

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	ASSESSING THE EFFECT OF AN INTERACTIVE DECISION-AID SMARTPHONE SMOKING CESSATION APPLICATION (APP) ON QUIT RATES: A DOUBLE-BLIND AUTOMATED RANDOMIZED CONTROL TRIAL PROTOCOL
<b>AUTHORS</b>	BinDhim, Nasser; McGeechan, Kevin; Trevena, Lyndal

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Dr Siti Munira Yasin Faculty of Medicine Universiti Teknologi MARA Malaysia
<b>REVIEW RETURNED</b>	07-May-2014

<b>GENERAL COMMENTS</b>	<p>Thank you for allowing me to review this article. This article discusses on a protocol for a randomized controlled trial using smoking cessation application in assessing quit rates. Overall, this study is one of the earlier studies looking into the usage of smartphones as a cessation aid.</p> <p>I have some comments for this article:</p> <p>Overall language: There are many grammatical errors and punctuation mark errors throughout the article. I would suggest the authors to send the article for editing after the corrections below.</p> <p>Title: Quite inappropriate. It sounds like a research article. I advise the author to include the word "research protocol" and shorten the wordings of the title.</p> <p>Abstract: Omit line 6-10. Starting with "In a previous study exploring.....attempts", as it adds little importance to title and abstract.</p> <p>Methodology</p> <ol style="list-style-type: none"><li>1. Authors mentioned using block randomisation. However it was not clear, how it was done. Please elaborate further.</li><li>2. Inclusion and Exclusion criteria. I feel that it is inadequate. How about smokers who had quit before or taking medication for quitting? Should those be included too? The smokers are cigarette smokers or include water pipes or other forms of smoking?</li><li>3. Meaning of abstinence: why was 10 days chosen as analysis instead of 1 week? Is there a particular reason?</li></ol>
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	<p>4. Relapse is expected to be high during the first 1 month as in previous studies. Hence, is assessing the quit status at 1 month then later 3 months adequate to assess decisional conflict?</p> <p>5. Questionnaires used for this research</p> <ul style="list-style-type: none"> <li>- Were the questionnaires to be used been validated locally?</li> <li>- Baseline questions: why were they chosen? Was it based on previous literatures?</li> <li>- Smoking History: Maybe more variable is required? E.g. Previous quit attempts</li> <li>- Who does “they” refer to in line 53 page 8</li> <li>- Line 6 page 9: “app regularly”. Please mention clearly how often is regularly</li> <li>- Page 9, line 12. “If the user relapses.....”. This is a confusing sentence; I do not understand what the authors are trying to explain.</li> <li>- Page 9, line 14 &amp; 15. Also a confusing sentence. What did the author mean by “multidimensional measure of informed choice for smoking”?</li> </ul> <p>Discussion section</p> <ul style="list-style-type: none"> <li>- I think more is required to be added as for example, more limitations and expected problems/ challenges that may be faced.</li> </ul>
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<b>REVIEWER</b>	Lorien Abrams George Washington University, USA
<b>REVIEW RETURNED</b>	23-May-2014

<b>GENERAL COMMENTS</b>	<p>Additional references should include smartphone study by Buller et al. (2013) and smartphone app review by Abrams et al. (2013).</p> <p>The limitation related to incomplete data needs to be more fully addressed. Based on the authors' preliminary study, only 36.7% of participants replied to surveys. While it is not clear what timeframe this refers to, it's likely to be a short-term follow-up point. Presumably by 6 months , response rates to outcomes will be &lt; 15%. I think the authors need to expand the methods and discussion on how to make sense of very limited outcome data.</p> <p>The exciting part of this paper is the methodology that makes uses of automated download and evaluation data. This should be given greater emphasis in the introduction and the discussion. The strengths of this method (i.e. low research staff burden, making use of automated computer technologies) should be fully explored, as well as the weaknesses (i.e. low response rates). This should also be discussed based on other published studies. Have there been other studies (on any topic) that have used this method? How did they deal with the associated challenges?</p> <p>I did not understand about how the outcome data will be collected. More detail should be provided. Will this be an alert within the app sent to participants? Will there be reminders and if so, of what</p>
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	nature? What happens to people who disable alerts or delete the app. This should be elaborated upon in the Recruitment and Data Collection section.
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### VERSION 1 – AUTHOR RESPONSE

Reviewer 1

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1- Response to the Author

Thank you for allowing me to review this article. This article discusses on a protocol for a randomized controlled trial using smoking cessation application in assessing quit rates. Overall, this study is one of the earlier studies looking into the usage of smartphones as a cessation aid.

Authors' response: Noted with Thanks.

2- Overall language: There are many grammatical errors and punctuation mark errors throughout the article. I would suggest the authors to send the article for editing after the corrections below.

Authors' response: The manuscript has been edited for grammatical errors and formatting.

3- Title: Quite inappropriate. It sounds like a research article. I advise the author to include the word "research protocol" and shorten the wordings of the title.

Authors' response: The title has been modified based on the editors' comments.

4- Abstract: Omit line 6-10. Starting with "In a previous study exploring.....attempts", as it adds little importance to title and abstract.

Authors' response: We have deleted this sentence as suggested.

5- Authors mentioned using block randomisation. However it was not clear, how it was done. Please elaborate further.

Authors' response: We have now included the block randomization variables to provide more detail as suggested. (see Page 5, line 94, Marked copy)

6- Inclusion and Exclusion criteria. I feel that it is inadequate. How about smokers who had quit before or taking medication for quitting? Should those be included too? The smokers are cigarette smokers or include water pipes or other forms of smoking?

Authors' response: This study focuses on current cigarette smokers and as such, previous smokers or users of other tobacco products are not included. We have specified cigarette smokers in the methods section. (see Page 7, lines 112-114, Marked copy)

7- Meaning of abstinence: why was 10 days chosen as analysis instead of 1 week? Is there a

particular reason?

Authors' response: There is no specific guideline that specifically recommends a one-week measure of abstinence or any other very short-term measure. The Society for Research on Nicotine and Tobacco recommended the first follow up to be between 1 to 2 weeks depending on the study design. However, the most important follow up points which are recommended by the Society for Research on Nicotine and Tobacco are 3 & 6 months which is included in our protocol. In our study, as our design is based on a decision aid that allows participants to choose between various options, we selected 10 days for follow-up to allow time for decision-making.

8- Relapse is expected to be high during the first 1 month as in previous studies. Hence, is assessing the quit status at 1 month then later 3 months adequate to assess decisional conflict?

Authors' response: Abstinence rates are the only variables that will be assessed continuously, as explained in the outcome section of the manuscript. The decisional conflict scale will be used to assess this aspect in more detail.

9- Questionnaires used for this research Were the questionnaires to be used been validated locally?

Authors' response: The questionnaires used were selected based on their strong validation across various age groups in English language.

10- Baseline questions: why were they chosen? Was it based on previous literatures?

Authors' response: Most variables were selected based on previous literature. We have included references to the tools selected to be included in our baseline questionnaire, which up to our knowledge the best available.

11- Smoking History: Maybe more variable is required? E.g. Previous quit attempts

Authors' response: As our stated aim is to compare the overall effect of the intervention on quit rates and it has been powered on this, a sub-analysis for previous quit attempts may not be possible. We are using 'willingness to quit' as predictor in the 'stage of change' model which is preferred by some to previous quitting attempts.

12- Who does "they" refer to in line 53 page 8

Authors' response: Changes have been made to clarify this point (see Page 11, lines 186-187, Marked copy)

13- Line 6 page 9: "app regularly". Please mention clearly how often is regularly.

Authors' response: We are monitoring the app use to know how often the participants use the app so, this is user-determined.

14- Page 9, line 12. "If the user relapses.....". This is a confusing sentence; I do not understand what the authors are trying to explain.

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16- Authors' response: Changes have been made. We are collecting the number of cigarettes the relapsed participants smoke to compare it to their baseline if possible. (see Page 11, lines 199-201, Marked copy)

17- Page 9, line 14 & 15. Also a confusing sentence. What did the author mean by "multidimensional measure of informed choice for smoking"?

Authors' response: Changes have been made. "multidimensional measure of informed choice" is a validated composite measured of knowledge, attitude and behavior toward specific treatment. We have adapted the multidimensional measure of informed choice for smoking in this study. (see Page 11, lines 202-203, Marked copy)

18- I think more is required to be added as for example, more limitations and expected problems/ challenges that may be faced.

Authors' response: The reviewer has not specified any limitations or challenges to be discussed further. We have already stated our solutions to some of the limitations that we think may affect the study in the appropriate parts of method section and based on our previous feasibility study. We then summarized them in the discussion section.

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Reviewer 2  
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1- Additional references should include smartphone study by Buller et al. (2013) and smartphone app review by Abrams et al. (2013).

Authors' response: We have included some information from the second reference in the introduction (see Page 2, lines 37-39, Marked copy)

2- The limitation related to incomplete data needs to be more fully addressed. Based on the authors' preliminary study, only 36.7% of participants replied to surveys. While it is not clear what timeframe this refers to, it's likely to be a short-term follow-up point. Presumably by 6 months, response rates to outcomes will be < 15%. I think the authors need to expand the methods and discussion on how to make sense of very limited outcome data.

Authors' response: Changes have been made. To increase the response rate to the baseline questionnaire we have implemented a reminder function described in the "Recruitment and data collection" section (see Page 7, lines 130-132, Marked copy). As this is a new methodology of conducting research via smartphone and there is no previous literature about the dropout rate or rates of participation. However, we have accounted for compliance adjustment by 20% in our

sample size calculation which is the maximum appropriate rate (see Page 12, line 212, Marked copy). In addition, our analysis section have also addressed that in the first part including: "To handle non-response at the follow up, pattern-mixture models will be used as recommended by the Society for Research on Nicotine and Tobacco (SRNT)" (see Page 12, lines 215-220, Marked copy). Finally, unlike survey designs, in a randomised trial only the participants who are randomised will be counted in the analysis and therefore the mentioned response rate from our previous study is not affecting our planned sample size.

3- The exciting part of this paper is the methodology that makes uses of automated download and evaluation data. This should be given greater emphasis in the introduction and the discussion. The strengths of this method (i.e. low research staff burden, making use of automated computer technologies) should be fully explored, as well as the weaknesses (i.e. low response rates). This should also be discussed based on other published studies. Have there been other studies (on any topic) that have used this method? How did they deal with the associated challenges?

Authors' response: Changes have been made. We have added to the methodology and some strengths and limitations to the discussion section (see Page 14, lines 259-264, Marked copy). However, we have not been able to find any previous studies implementing an automated smartphone recruitment and data collection. We have addressed challenges in the methodology (see Page 7, lines 126-132, Marked copy). For example the problem of duplication and confirming participants' location etc. We then summarised these limitations and challenges in the discussion section. However, the suggestion of low response rates is not conclusive as there is only one smartphone study reporting response rates. There are many factors that can potentially influence the response rate more than the medium itself, and most importantly the study design. Therefore, we cannot claim that specific medium (eg. Smartphone or Internet) will always yield a low response rate.

4- I did not understand about how the outcome data will be collected. More detail should be provided. Will this be an alert within the app sent to participants? Will there be reminders and if so, of what nature? What happens to people who disable alerts or delete the app. This should be elaborated upon in the Recruitment and Data Collection section.

Authors' response: Changes have been made. We have added more information about how the follow up data will be collected in the "Measures" section (see Page 11, lines 190-192, Marked copy).

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Lorien Abrams GWU, USA
<b>REVIEW RETURNED</b>	03-Jul-2014

<b>GENERAL COMMENTS</b>	Concerns have been addressed. It's not clear that publishing a protocol will be of high interest to the readers of the journal.
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