

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	A smoking prevention photoaging intervention for secondary schools in Brazil delivered by medical students: randomized trial – study protocol
<b>AUTHORS</b>	Faria, Bianca; Brieske, Christian; Cosgarea, Ioana; Omlor, Albert; Fries, Fabian; de Faria, Olber; Lino, Henrique; Oliveira, Ana; Lisboa, Oscar; Klode, Joachim; Schadendorf, Dirk; Bernardes-Souza, Breno; Brinker, Titus

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Paulo Vitória Faculdade de Ciências da Saúde (Health Sciences Faculty), Universidade da Beira Interior, Portugal
<b>REVIEW RETURNED</b>	24-Jul-2017

<b>GENERAL COMMENTS</b>	<p>This paper presents a study protocol aimed to evaluate the use of a novel method, called mirroring intervention, to prevent smoking amongst adolescents.</p> <p>In the strengths and limitations section of the paper I would like to see that this is the first study measuring the longitudinal effectiveness of mirroring intervention in changing smoking behavior (as stated in the beginning of the discussion section).</p> <p>In the Introduction of the paper was highlight a secondary aim of the project, in the framework of the Education Against Tobacco project: to sensitize medical students (prospective doctors) to address smoking prevention and cessation in their future practice. I would like to know that the project contemplates an evaluation on how this experience is perceived by the medical students and if the experience improved their motivation to address tobacco prevention and cessation in their future practice.</p> <p>Page 5, line 42, was stated: “Physician-based programs relying on fear inducing statements show no overall long-term effectiveness in reducing the smoking prevalence”. This statement is not discussed in the paper. I would like to see, here in the introduction and after in the discussion section, which are the similarities and the differences of the approach used in this study (Smokerface App and the mirroring intervention) and the ones based in fear inducing.</p> <p>A second research question is presented in the end of introduction: “does the mirroring intervention sustainably alter the predictors of smoking in accordance with the theory of planned behavior?” I don’t see these predictors defined and operationalized in the methods section.</p>
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	<p>This is the reason to point out in the review checklist of the paper the answer “no” in the questions “Are the methods described sufficiently to allow the study to be repeated?” and “Are the outcomes clearly defined?”.</p> <p>It is missed in the Methods / procedure section of the paper a mention that the students and parents consent collection was a condition to be included in the study (this appears only in the dissemination section in the end of the paper). This is a very important ethical procedure. In the other hand, what are the expected effect of this procedure in participants exclusion and in the study bias.</p> <p>According to authors, contamination will be the main limitation of the study. Why not to perform the randomization process by county instead of by class?</p>
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<b>REVIEWER</b>	Laetitia Minary Université de Lorraine, France
<b>REVIEW RETURNED</b>	02-Aug-2017

<b>GENERAL COMMENTS</b>	<p>This study protocol describes a randomized controlled trial which aims at evaluating the effectiveness of the mirroring approach on smoking behavior in secondary schools in Brazil. The intervention studied is an innovative approach that might provide a promising strategy for tobacco prevention in secondary schools.</p> <p>Introduction: The citation refers to a study focusing on e-cigarette thus I am rather uncomfortable with such an extrapolation of results to tobacco smoking.</p> <p>Page 6: The transition with the Brazilian context paragraph (“Baseline data from our school-based study [...]”) should be improved. We don’t understand why such data (of such area) are presented there. Maybe the presentation of EAT intervention should appear after the presentation of Brazilian context and after the first paragraph about school-based tobacco prevention?</p> <p>Page 7, line 7: what are the outcomes? Tobacco cessation or tobacco initiation (or both?)</p> <p>Methods: My major comment concerns the question of the process evaluation of the intervention. According to the literature about complex interventions (Moore 2015), an evaluation of effectiveness can not be sufficient to provide the knowledges necessary to the adaptation of the intervention in another context. In order to better understand the effects of an intervention, evaluators have to consider the mechanisms of this intervention. Such perspective implies to use a mixed approach and to drive such evaluation on a theory. In this evaluation, what is the place of the theory?</p> <p>Trial design: The choice of the primary end point should be explained.</p> <p>Intervention:</p> <p>Page 10: What are the 2 categories raised in the text? The difference between phase 1 and 2 is not clear.</p>
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	<p>I guess that phase 1 used only one volunteer by contrast to phase 2 where all students could try the app (but it is confusing because the authors first indicate that “the displayed face of one student volunteer is used to show the app’s altering features” and they then explain that “students may interact with their own animated face”).</p> <p>Data collection:  How many secondary school classes are concerned by the study (70 or 35 classes?).  According to the subject of the study, are there any items about the representation of smoking?  How do the authors plan to treat occasional smokers? Indeed, some students smoke less than one cigarette a week without being an ex-smoker.</p> <p>Why is the difference of the 30 day and daily smoking prevalence analyzed at three months but not at 6 months?  The 2d objective aims to analyze if mirroring intervention alter predictors of smoking in accordance with the theory of planned behavior. Thus what about covariates referring to attitudes, subjective norms or perceived behavioral control?</p> <p>Discussion  This section would be improved by adding a theoretical consideration of the intervention. If the evaluation does not integrate a process evaluation, a paragraph should be added in the limitations section.</p>
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### VERSION 1 – AUTHOR RESPONSE

**Reviewer: 1**

Reviewer Name: Paulo Vitória

Institution and Country: Faculdade de Ciências da Saúde (Health Sciences Faculty), Universidade da Beira Interior, Portugal

Please state any competing interests: None declared

Please leave your comments for the authors below

This paper presents a study protocol aimed to evaluate the use of a novel method, called mirroring intervention, to prevent smoking amongst adolescents.

Comment: In the strengths and limitations section of the paper I would like to see that this is the first study measuring the longitudinal effectiveness of mirroring intervention in changing smoking behavior (as stated in the beginning of the discussion section).

Reply: Thank you for helping us to improve our manuscript which we highly appreciate. We added this sentence to the strengths and limitations section as suggested.

Comment: In the Introduction of the paper was highlight a secondary aim of the project, in the framework of the Education Against Tobacco project: to sensitize medical students (prospective doctors) to address smoking prevention and cessation in their future practice. I would like to know that the project contemplates an evaluation on how this experience is perceived by the medical students and if the experience improved their motivation to address tobacco prevention and cessation in their future practice.

Reply: We completely agree with your reasoning as we had the same idea earlier in the process. In accordance, we specifically evaluate this question in a prospective design in another study that is already running. However, the present study focusses on the effectiveness of our tobacco prevention efforts in schools, not how it sensitizes medical students to tobacco cessation.

Comment: Page 5, line 42, was stated: “Physician-based programs relying on fear inducing statements show no overall long-term effectiveness in reducing the smoking prevalence”. This statement is not discussed in the paper. I would like to see, here in the introduction and after in the discussion section, which are the similarities and the differences of the approach used in this study (Smokerface App and the mirroring intervention) and the ones based in fear inducing.

Reply: The ineffectiveness of fear approaches (i.e. approaches that focus on health consequences) is well understood and very present in the literature. Smokerface is not a fear approach, as a change in facial attractiveness is different from serious health consequences due to smoking such as cancer, COPD and heart disease. As we agree that it makes sense to explain this fact, we added a paragraph on „Theoretical Considerations“ in the Discussion section of the manuscript.

Comment: A second research question is presented in the end of introduction: “does the mirroring intervention sustainably alter the predictors of smoking in accordance with the theory of planned behavior?” I don’t see these predictors defined and operationalized in the methods section. This is the reason to point out in the review checklist of the paper the answer “no” in the questions “Are the methods described sufficiently to allow the study to be repeated?” and “Are the outcomes clearly defined?”.

Reply: The theory of planned behavior is documented elsewhere. We added details on the questions used in the Methods section. It would be highly unusual to add the whole questionnaire to the published study protocol. This can be obtained by sending a request to the corresponding author of the publication. Thus, the study now can clearly be repeated based on the information in the manuscript which includes the address of the corresponding author to obtain the original questionnaire if needed.

Comment: It is missed in the Methods / procedure section of the paper a mention that the students and parents consent collection was a condition to be included in the study (this appears only in the dissemination section in the end of the paper). This is a very important ethical procedure. In the other hand, what are the expected effect of this procedure in participants exclusion and in the study bias.

Reply: We agree with the importance of this procedure and added a sentence in the methods section.

Comment: According to authors, contamination will be the main limitation of the study. Why not to perform the randomization process by county instead of by class?

Reply: This is a very good question. We had the same discussion within our group and then also involved a statistician from the University of Essen. In the end, we calculated that using counties or schools as clusters would not make sense for us, as the sample size would have to be extremely high in order to achieve significance with realistic effects. Thus, we had to choose classes as smaller clusters. Thank you again for helping us to improve our manuscript which we highly appreciate.

**Reviewer: 2**

Reviewer Name: Laetitia Minary

Institution and Country: Université de Lorraine, France

Please state any competing interests: None declared

Please leave your comments for the authors below

This study protocol describes a randomized controlled trial which aims at evaluating the effectiveness of the mirroring approach on smoking behavior in secondary schools in Brazil. The intervention studied is an innovative approach that might provide a promising strategy for tobacco prevention in secondary schools.

Introduction:

The citation refers to a study focusing on e-cigarette thus I am rather uncomfortable with such an extrapolation of results to tobacco smoking.

Reply: We agree, but the original reference (Report on the global tobacco epidemic 2013; WHO) appeared not recent enough and too bulky. However, we removed the reference.

Comment: Page 6: The transition with the Brazilian context paragraph (“Baseline data from our school-based study [...]”) should be improved. We don’t understand why such data (of such area) are presented there. Maybe the presentation of EAT intervention should appear after the presentation of Brazilian context and after the first paragraph about school-based tobacco prevention?

Reply: In this case, we disagree. This section sums up the smoking prevalence in the region and we report very recent baseline data from a city of comparable size and infrastructure which is geographically nearby. As the data was obtained by our own study group, we know exactly how it was obtained and can ensure its integrity.

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Paulo Vitória Faculdade de Ciências da Saúde da Universidade da Beira Interior, Portugal
<b>REVIEW RETURNED</b>	21-Aug-2017

<b>GENERAL COMMENTS</b>	<p>I would like to insist in the issue of the theoretical support of the “novel method called mirroring” to prevent smoking behaviour among adolescents. Why this “novel” method will work? Which is the theoretical background to support the hypothesis that this method is effective to prevent smoking behaviour?</p> <p>The authors seem to use the Theory of Planned Behaviour (TPB) as a theoretical background for this method. But this is not explicit in the Introduction of the paper. The TPB appears in the paper for the first time in the last sentence of the Introduction section (p. 7, l. 55), as a secondary research question, to evoke smoking behaviour predictors that could also be changed by the method.</p> <p>Further ahead in the paper the TPB appears again in Methods and in Discussion sections. I will not discuss if the options on the operationalization of TPB used in this study are the best ones.</p>
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	But, if the TPB is the theoretical background of the mirroring method, to strengthen the theoretical background of this method and to support the decision of using TPB in the second research question of this paper, I will suggest moving to the Introduction section the text on TPB that is in the Discussion section (p. 16, l. 14-30) with the due adaptations.
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## VERSION 2 – AUTHOR RESPONSE

### Reviewer 1:

Comment: I would like to insist in the issue of the theoretical support of the “novel method called mirroring” to prevent smoking behaviour among adolescents. Why this “novel” method will work? Which is the theoretical background to support the hypothesis that this method is effective to prevent smoking behaviour?”

Reply: Thank you again for your valuable feedback which we highly appreciate and which helps us to improve our manuscript. However, we think there is a misunderstanding concerning the aim of our study: We do not seek to develop a new intervention but we aim to evaluate an established one that is already implemented in schools. The development of this new method took place earlier and is described here: <https://www.jmir.org/2016/6/e183/>

Comment: The authors seem to use the Theory of Planned Behaviour (TPB) as a theoretical background for this method. But this is not explicit in the Introduction of the paper. The TPB appears in the paper for the first time in the last sentence of the Introduction section (p. 7, l. 55), as a secondary research question, to evoke smoking behaviour predictors that could also be changed by the method.

Comment: Further ahead in the paper the TPB appears again in Methods and in Discussion sections. I will not discuss if the options on the operationalization of TPB used in this study are the best ones. But, if the TPB is the theoretical background of the mirroring method, to strengthen the theoretical background of this method and to support the decision of using TPB in the second research question of this paper, I will suggest moving to the Introduction section the text on TPB that is in the Discussion section (p. 16, l. 14-30) with the due adaptations.“

Reply: We agree with your suggestion as it also appears more logical to us to put more theoretical background on the intervention earlier in the paper. We moved it to the introduction section. Thank you again for your kind support to improve our manuscript which we highly appreciate

## VERSION 3 – REVIEW

<b>REVIEWER</b>	Paulo dos Santos Duarte Vitória Faculdade de Ciências da Saúde - Universidade da Beira Interior, Portugal
<b>REVIEW RETURNED</b>	14-Sep-2017
<b>GENERAL COMMENTS</b>	I recommend the publication of this paper. I'm not an english speaker, but in my opinion the english of the paper still needs a professional revision.