. Intensity will, however, be examined as a possible predictor for successful quitting, based on number of meetings and the duration of each meeting. We have included this in the manuscript.

“The counsellors register details of the cessation intervention and process (both planned and performed), and follow-up at the end of the intervention, including:

- Dates of initiating and ending the cessation intervention; date of quitting; setting.
- Details of intervention method; individual/group format; group size; intensity of the intervention (number of meetings and duration); supplemental contacts; relapse prevention; user fees.”

Reviewer 2

Dr. Mateusz Jankowski, Centrum Medyczne Ksztalcenia Podyplomowego

Comments to the Author:

This is a well-prepared study protocol.

The Authors provided comprehensive information on an interesting prospective cohort study.

There are two minor comments:

1. Please clearly define the study aim. It will be more accurate to present a precise study aim in the first sentence, rather than the current version of line 47 that is focused on the novelty of the study.

Thank you for pointing this out. We have no moved the first sentence and the Study aim section is initiated by the following:

“The purpose of this study is to facilitate and improve the evaluation of the national tobacco cessation efforts, emphasising on which programmes are most effective for different groups throughout Sweden…”

2. The Authors will analyze three different groups of behaviors: smoking, use of snus and/or e-cigarettes. Line 31 We aim to recruit a total of 8,000 tobacco users". Thorugh the text, the authors referred to the e-cigarette uses as tobacco users. It would be more accurate to clearly define tobacco or e-cigarette users. Please consider changing this sentence (and other parts of the text) to specify. E-cigarettes are not tobacco products but nicotine-containing products, even if they are regulated in the same way as traditional tobacco.

Thank you, we do agree and have changed this issue throughout the manuscript.

I would like to congratulate the Authors. The research topic is interesting and the findings of this study may have a significant contribution to the tobacco control research.
Reviewer: 3
Dr. Hiroki Tateno, Saitama City Hospital
Comments to the Author:
This paper describes the protocol for an ongoing national level prospective cohort to evaluate the effectiveness of the Swedish smoking cessation intervention, focusing on disadvantaged and vulnerable tobacco users, including ten groups: without a job, with short or no education, without permanent housing, diagnosed with mental illness, diagnosed with COPD, undergoing surgery, adolescents, elderly, migrants, and pregnant women. This protocol describes recruitment of 8,000 participants and at least 200 contributing certified counsellors during 33 months study period.
There are several notable strengths of the study: large and national level prospective cohort, focusing on disadvantaged and vulnerable population, which is needless to say important, including snus and/or e-cigarette users, long term abstinence (6 months), and an objective follow-up call by a project member. Overall, the authors have written the protocol for this study in a clear and concise way. I have a number of comments and concerns about the current proposal.

1. Introduction:
a. What is the prevalence of snus and e-cigarettes use in Sweden? Is there any national survey or alternatives?
Smoking, use of snus, and e-cigarette use have been recorded through a national health survey in Sweden every year (2004-2016) or every second year (2018-2020). The use of e-cigarettes have only been recorded since 2018. Based on this survey we have added the following information:
“Sweden has a unique high prevalence of snus users, with 18% daily users among men and 4% among women in 2016 [15]. At that time the daily smoking prevalence in Sweden was 8% and 10% for men and women respectively, resulting in a daily tobacco prevalence of 25% for men and 14% for women [15]. Regarding the use of e-cigarettes the prevalence of daily users in 2020 was 0.4% for both men and women [15]. In addition, products such as cigarettes, snus, and e-cigarettes are often mixed.”
b. What is the prevalence of snus and e-cigarettes among disadvantaged and vulnerable people in Sweden? Is the prevalence among those higher than that of other population?
We have added a bit of information regarding snus use in disadvantaged groups:
“Though the smoking prevalence is relatively low in Sweden in an international context, specific groups have a very high prevalence; about 80% in alcohol and drug abusers [14]. A similar extreme level of daily snus uses was not seen in the group of abusers, where the prevalence was 24-25% [14].”
c. What kind of cessation intervention is usually provided for snus or e-cigarette users in Sweden? Is there a specific program for it?
In general these programmes are similar to those for smoking cessation, including pharmaceutical support.
d. It is still not clear to me whether the cessation intervention provided by the certified counsellors could be considered generally unvarying, even if adjusting model for hierarchical clustering would be utilized. Is there a national guideline or protocol for smoking cessation in Sweden which should be followed by the counsellors?
Thanks for bringing attention to this issue. From our point of view the cessation interventions used in the study do not have to be similar. This is why we ask the counsellor to fill in information on each intervention registered. This allows for interventions of different intensity, content and methods, which will enable us to investigate if specific interventions are more suited for specific groups of users that others. That being said, there are general national guidelines used when educating the counsellors. To clarify we have added the following:
“Despite the fact that about a thousand counsellors in Sweden have been trained in manual-based person-centred tobacco cessation interventions [21], following the general Swedish guidelines [12]

(i.e. the intervention is tailored to the individual tobacco user, regarding tobacco profile, health profile, needs and preferences according to the clinical guideline, allowing for variations in length as well as in content), it is unknown how effective the interventions are."
e. There is a growing interest in heated tobacco products (HTPs) worldwide, including IQOS and glo. Does tobacco described in the paper include HTPs, and what is the prevalence of HTPs users in Sweden, especially in the target population of the study?
We have added a sentence about HTP use in Sweden:
"Cessation programmes are increasingly offered to users of snus and e-cigarettes, as well as heated tobacco products, though the use of the last is still very low in Sweden…"

2. Study design:
a. There is a lack of detailed information about confounders being analyzed.
The following has been added to the Statistical analyses section:
"Potential predictors including confounders concerning patients, intervention and tobacco cessation clinic will be included, and as a minimum the following will be examined:

- Patients: Sex, age, compliance with the intervention, tobacco/e-cigarette history, level of nicotine dependency, previous quit attempts, living with a smoker, level of education, job situation, and belonging to more than one vulnerable group.
- Intervention: Intensity, individual or group sessions, and treatment method.
- Clinic: Setting, and geographic location."

b. What king of pharmacotherapy can be included in the intervention? Will pharmacotherapy be one of the confounders to be controlled for?
As this is an evaluation of already implemented tobacco cessation interventions, we do not have any limits on what pharmacological support can be used. On the questionnaire we have added the following option: NRT, bupropion, varenicline and "Other", were the instructor can specify any other product used. We have added the standard options to the text:
"… present use of pharmacologic support (nicotine replacement therapy (NRT), bupropion, varenicline, or other); …"
We do not plan to control for pharmacotherapy in our primary analysis, as we consider it to be an integrated part of the intervention offered to the patients.
c. Although the paper describes "real life setting" several times, there are some concerns about it.
c-1. The consented participants agree with answering additional questionnaires and being followed 6 months later. These processes of the consenting itself, whether it is intended or not, could affect participants' motivation to quit and cessation outcome.
c-2. The contributing counsellors could have higher skills and motivations than the other usual counsellors.
This answer concerns the "c" section: This is a valid point, and yes your concerns could absolutely be the case. However, we are not in any way able to avoid this issue, at it is not possible to do any kind of data collection without consent, thus this is a general issue when dealing with research. Still it should absolutely be considered as a possible bias.
In our experiences from Denmark however, we have seen that this kind of study and data collection further the opportunities to future dissemination and learning from the best. Hence we have added the following:
"A positive side-effect would be the possibility to consolidate that the culture of systematic monitoring, and follow-up and dissemination of on effect after the project, which raises the awareness of effectiveness and exchange of knowledge between smoking among cessation provides across sectors."
d. An estimated 6-month continuous abstinence rate of 35% in the control group looks high. Please show the current abstinence rate in Sweden as a reference.
We have based the 6-months continuous abstinence rate on results from a similar study from Denmark, as this is the best estimate we have got. Unfortunately, there are no available national

abstinence rates in Sweden regarding in-person interventions. Through this study we will be able to provide quit rate.

VERSION 2 – REVIEW

REVIEWER	Vogel, Erin Stanford Prevention Research Center, Department of Medicine, Stanford University, Medicine
REVIEW RETURNED	26-Sep-2021

GENERAL COMMENTS	The authors were highly responsive to reviewer comments and the manuscript is now much clearer. My only remaining suggestion is to consider using terminology such as "people with substance use disorders" or "people who abuse drugs or alcohol" rather than "alcohol and drug abusers." The term "abuser" can be stigmatizing.

REVIEWER	Tateno, Hiroki Saitama City Hospital
REVIEW RETURNED	19-Sep-2021

GENERAL COMMENTS	The authors have well addressed the issues of my concern. I could say that they may discuss my concern at Study Design - "c" section, when they will write the final report, as a limitation of the study. Anyway, thanks for giving me a precious opportunity to review your paper, which is absolutely valuable to promote tobacco cessation around the world.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. Erin Vogel, Stanford Prevention Research Center, Department of Medicine, Stanford University

Comments to the Author:

The authors were highly responsive to reviewer comments and the manuscript is now much clearer. My only remaining suggestion is to consider using terminology such as "people with substance use disorders" or "people who abuse drugs or alcohol" rather than "alcohol and drug abusers." The term "abuser" can be stigmatizing.

Thank you for pointing this out. The term “alcohol and drug abusers” were used in the 5th paragraph in the introduction, and has now been changed to:

“Though the smoking prevalence is relatively low in Sweden in an international context, specific groups have a very high prevalence; about 80% in people who abuse alcohol or drugs [14]. A similar extreme level of daily snus users was not seen in the group of people who abuse alcohol or drugs, where the prevalence was 24-25% [14]. …”

Reviewer: 3

Dr. Hiroki Tateno, Saitama City Hospital

Comments to the Author:

The authors have well addressed the issues of my concern. I could say that they may discuss my concern at Study Design - "c" section, when they will write the final report, as a limitation of the study.

We absolutely agree that we have to take the strengths and limitations into consideration when wring the final report. This includes the potential bias you mention in section c (see below).

Study Design, section c (from earlier version of peer-review)

c. Although the paper describes "real life setting" several times, there are some concerns about it.

c-1. The consented participants agree with answering additional questionnaires and being followed 6 months later. These processes of the consenting itself, whether it is intended or not, could affect participants' motivation to quit and cessation outcome.

c-2. The contributing counsellors could have higher skills and motivations than the other usual counsellors.

Anyway, thanks for giving me a precious opportunity to review your paper, which is absolutely valuable to promote tobacco cessation around the world.