

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

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| TITLE (PROVISIONAL) | A skin cancer prevention photoaging intervention for secondary schools in Brazil delivered by medical students: protocol for a randomized controlled trial |
| AUTHORS | Brinker, Titus; Faria, Bianca; Gatzka, Martina; de Faria, Olber; Heppt, Markus; Kirchberger, Michael; Schadendorf, Dirk; Nakamura, Yasuhiro; Buslaff, Fabian; Lisboa, Oscar; Oliveira, Ana; Lino, Henrique; Bernardes-Souza, Breno |

VERSION 1 – REVIEW

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| REVIEWER | Matthew Winslade Charles Sturt University Australia |
| REVIEW RETURNED | 24-Jul-2017 |

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| GENERAL COMMENTS | <p>This is an engaging study and one that has many merits and when the study is complete will add to the much needed global knowledge base of sun safe behaviours and adolescents. I have included a number of small suggestions and comments in the review and a number of questions to consider.</p> <p>Please find review</p> <p>Thank you for the opportunity to review the manuscript; A skin cancer prevention photo aging intervention for secondary schools in Brazil delivered by medical students: Randomised control trial – study protocol.</p> <p>This was a well-constructed informative protocol paper and the associated study has the potential to add to the growing body of literature relating to the partnership between health agencies and schools in relation to tackling global concern surrounding skin cancer. By providing a regionally specific focus this research will serve as a catalyst for other regions (such as Australia and New Zealand) to follow suit and establish similar procedures. The use of engaging stimulus materials (apps and smartphone /tablets) aimed at adolescent participants (selfies) is a novel and effective approach.</p> <p>Abstract: Just for consideration of author, the term subjects is used on line 31 whereas on page 16 the term students is used, it may be confusing for international readers using both the terms classes and subjects in close proximity.</p> <p>Perhaps expanding acronym ABCDE rule might be of benefit for the reader (also in outcomes section of paper on page 15)</p> <p>Introduction: This section is informative and well-constructed and provides a good rationale for the regional context of the proposed study.</p> <p>The double pronged themes linked to school students and medical students as role models is to be commended.</p> <p>For consideration, the claim of melanoma as the most common cancer for young adults is linked to a single 2011 reference – is there any other corroborating evidence that can be included here?</p> |
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| | <p>For example Weir et al. (2011) list invasive melanoma as the third most common cancer in young adults in the United States. Perhaps one of the most common cancers in Young Adults? Or provide evidence to suggest this is localised to the specific region of the study.</p> <p>Participants: For consideration of author, what level of approval is needed to conduct research in schools in Itauna? Has this already been solicited? For example is approval needed only at a school level or must it be granted by an association or higher educational authority? The study aims to recruit a significant number of students and classes and will cause some disruption to the normal school routine.</p> <p>Procedure /Discussion: The project has been well thought and conceptually addresses the issues and research questions raised. The outlined procedure supports the notion of internal consistency of adopting a modified approach and recognising factor analysis to ensure factors are correlational. The use of Theory of Planned Behaviour makes for an appropriate and informed theoretical discussion.</p> <p>It is noted that ethics approval has been obtained and that the trial has been registered. Is there an accompanying ethics number available?</p> <p>Is there any funding to be declared for the study?</p> <p>Conclusion: I agree with the authors that this is a novel approach integrating RCT and photo aging to engage adolescents in a valuable research study.</p> <p>References: Please check reference details for consistency throughout reference list For example, reference 1 capitalisation of Journal title</p> |
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| REVIEWER | Dr Veronique Bataille West Herts NHS Trust |
| REVIEW RETURNED | 17-Sep-2017 |

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| GENERAL COMMENTS | This paper does not present any results at all and just the outline of what appear to a grant proposal. The authors need to submit the paper when the results are through next year |
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| REVIEWER | W. Clark Lambert, MD, PhD Rutgers-New Jersey Medical School Newark, NJ USA |
| REVIEW RETURNED | 20-Sep-2017 |

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| GENERAL COMMENTS | This is an excellent study that should produce meaningful results. I suggest being as specific as possible regarding the computer program used to generate these images. Also it is possible that some students may doubt the validity of the photographs of expected alterations and this should be noted in the limitations. Otherwise, I can find no flaws. It would be useful to use this or a related program for similar studies in other countries. |
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| REVIEWER | Suzanne Dobbison Cancer Council Victoria Australia |
| REVIEW RETURNED | 29-Sep-2017 |

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| GENERAL COMMENTS | This paper describes the protocol for a randomized trial of a |
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photaging intervention to be implemented in secondary schools in Brazil to impact daily sunscreen use of students. The proposed intervention is novel in terms of its delivery via an app and mirroring in the class setting for skin cancer prevention. Aging software has been used in one UK study targeting young women's perceived susceptibility to skin cancer and their sun protection intentions, while the use of photography to portray future sun-related skin damage/lesions on sunscreen use has also been found to be effective (Novick, Cutis 1997). Medial students are to be trained to deliver the proposed intervention, which has the potential to influence their sun protection behaviour as well but this is not to be evaluated in the proposed study. This is somewhat surprising given this appears to be a rationale for the long-term goals of the study, as indicated by including it in the strengths and limitations section (Page 7, line 16).

The proposed study has the potential to provide an important contribution to understanding the role of interactive educational apps in conveying risk of future skin damage, lesions and cancer to impact daily sunscreen use of adolescents. Although the writing for the paper is generally clear, the rationale and methods are difficult to follow at times due mainly to the order in which various components are introduced. To better introduce the rationale for the study the introduction could be structured to 1 identify the disease and extent of the problem in Brazil, 2 discuss what successful interventions have been implemented with the target group and reasons for the choice of the current intervention and stating the aims/hypotheses. The introduction does describe a range of relevant studies, while there are gaps in reporting of successful interventions for promoting sun protection among adolescents the review paper is adequate for the scope of this study. However, the paper would benefit from referencing some of the theoretical models of tanning and sun protective behaviours in the introduction. Another element for consideration is whether sun protection alone should be the goal given the acknowledged tanning/overexposure of the population in Brazil. Assessing the impact of the intervention on tanning behaviour (as well as daily sunscreen use) would be useful given that the app focuses on weekly tanning. It therefore seems logical to consider this as a secondary outcome measure.

The aging app itself does seem to provide extreme/unrealistic 25 year outcomes which may impact the credibility of the messages. Given the images seem much worse than the 35-40 year olds most people are familiar with in daily life. Possibly people would have treatment for these lesions before they reached this stage. It would be helpful to include a few sentences on the rationale for presenting the exaggerated examples in the app and any disclaimers about the scenarios to be explained to students.

It would also be useful to provide some further details on the statistical analysis.

The figures are clear and very useful.

Specific issues

Title

The title should highlight that secondary school students are the target of the intervention.

Abstract

Line 12. What is it 'comparably low' to?

Methods and analysis – replace 'subjects' with 'students'

Line 35. '45 minutes' should be in a '45-minute' classroom seminar

Line 35. The description of the intervention is ambiguous/unclear.

Line 53. Do you mean 'group' difference of daily sunscreen use...

Page 7. Strengths and limitations

It is unclear what is meant by 'sensitizing prospective physicians for the importance of skin cancer is mandatory.' The methods do not assess the impact of the intervention on medical students.
Page 7-8 Lines 52 to 14 – move after the paragraph on Brazil (Page 8).

Page 8.

Line 28-29 'first country to forbid' word usage – should this be the government introduced laws to forbid indoor tanning? Also was this commercial and self-owned indoor tanning equipment?

Line 33 'European ethnicity and therefore has' – use 'ancestry' not 'ethnicity'. Also this is insufficient justification for the incidence of melanoma. Suggest adding 'and given their sun-loving culture'...therefore.

Line 47. 'had already had sunburns in the past' 'had past sunburn(s).
Page 9.

Lines 26-28. Repeats earlier.

Lines 29-35. Are these studies relevant given there is some evidence of its utility for skin cancer prevention? The shift to obesity and tobacco is a bit distracting here.

Line 42. The details of mean age seem unnecessary, the study population could be described as 'young women' rather than 'young females'.

Line 46-47. It seems a stretch to claim such a small study as 'effective' -revise...'showed promising reduction in their tanning intentions'.

Page 10.

Line 13. 'weekly sunbed' – figures 1-4 show the app describes this as 'weekly tanning'.

Line 13. 'altered face 5-25 years' – revise to: 5 years and also 25 years into the future.

Line 20. 'odds ratio' is this increased risk of melanoma with weekly tanning and use of sun protection?

Line 22. This sentence is incomplete.

Line 32. It is unclear how the students will be able to share the app with their family and friends if it is on a tablet they don't own and potentially won't have access to their email from the tablet to send it.

Line 39. 'learn about the app' – learn about the benefits of using the app

Line 53. It would be useful to add a sentence on what basis the extrapolations were made and also whether they are realistic or not.

Line 21. The use of the theory of planned behaviour for development of the intervention should be introduced earlier.

Page 11-12 Study design

Page 11, Lines 32-35: Is it appropriate to call this a superiority trial, given only the intervention group receive a treatment?

Lines 39-43. The limitations of randomising classes to intervention and control within the same school are described, however, it should be clearer how clustering will be accounted for in the analysis section.

The risk of contamination of the intervention effect via students discussing their experiences with students from other class-rooms cannot be overcome. Is there a rationale for why individual schools could not be randomised to control or intervention group?
The other weakness is in having teachers deliver the surveys, given students may feel their answers may be less confidential and this should be acknowledged in discussing limitations of the study outcomes.

Conducting the intervention immediately after the baseline survey will reduce generalisability if the survey has an effect? If there was a short gap of a week the survey may have less influence on the response to the intervention and improved generalisability.
Lines 52-55: It would assist readers to more clearly describe the intervention in this sentence; e.g. 'students in the intervention classes will receive an educational session utilising the Sunface facial ageing app.'

Page 14

There is limited information on the recruitment process. What is the approach to schools mail/telephone invitation, scheduling considerations/timelines? Will reasons for non-participation be recorded?

Page 15

Line 16. Include the reference to the guidelines e.g. <http://ieaweb.org/good-epidemiological-practice-gep/>

Page 16

Lines 36-38. How will any group differences in student characteristics at baseline be used in the main analysis? Specifically, randomisation is considered to be better than any post hoc adjustment for group differences – so how do you plan to use these findings e.g. is it in the secondary analyses.

Line 41. Why is there an analysis of smoking prevalence? Is this a joint smoking and sun protection intervention using the aging app? If yes, this should be described in the paper.

Lines 45-52. Is the 'main' analysis the 'primary' analysis? i.e. should this describe within group changes in the primary outcome variable daily sunscreen use in the past 30 days?

Lines 52-57. Describe how/what additional sun protection behaviours and early detection behaviours (secondary measures) will be analysed.

Lines 57-59. Delete 'the newest version of'

Page 17

Lines 10-12. Reduce the repetition in this sentence.

Discussion

Page 17

Line 23. First 'randomised controlled' trial...

Line 23. Although this is the first trial using medical students other studies have involved clinicians in delivering skin cancer prevention education to children and adolescents e.g. (i). Norman GJ, et al. A randomized trial of a multicomponent intervention for adolescent sun protection behaviors. Arch Pediatr Adolesc Med. 2007

Feb;161(2):146-52. (ii). Olson AL et al. SunSafe in the Middle School Years: a community-wide intervention to change early-adolescent sun protection. Pediatrics. 2007 Jan;119(1):e247-56.

Line 38. This sentence is somewhat repetitive (from introduction).

Lines 55-59. Do you mean to say here that other vectors could be tested in future studies?

Page 18

Lines 11-31. This is a useful comment on the theory for the expected intervention effects. However, discussion of the role of perceived susceptibility of skin cancer and the Health Belief Model would also be relevant for this intervention.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Matthew Winslade

Institution and Country: Charles Sturt University, Australia

Please state any competing interests: None declared

Please leave your comments for the authors below

This is an engaging study and one that has many merits and when the study is complete will add to the much needed global knowledge base of sun safe behaviours and adolescents. I have included a number of small suggestions and comments in the review and a number of questions to consider.

Please find review

Comment: Thank you for the opportunity to review the manuscript; A skin cancer prevention photo aging intervention for secondary schools in Brazil delivered by medical students: Randomised control trial – study protocol.

This was a well-constructed informative protocol paper and the associated study has the potential to add to the growing body of literature relating to the partnership between health agencies and schools in relation to tackling global concern surrounding skin cancer. By providing a regionally specific focus this research will serve as a catalyst for other regions (such as Australia and New Zealand) to follow suit and establish similar procedures. The use of engaging stimulus materials (apps and smartphone /tablets) aimed at adolescent participants (selfies) is a novel and effective approach.

Reply: Thank you for your encouraging feedback which is highly appreciated by the whole group.

Abstract: Just for consideration of author, the term subjects is used on line 31 whereas on page 16 the term students is used, it may be confusing for international readers using both the terms classes and subjects in close proximity.

Reply: We replaced the word “subjects” with “students” in the Abstract.

Comment: Perhaps expanding acronym ABCDE rule might be of benefit for the reader (also in outcomes section of paper on page 15)

Reply: We agree, but the Abstract is limited to 300 words so we can not add this in the Abstract but provided an explanation in the Outcomes section of the manuscript as you suggested.

Introduction: This section is informative and well-constructed and provides a good rationale for the regional context of the proposed study. The double pronged themes linked to school students and medical students as role models is to be commended.

Reply: Thank you for your encouraging feedback which we highly appreciate.

Comment: For consideration, the claim of melanoma as the most common cancer for young adults is linked to a single 2011 reference – is there any other corroborating evidence that can be included here? For example Weir et al. (2011) list invasive melanoma as the third most common cancer in young adults in the United States. Perhaps one of the most common cancers in Young Adults? Or provide evidence to suggest this is localised to the specific region of the study.

Reply: Thank you for your insightful comment. As the data on prevalence is scarce (especially for our specific region) we attenuated the statement to “one of the most common cancers in young adults” as suggested.

Participants: For consideration of author, what level of approval is needed to conduct research in schools in Itauna? Has this already been solicited? For example is approval needed only at a school level or must it be granted by an association or higher educational authority? The study aims to recruit a significant number of students and classes and will cause some disruption to the normal school routine.

Reply: The procedure to obtain ethical consent and to be allowed to conduct the study in schools of Itauna is comparable to the procedure in Germany and is already performed. The following is obtained: Ethics approval by the ethics committee of the conducting University, approval of the schools one wants to conduct the intervention in and consent participants. In Itauna, we also had to involve the Department of Education of the City Hall of Itauna which also approved the study.

Procedure /Discussion: The project has been well thought and conceptually addresses the issues and research questions raised. The outlined procedure supports the notion of internal consistency of adopting a modified approach and recognising factor analysis to ensure factors are correlational. The use of Theory of Planned Behaviour makes for an appropriate and informed theoretical discussion. It is noted that ethics approval has been obtained and that the trial has been registered. Is there an accompanying ethics number available?

Reply: Should we add this number to the manuscript as well? We thought that CT registration number would be enough.

Comment: Is there any funding to be declared for the study?

Reply: The used tablets are funded by the Young Research Award from La Fondation La Roche Posay that has been awarded to Titus J. Brinker for his research on the Surface App (funding was not fully clear when the protocol was submitted initially). We added a funding section to the manuscript.

Conclusion: I agree with the authors that this is a novel approach integrating RCT and photo aging to engage adolescents in a valuable research study.

Reply: Thank you for your encouraging feedback which we highly appreciate.

References:

Please check reference details for consistency throughout reference list
For example, reference 1 capitalisation of Journal title

Reply: Thank you for your comment. We edited the references for consistency.

Reviewer: 2

Reviewer Name: Dr Veronique Bataille

Institution and Country: West Herts NHS Trust

Please state any competing interests: No conflict of interest

Please leave your comments for the authors below

This paper does not present any results at all and just the outline of what appear to a grant proposal. The authors need to submit the paper when the results are through next year

Reply: Dear Dr. Bataille, we submitted a study protocol, not a research paper. Study protocols do not present any results.

Reviewer: 3

Reviewer Name: W. Clark Lambert, MD, PhD

Institution and Country: Rutgers-New Jersey Medical School, Newark, NJ, USA

Please state any competing interests: None

Please leave your comments for the authors below

Comment: This is an excellent study that should produce meaningful results. I suggest being as specific as possible regarding the computer program used to generate these images. Also it is possible that some students may doubt the validity of the photographs of expected alterations and this should be noted in the limitations. Otherwise, I can find no flaws. It would be useful to use this or a related program for similar studies in other countries.

Reply: Thank you for your encouraging feedback which we highly appreciate.

Reviewer: 4

Reviewer Name: Suzanne Dobbison

Institution and Country: Cancer Council Victoria, Australia

Please state any competing interests: None declared

Please leave your comments for the authors below

BMJ Open

A skin cancer prevention photoaging intervention for secondary schools in Brazil delivered by medical students: randomized controlled trial – study protocol

Comment: This paper describes the protocol for a randomized trial of a photaging intervention to be implemented in secondary schools in Brazil to impact daily sunscreen use of students. The proposed intervention is novel in terms of its delivery via an app and mirroring in the class setting for skin cancer prevention. Aging software has been used in one UK study targeting young women's perceived susceptibility to skin cancer and their sun protection intentions, while the use of photography to portray future sun-related skin damage/lesions on sunscreen use has also been found to be effective (Novick, Cutis 1997). Medical students are to be trained to deliver the proposed intervention, which has the potential to influence their sun protection behaviour as well but this is not to be evaluated in the proposed study. This is somewhat surprising given this appears to be a rationale for the long-term goals of the study, as indicated by including it in the strengths and limitations section (Page 7, line 16).

Reply: Thank you for your insightful review which is highly appreciated. We also want to congratulate you on your remarkable publication record on the matter and feel very humbled that you spent so much time in reviewing our paper. In this specific study, we focus on the effect on the adolescents. However, we felt it would be appropriate to discuss potential benefits for the health educators.

Comment: The proposed study has the potential to provide an important contribution to understanding the role of interactive educational apps in conveying risk of future skin damage, lesions and cancer to impact daily sunscreen use of adolescents. Although the writing for the paper is generally clear, the rationale and methods are difficult to follow at times due mainly to the order in which various components are introduced. To better introduce the rationale for the study the introduction could be structured to 1 identify the disease and extent of the problem in Brazil, 2 discuss what successful

interventions have been implemented with the target group and reasons for the choice of the current intervention and stating the aims/hypotheses.

Reply: Thank you for your feedback which is highly appreciated. However, we spent a lot of time to write the introduction in a way that engages the reader. Reviewer 1 has commended this. The Methods section follows the SPIRIT protocol as requested by BMJ Open.

The introduction does describe a range of relevant studies, while there are gaps in reporting of successful interventions for promoting sun protection among adolescents the review paper is adequate for the scope of this study. However, the paper would benefit from referencing some of the theoretical models of tanning and sun protective behaviors in the introduction. Another element for consideration is whether sun protection alone should be the goal given the acknowledged tanning/overexposure of the population in Brazil. Assessing the impact of the intervention on tanning behaviour (as well as daily sunscreen use) would be useful given that the app focuses on weekly tanning. It therefore seems logical to consider this as a secondary outcome measure.

Reply: We added this as a secondary outcome.

Comment: The aging app itself does seem to provide extreme/unrealistic 25 year outcomes which may impact the credibility of the messages. Given the images seem much worse than the 35-40 year olds most people are familiar with in daily life. Possibly people would have treatment for these lesions before they reached this stage. It would be helpful to include a few sentences on the rationale for presenting the exaggerated examples in the app and any disclaimers about the scenarios to be explained to students.

Reply: As Dermatologists, we see the patients that will not go out on the street / in public because they feel ashamed of the condition of their skin. From a clinician perspective, these images are very realistic. From a citizen perspective, they might be not because severe cases do not expose themselves to the public very often.

Comment: It would also be useful to provide some further details on the statistical analysis.

Reply: We provided as much detail as possible at this stage and adhered to the SPIRIT protocol. If you have anything specific in mind, please let us know.

Comment: The figures are clear and very useful.

Reply: Thank you!

Specific issues

Comment: Title

The title should highlight that secondary school students are the target of the intervention.

Reply: In our view, the title does that already. One would have an unnecessary doubling of the word "students" otherwise. This is our sixth school-based study in secondary schools and they all use this wording (and other articles in the field appear to follow this wording as well).

Comment: Abstract

Line 12. What is it 'comparably low' to?

Reply: ..to the worldwide rates. However, the word limit is 300, this is why we were not able to put that down (we already reached 300). We omitted the word “comparably”.

Comment: Methods and analysis – replace ‘subjects’ with ‘students’

Reply: Thank you, we agree and changed it for consistency.

Comment: Line 35. ‘45 minutes’ should be in a ‘45-minute’ classroom seminar

Reply: We are no native speakers, so thank you for your advice which we are happy to follow. We also hired a copyeditor after receiving the decision for “major revision” and believe that most of your comments below have been addressed by the copyeditor.

Comment: Line 35. The description of the intervention is ambiguous/unclear.

Reply: We only have 300 words (which we fully use) and tried to be as specific as possible. Please let us know if you have any specific wishes.

Comment: Line 53. Do you mean ‘group’ difference of daily sunscreen use...

Reply: Yes, we changed the wording as suggested.

Comment: Page 7. Strengths and limitations

It is unclear what is meant by ‘sensitizing prospective physicians for the importance of skin cancer is mandatory.’ The methods do not assess the impact of the intervention on medical students.

Reply: We omitted the sentence.

Comment: Page 7-8 Lines 52 to 14 – move after the paragraph on Brazil (Page 8).

Reply: Thank you, we did that.

Comment: Page 8.

Line 28-29 ‘first country to forbid’ word usage – should this be the government introduced laws to forbid indoor tanning? Also was this commercial and self-owned indoor tanning equipment?

Reply: Please see changes made by the copyeditor. Indoor tanning was banned completely.

Comment: Line 33 ‘European ethnicity and therefore has’ – use ‘ancestry’ not ‘ethnicity’. Also this is insufficient justification for the incidence of melanoma. Suggest adding ‘and given their sun-loving culture’...therefore.

Reply: We changed it to ancestry. However, we already explain in the same paragraph that “tanning is culturally established and Brazilians are used to unprotected overexposure to sun” and therefore, we will not add this again because it makes the paper less concise. That UV causes melanoma is already explained earlier.

Comment: Line 47. ‘had already had sunburns in the past’ ‘had past sunburn(s).
Page 9.

Reply: Thank you, we edited it accordingly.

Comment: Lines 26-28. Repeats earlier.

Reply: We do not understand what you mean here.

Comment: Lines 29-35. Are these studies relevant given there is some evidence of its utility for skin cancer prevention? The shift to obesity and tobacco is a bit distracting here.

Reply: We do think they are, as the literature on photoaging interventions in skin cancer prevention is still very slim.

Comment: Line 42. The details of mean age seem unnecessary, the study population could be described as 'young women' rather than 'young females'.

Reply: We changed it accordingly.

Comment: Line 46-47. It seems a stretch to claim such a small study as 'effective' -revise...'showed promising reduction in their tanning intentions'.

Reply: We fully agree and changed it according to your suggestion.

Comment: Page 10.

Line 13. 'weekly sunbed' – figures 1-4 show the app describes this as 'weekly tanning'.

Reply: Correct, we changed it accordingly.

Comment: Line 13. 'altered face 5-25 years' – revise to: 5 years and also 25 years into the future.

Reply: This would not be correct, as the app does 5, 10, 15, 20 and 25 year predictions.

Comment: Line 20. 'odds ratio' is this increased risk of melanoma with weekly tanning and sue of sun protection?

Response: Yes, correct, it roughly estimates the odds ratio based on UV-behavior (the three categories shown in the app).

Comment: Line 22. This sentence is incomplete.

Reply: Yes, we corrected this.

Comment: Line 32. It is unclear how the students will be able to share the app with their family and friends if it is on a tablet they don't own and potentially won't have access to their email from the tablet to send it.

Reply: Correct, but the medical students can send it to them if they wish. Also, this is a general description of the app functionality.

Comment: Line 39. 'learn about the app' – learn about the benefits of using the app

Reply: We changed it accordingly.

Comment: Line 53. It would be useful to add a sentence on what basis the extrapolations were made and also whether they are realistic or not.

Reply: We added a sentence.

Comment: Line 21. The use of the theory of planned behaviour for development of the intervention should be introduced earlier.

Reply: We felt that it would make the paper less concise. Also, we feel that the theory of planned behavior is a good theoretical framework for our intervention, however, it was designed purely based on the fact that adolescents love smartphones, selfies and are focused on their own appearance (more than on their health) – we did not use the TPB to develop it.

Comment: Page 11-12 Study design

Page 11, Lines 32-35: Is it appropriate to call this a superiority trial, given only the intervention group receive a treatment?

Reply: Yes, as our intervention would be superior to standard education.

Comment: Lines 39-43. The limitations of randomising classes to intervention and control within the same school are described, however, it should be clearer how clustering will be accounted for in the analysis section.

The risk of contamination of the intervention effect via students discussing their experiences with students from other class-rooms cannot be overcome. Is there a rationale for why individual schools could not be randomised to control or intervention group?

Reply: Yes, it is just not doable as there are not enough schools in Itauna to have a realistic number of clusters from a sample size stand point. While we agree that clustering is the main limitation of our study (and clearly point that out in our discussion section), the class setting is our best chance to test for realistic intervention effects. The ICC has been calculated and is discussed in the sample size calculation section.

Comment: The other weakness is in having teachers deliver the surveys, given students may feel their answers may be less confidential and this should be acknowledged in discussing limitations of the study outcomes.

Conducting the intervention immediately after the baseline survey will reduce generalisability if the survey has an effect? If there was a short gap of a week the survey may have less influence on the response to the intervention and improved generalisability.

Reply: There appears to be a misunderstanding (due to language problems) – the survey is supervised by the teachers, but conducted by externally trained data collectors (students from Itauna who are not involved in the conduction of the intervention) – we made this more clear in the manuscript. We agree that the baseline survey should be one week or more away from the intervention and changed this in the manuscript.

Comment: Lines 52-55: It would assist readers to more clearly describe the intervention in this sentence; e.g. 'students in the intervention classes will receive an educational session utilising the Sunface facial ageing app.'

Reply: We added your suggestion as an introduction sentence to the Intervention section.

Comment: Page 14

There is limited information on the recruitment process. What is the approach to schools mail/telephone invitation, scheduling considerations/timelines? Will reasons for non-participation be recorded?

Reply: Reasons for non-participation are not recorded. The schools are recruited via E-Mail, telephone and personal appointment (in most cases with the principal). We added this information in the manuscript.

Comment: Page 15

Line 16. Include the reference to the guidelines e.g. <http://ieaweb.org/good-epidemiological-practice-gep/>

Reply: We referenced the German GEP guidelines we used.

Comment: Page 16

Lines 36-38. How will any group differences in student characteristics at baseline be used in the main analysis? Specifically, randomisation is considered to be better than any post hoc adjustment for group differences – so how do you plan to use these findings e.g. is it in the secondary analyses.

Reply: In a secondary analysis the baseline differences would be taken into account (i.e. differences of differences analysis). However, we do not suspect this to occur as randomization should omit any relevant baseline differences.

Comment: Line 41. Why is there an analysis of smoking prevalence? Is this a joint smoking and sun protection intervention using the aging app? If yes, this should be described in the paper.

Reply: Sorry, this was a mistake that we corrected to “To test for differences in baseline and follow-up daily sunscreen use in the past 30 days between groups, we will use a cluster-adjusted Mantel-Haenszel χ^2 test[63] at a significance level of 5% (two-sided).”

Comment: Lines 45-52. Is the ‘main’ analysis the ‘primary’ analysis? i.e. should this describe within group changes in the primary outcome variable daily sunscreen use in the past 30 days?

Reply: Yes, correct.

Comment: Lines 52-57. Describe how/what additional sun protection behaviours and early detection behaviours (secondary measures) will be analysed.

Comment: Lines 57-59. Delete ‘the newest version of’

Reply: We did that.

Comment: Page 17

Lines 10-12. Reduce the repetition in this sentence.

Reply: We changed it to “Dropouts (essentially participants who withdraw consent for continued follow-up or who are missing in the classroom during the survey) will be included in the analysis and multiple imputation will be used to estimate treatment effect [64].”

Discussion

Page 17

Line 23. First ‘randomised controlled’ trial...

Line 23. Although this is the first trial using medical students other studies have involved clinicians in delivering skin cancer prevention education to children and adolescents e.g. (i). Norman GJ, et al. A randomized trial of a multicomponent intervention for adolescent sun protection behaviors. Arch Pediatr Adolesc Med. 2007 Feb;161(2):146-52. (ii). Olson AL et al. SunSafe in the Middle School Years: a community-wide intervention to change early-adolescent sun protection. Pediatrics. 2007 Jan;119(1):e247-56.

Reply: Yes, but it is the first study involving medical students.

Comment: Line 38. This sentence is somewhat repetitive (from introduction).

Reply: We deleted it.

Comment: Lines 55-59. Do you mean to say here that other vectors could be tested in future studies?

Reply: Yes. We hope you like the wording better with the copyeditor having done his work,

Comment: Page 18

Lines 11-31. This is a useful comment on the theory for the expected intervention effects. However, discussion of the role of perceived susceptibility of skin cancer and the Health Belief Model would also be relevant for this intervention.

Reply: We agree, but we chose the TPB as our model of choice for discussion (as there are many models that potentially fit, we thought it is best to pick one.

Again, thank you for your valuable time and your insightful comments which we highly appreciate and helped us to improve our manuscript.

VERSION 2 – REVIEW

| | |
|------------------------|--------------------------------------------------------------|
| REVIEWER | Dr Matthew Winslade Charles Sturt University Australia |
| REVIEW RETURNED | 19-Nov-2017 |

| | |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GENERAL COMMENTS | This is the second review of this particular study protocol paper and as such I am happy that my original concerns have been addressed. I wish the authors the best of luck with their study and look forward to reading the results of their research. |
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| | |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| REVIEWER | W. CLARK LAMBERT, MD,PhD RUTGERS-NEW JERSEY MEDICAL SCHOOL MSB ROOM H576 185 SOUTH ORANGE AVENUE NEWARK, NJ USA |
| REVIEW RETURNED | 17-Nov-2017 |

| | |
|-------------------------|-----------------------------------------------|
| GENERAL COMMENTS | EXCELLENT STUDY AND I CONGRATULATE YOU ON IT. |
|-------------------------|-----------------------------------------------|

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|-----------------|-----------------------------------------------------------|
| REVIEWER | Suzanne Dobbison Cancer Council Victoria, Australia |
|-----------------|-----------------------------------------------------------|

GENERAL COMMENTS

There was a problem opening the multimedia files.

I have only minor comments to improve clarity.

1. “Unhealthy behavior in regards of UV exposure is mostly initiated in early adolescence [7], often with the idea that a tan increases attractiveness [8-10]; the problems related to melanoma and skin atrophy are too far in the future to fathom.”

This sentence is not clear/ambiguous because ‘in regards of’ is not grammatically correct/common usage. I suggest replacing this with more commonly used terms: ‘with respect to’, ‘pertaining to’, ‘concerning’. Also, what do you mean by ‘often’ here? Do you mean ‘commonly’ i.e. a lot of people have risky UV exposure behaviour; or is it people frequently believe that a tan increases their attractiveness? Similarly, ‘idea’ seems an unusual term to use, in the psychology and public health literature the term ‘beliefs’ are more commonly used. One last issue is the punctuation and grammar. I suggest removing the semi-colon and replacing it with ‘and’.

2. “In addition, the success of appearance-based photoaging interventions, in which an image is altered to predict future appearance in the fields of tobacco and adiposity prevention, shows promise for these interventions in behavioral change settings [45-50].”

This sentence is also a little ambiguous and requires improvement for clarity. I believe the authors are referring to interventions using digital app technology here, as there are other studies on the effects of altering images to promote sunscreen use.

Mahler HI, Kulik JA, Harrell J, Correa A, Gibbons FX, Gerrard M. Effects of UV photographs, photoaging information, and use of sunless tanning lotion on sun protection behaviors. Arch Dermatol. 2005 Mar;141(3):373-80.

Novick M. To burn or not to burn: use of computer-enhanced stimuli to encourage application of sunscreens. Cutis. 1997 Aug;60(2):105-8.

3. “Students can interact with their own animated face via touch (sneezing, coughing, etc.; see Multimedia Appendix 1).” I agree that the reference to coughing and sneezing is confusing and should be deleted.

4. “Although multiple studies have shown that skin cancer risk is predominantly associated with sun exposure early in life, there is a lack of awareness regarding risk groups.”

The second claim in this sentence appears to be incorrect. There are many studies examining risk of melanoma by phenotype, hair colour, eye colour, family history etc and it is unclear what the authors mean.

5. “According to the theory of planned behavior (TPB), the subjective norm and the expected self-efficacy of the participants play a substantial role in their resulting behavior: What do their peers think about tanning? Is the result of tanning regarded as attractive and does it therefore increase one’s chances of finding a boy/girlfriend?”

Before the : Insert ‘For example:’

6. The claims to ‘first RCT to...’ were made both in the opening paragraph of the discussion and in the summing up at the end of the limitations section. I think it only needs to be stated once.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 3

Reviewer Name: W. CLARK LAMBERT, MD, PhD

Institution and Country: RUTGERS-NEW JERSEY MEDICAL SCHOOL, MSB ROOM H576, 185
SOUTH ORANGE AVENUE
NEWARK, NJ, USA

Please state any competing interests: NONE

Please leave your comments for the authors below

Comment: EXCELLENT STUDY AND I CONGRATULATE YOU ON IT.

Reply: Thank you!

Reviewer: 1

Reviewer Name: Dr Matthew Winslade

Institution and Country: Charles Sturt University, Australia

Please state any competing interests: None declared

Please leave your comments for the authors below

Comment: This is the second review of this particular study protocol paper and as such I am happy that my original concerns have been addressed. I wish the authors the best of luck with their study and look forward to reading the results of their research.

Reply: Thank you!

Reviewer: 4

Reviewer Name: Suzanne Dobbinson

Institution and Country: Cancer Council Victoria, Australia

Please state any competing interests: None declared

Please leave your comments for the authors below

Comment: I have only minor comments to improve clarity as per the attached file.

Reply: Thank you. We implemented all the suggested changes.