

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

TITLE (PROVISIONAL)	Total skin self-examination at home for people treated for cutaneous melanoma: development and pilot of a digital intervention.
AUTHORS	Murchie, Peter; Allan, Julia; Brant, William; Dennis, Matthew; Hall, Susan; Masthoff, Judith; Walter, Fiona; Johnston, Marie

VERSION 1 - REVIEW

REVIEWER	Monika Janda Queensland University of Technology
REVIEW RETURNED	31-Mar-2015

GENERAL COMMENTS	<p>This is a detailed report on the development and pilot testing of an electronically facilitated intervention for patients with melanoma to engage in monthly total-body skin self-examination. The authors make a good case for the need for such an intervention, and have employed theoretical behavioral models to develop it. They then innovatively tested the intervention first in a laboratory setting using actors, followed by a subsequent pilot with 20 patients in their homes.</p> <p>Some comments: page 7 overview could probably be deleted as subsequent pages describe the four steps A-D in greater detail, or alternatively overview can be kept and detailed description A-C moved to appendix.</p> <p>The pilot study (step D): some more details should be reported of important markers of feasibility:</p> <p>Page 14, last paragraph: How many patients were approached by the GPs for the 20 recruited? What are their demographic and clinical characteristics and were they about similar to those expected to be recruited for the main study? In the larger study would all participants also be given the tablet? How will this influence the potential for translatability into practice in the future? What would be the control group in the larger study and was this also pilot tested? Why did 4 (20%) of the participants not complete the questionnaires? How much missing data was on the remainder of the questionnaires? An important feasibility issue is whether the intervention led to increases in anxiety? In Table 2, it's unclear what the numbers stand for is 5 for example the number of body areas examined? It would not be number of checks, because the participants were asked to do one check per month?</p>
-------------------------	--

REVIEWER	Adina Coroiu and Annett Korner McGill University, Montreal Canada
REVIEW RETURNED	21-Apr-2015

GENERAL COMMENTS	<p>Bmjopen-2015-007993: Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.</p> <p>This manuscript summarizes four different stages of a project aimed at developing and pilot testing a self-administered intervention (ASICA) to prompt, support, and respond to total skin self-examinations (TSSE) among individuals already diagnosed with melanoma. The first included phase encompasses a systematic review and qualitative interviews reporting on the use of technology to support self-monitoring interventions. The second phase encompasses the selection of a theoretical framework for the intervention. The third phase covers the simulation and preliminary testing of the components of the intervention in isolation. The 4th and last phase constitutes the pilot testing of the newly developed intervention in 20 melanoma patients. The authors concluded that ASICA is a feasible and acceptable intervention with high potential to improve the rates of TSSE among melanoma patients and they recommend future more rigorous testing via a randomized control trial.</p> <p>Major Comments:</p> <ol style="list-style-type: none"> 1) We are wondering if this manuscript would make a stronger point if it primarily focused on the last two phases, C (simulation) and D (pilot testing), with phase B conceptualized as a background section. Points #2 and #3 below relate closely to this point. 2) The title and the abstract seem somewhat disconnected. While the title hints at the development and preliminary testing of an intervention, the abstract almost exclusively focuses on the pilot testing results. We encourage the authors to clearly capture the manuscript goals in the title and to transparently address/report all goals in the abstract. 3) The abstract in its current form (e.g., primary and secondary outcomes) does not reflect all the stages of this project. Authors should revise the abstract to accurately describe all the components of this complex intervention (i.e., each stage of the project) so that every stage of the project covered throughout the manuscript is also referred to in the abstract. Alternatively, if the authors decide to focus their manuscript on stages C and D, as suggested at point #1 above, they could revise the abstract accordingly. 4) The information currently included in the “Article Summary” is more appropriate for an “Abstract” and should be incorporated accordingly. Similarly, the Overview on page 7 also reads like an abstract. Authors should integrate these sections of their manuscript, which will improve overall readability. 5) The introduction could be more precisely referenced: in more than one occasion second hand citations are used instead of source articles. For example, on page 5, the second paragraph reports results from a study conducted by Berwick et al., 1996. Yet, the
-------------------------	---

	<p>citations (#4 and 5) refer to studies that have cited the Berwick paper (citation # 7).</p> <p>6) The current method section reports on project stages A through D. Given that the results of the systematic review were reported in a separate publication (citation #23), this should be stated in the current manuscript (e.g., The methodology and results of this systematic review were reported in detail elsewhere [cite]). Same comment applies to the methodology and findings pertaining to the qualitative interviews. Such statements about previously published data would improve the quality of this manuscript and are indicative of the rigorous methodology involved in the development and testing of the TSSE complex intervention.</p> <p>7) Section B starting on page 9: The rationale for the selection of the theoretical model (paragraph one) could be summarized in a more succinct manner. The claims about the needed components of the intervention under development should be referenced properly, as currently, this paragraph reads like an informal text. For example, if these decisions were reached by consensus or drawn from the qualitative interviews, this should be clearly stated.</p> <p>8) The three theoretical models that guided the development of the intervention (IMB, Control Theory; Implementation Intentions) require proper citation and more detail, e.g., main theoretical components [cite source for the model], key outcomes previously used in studies using these models [cite studies using this model], etc. It is somewhat unclear what the direct link is between the three theoretical models (cited above) and the actual intervention components (cue to action; instructional video; the skin map; the report sent to professionals) and this requires further clarification.</p> <p>9) The pilot testing of the intervention: feasibility and acceptability. It is unclear whether the data analyses were planned (if any) a priori for the quantitative or qualitative portions of the pilot testing. The authors should transparently report the methodology employed, the pilot goals and the planned analyses to address each goal. Given that this is a pilot, it is appropriate that no hypotheses be set or tested.</p> <p>10) The discussion should focus almost exclusively on the findings reported in this manuscript and limit as much as possible the reporting of findings previously published.</p> <p>11) Finally, we believe that using paragraph form throughout the manuscript instead of point format would increase the readability of the manuscript.</p> <p>Last, we want to congratulate this team for taking up such a challenging project and want to thank them for sharing their preliminary results and methodology with the wider academic community. Projects like this are invaluable pieces of research in the field of melanoma prevention. We also want to wish this team good luck with testing the newly developed intervention further.</p> <p>The reviewer also provided a marked copy with detailed comments. Please contact the publisher for full information about it.</p>
--	---

Reviewer: Janda

1. Page 7 overview could probably be deleted as subsequent pages describe the four steps A-D in greater detail, or alternatively overview can be kept and detailed description A-C moved to appendix.

We accept the reviewers' point that the overview may appear slightly repetitious. However, we have used this same structure in a previous BMJ Open paper describing how we developed a complex intervention. We believe it is useful for the reader of the full article to be given a high-level summary of the whole process at the beginning in a way that a brief abstract would not permit. We believe this is effective, and that the following more detailed sections, give a thorough sense of the iterative phases we worked through to develop our intervention. We would, of course, appreciate the editor's steer but we worked hard to narrate our work within the 5,000 word limit and believe we have been successful in doing so. We would be reluctant to alter the structure of the article at this stage.

2. How many patients were approached by the GPs for the 20 recruited?

In fact together the six study GPs together approached 20 potential participants all of whom agreed to take part in the study with, as far as we are aware, no refusals. As described, one participant agreed to take part, but subsequently withdrew.

3. What are their demographic and clinical characteristics and were they about similar to those expected to be recruited for the main study?

We have supplied relevant demographic characteristics in table 1. Inclusion criteria were pre-specified before recruitment of the pilot participants began. All participants had completed initial treatment for stage 0-2C cutaneous melanoma. This is the same group who will be recruited to subsequent planned randomised trials of the ASICA intervention.

4. In the larger study would all participants also be given the tablet? How will this influence the potential for translatability into practice in the future?

These are both excellent points which have not been raised or discussed within the manuscript but will be addressed in future trials of the ASICA intervention. We anticipate that a future phase II trial will issue a tablet to all participants. However, subsequent wide-scale implementation will likely be easier if the app component of the ASICA intervention can be made available on a variety of digital platforms, from which participants can self-select the most suitable for themselves. We acknowledge that they are key points but believe they are beyond the scope of the current manuscript and have elected not to discuss them here. We hope this is acceptable.

5. What would be the control group in the larger study and was this also pilot tested?

The reviewer raises an excellent point. We have not commented specifically on this within the manuscript since which we currently carefully considering this very challenging issue as we prepare and application to fund a phase II randomised trial of the ASICA intervention.

6. Why did 4 (20%) of the participants not complete the questionnaires?

We cannot comment on this specifically. Four participants did not return an outcome questionnaire despite a postal reminder, but we do not have data on the specific reasons for this.

7. An important feasibility issue is whether the intervention led to increases in anxiety?

We agree completely. With the caveat that only 16 participants completed baseline and outcome questionnaires, we found no significant differences between baseline and outcome questionnaires in measures of anxiety, depression and cancer worry.

In the final paragraph of the results section (page 18) we state: “No significant changes were observed between baseline and outcome in anxiety, depression or cancer worry.”

8. In Table 2, it's unclear what the numbers stand for is 5 for example the number of body areas examined? It would not be number of checks, because the participants were asked to do one check per month?

We have made table 2 clearer by changing the appropriate column headings to “Number of body areas checked.”

Reviewer: Coroiu and Korner

1) We are wondering if this manuscript would make a stronger point if it primarily focused on the last two phases, C (simulation) and D (pilot testing), with phase B conceptualized as a background section. Points #2 and #3 below relate closely to this point.

We respectfully disagree with this point, and would ask the editor to adjudicate. We are describing the development of a complex healthcare intervention. We are strongly of the view that this process should be reported in its entirety and that this accords with guidance on how complex intervention development should be described. We feel the article would be significantly lacking if the reader was not given a sense of how we arrived at a position of believing that it was necessary, desirable to patients and offered the real prospect of benefit.

2) The title and the abstract seem somewhat disconnected. While the title hints at the development and preliminary testing of an intervention, the abstract almost exclusively focuses on the pilot testing results. We encourage the authors to clearly capture the manuscript goals in the title and to transparently address/report all goals in the abstract.

We agree with this point. We closely followed the stipulated structure for authors in preparing our abstract and agree that it may read as somewhat disconnected. We have, therefore, prepared and included an alternative abstract which we believe provides a more thorough representation of the whole of our work. We would appreciate the editor's advice on which version of the abstract should be included.

3) The abstract in its current form (e.g., primary and secondary outcomes) does not reflect all the stages of this project. Authors should revise the abstract to accurately describe all the components of this complex intervention (i.e., each stage of the project) so that every stage of the project covered throughout the manuscript is also referred to in the abstract. Alternatively, if the authors decide to focus their manuscript on stages C and D, as suggested at point #1 above, they could revise the abstract accordingly.

We agree and refer the reviewers to the previous point and to our alternative abstract now included in the manuscript.

4) The information currently included in the “Article Summary” is more appropriate for an “Abstract” and should be incorporated accordingly. Similarly, the Overview on page 7 also reads like an abstract. Authors should integrate these sections of their manuscript, which will improve overall readability.

We agree with the reviewers and hope our alternative abstract also addresses this concern. We

would also refer these reviewers to our response to point 1 from reviewer 1 as to why we believe our overview, as currently presented is important. We would also point out that the “Article Summary” is a section distinct from the abstract and specifically requested by BMJ Open in its guidance for authors.

5) The introduction could be more precisely referenced: in more than one occasion second hand citations are used instead of source articles. For example, on page 5, the second paragraph reports results from a study conducted by Berwick et al., 1996. Yet, the citations (#4 and 5) refer to studies that have cited the Berwick paper (citation # 7).

We apologise for this oversight. References 4 and 5 support our contention that regular TSSE could result in improved survival for people previously treated for cutaneous melanoma. The reviewers point out that the potential 63% in reduction comes from the paper by Berwick et al. It has moved up the citation list to 6 and is now specifically cited here.

6) The current method section reports on project stages A through D. Given that the results of the systematic review were reported in a separate publication (citation #23), this should be stated in the current manuscript (e.g., The methodology and results of this systematic review were reported in detail elsewhere [cite]). Same comment applies to the methodology and findings pertaining to the qualitative interviews. Such statements about previously published data would improve the quality of this manuscript and are indicative of the rigorous methodology involved in the development and testing of the TSSE complex intervention.

The reviewers raise a good point about assuring rigour. We have added three appropriate statements, as suggested, to the three references to which it applies. These are all in the first paragraph of section A.

7) Section B starting on page 9: The rationale for the selection of the theoretical model (paragraph one) could be summarized in a more succinct manner. The claims about the needed components of the intervention under development should be referenced properly, as currently, this paragraph reads like an informal text. For example, if these decisions were reached by consensus or drawn from the qualitative interviews, this should be clearly stated.

We agree that this section and the process followed could be clearer. First, the chief investigator (PM) conceptualized the aims, processes and outcomes that the digital intervention should achieve. This has now been expressed more succinctly as recommended by the reviewers. This acted as the starting point and the final theoretical intervention was produced after three consensus meetings amongst the whole research team, a process informed by the results of the qualitative interviews. We have restructured the section to reflect this and hope it is now clearer.

8) The three theoretical models that guided the development of the intervention (IMB, Control Theory; Implementation Intentions) require proper citation and more detail, e.g., main theoretical components [cite source for the model], key outcomes previously used in studies using these models [cite studies using this model], etc. It is somewhat unclear what the direct link is between the three theoretical models (cited above) and the actual intervention components (cue to action; instructional video; the skin map; the report sent to professionals) and this requires further clarification.

We thank the reviewer for this point. We have extensively revised our manuscript to, specifically our overview and section B to take account of the reviewers comment. We hope we have improved the manuscript and provide greater clarity.

9) The pilot testing of the intervention: feasibility and acceptability. It is unclear whether the data analyses were planned (if any) a priori for the quantitative or qualitative portions of the pilot testing.

The authors should transparently report the methodology employed, the pilot goals and the planned analyses to address each goal. Given that this is a pilot, it is appropriate that no hypotheses be set or tested.

These are good points and we hope that we can provide clarity. The interviews were intended to capture the practical experiences of participants, with the aim of identifying practical strengths and weaknesses within the processes of the intervention that should be subsequently consolidated or improved. They were guided by a topic schedule, conducted by telephone and were recorded and transcribed for analysis and reflection upon by the research team.

We have captured this by adding the following paragraph to the manuscript:

At the conclusion of the pilot the project researcher SH contacted all participating patients and the overseeing clinical nurse specialist to conduct a brief telephone interview. These interviews aimed to capture the practical experiences and personal reflection of participants in the pilot study. They were conducted to identify participants' perceptions of strengths and weaknesses with the components, or the process and delivery of the intervention, so that subsequent improvements could be made. The interviews were guided by a topic schedule. Questions focused on patients' perceptions of the strengths and weakness of the ASICA application and how it had functioned. The interviewer also gathered information about how well the technical aspects of the intervention had worked from the nurse-specialist and patient perspective. The interviews were conducted by telephone and were recorded and transcribed for subsequent analysis and reflection by the research team.

The authors are correct that no a priori hypotheses were set or explored in the current project. We did, however, pilot a potential questionnaire for a subsequent randomized trial.

We have addressed this well-made point by adding the following paragraph to the section:

As this was a pilot study no apriori hypotheses were determined based on clinical or psychological outcomes. We did, however, ask participants to complete a questionnaire seeking information about clinical, behavioural and psychological outcomes to aid preparation for a subsequent clinical trial.

10) The discussion should focus almost exclusively on the findings reported in this manuscript and limit as much as possible the reporting of findings previously published.

We agree. We have deleted the first two sentences of our "Lessons learned from this study section" since they allude to the results of the systematic review and interviews of stage A which are not presented in this manuscript.

11) Finally, we believe that using paragraph form throughout the manuscript instead of point format would increase the readability of the manuscript.

We think the reviewers are referring to the way we have structured section A. We agree and have removed the bullet points and re-written the text as paragraphs.

VERSION 2 – REVIEW

REVIEWER	Annett Korner and Adina Coroiu McGill University, Canada
REVIEW RETURNED	04-Jun-2015

GENERAL COMMENTS	Bmjopen-2015-007993. R1: Digitally supported total skin self-
-------------------------	---

	<p>examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.</p> <p>The authors have addressed the vast majority of our comments and their manuscript is now in great shape. We agree with the authors' arguments for presenting all phases A through D in their manuscript to adequately capture the complexity of the current project. In the same vein, we believe that the alternative abstract is more appropriate.</p> <p>We only have one minor revision to suggest, which we think is easy to address, as it relates to our previous comment #5) The introduction could still benefit from improved referencing and as much as possible, evidence produced by teams other than the one involved in the current study could be used to support and/or substantiate the claims. We noticed that the first sentence, for example does not have a citation. The third sentence combines two pieces of information, yet only one source was cited. The fourth sentence states "many experts advocate...." yet only one citation was provided. Lastly, in the second paragraph, first sentence: three citations are provided which seemingly support the finding that skin self examination might result in 63% reduction in mortality, when in fact only Berwick et al 1996 reported such results. In order to avoid this finding being misinterpreted (i.e., comparable survival benefit found in more than one study), we suggest that the authors break down this sentence and cite their claims accordingly.</p> <p>Once these issues have been addressed we recommend that this manuscript be considered for publication, pending the editor's approval.</p>
--	---

VERSION 2 – AUTHOR RESPONSE

Bmjopen-2015-007993. R1: Digitally supported total skin self-examination at home for people treated for cutaneous melanoma: developing and simulating experience of the ASICA intervention.

The authors have addressed the vast majority of our comments and their manuscript is now in great shape. We agree with the authors' arguments for presenting all phases A through D in their manuscript to adequately capture the complexity of the current project. In the same vein, we believe that the alternative abstract is more appropriate.

We only have one minor revision to suggest, which we think is easy to address, as it relates to our previous comment #5) The introduction could still benefit from improved referencing and as much as possible, evidence produced by teams other than the one involved in the current study could be used to support and/or substantiate the claims. We noticed that the first sentence, for example does not have a citation. The third sentence combines two pieces of information, yet only one source was cited. The fourth sentence states "many experts advocate...." yet only one citation was provided. Lastly, in the second paragraph, first sentence: three citations are provided which seemingly support the finding that skin self examination might result in 63% reduction in mortality, when in fact only Berwick et al 1996 reported such results. In order to avoid this finding being misinterpreted (i.e., comparable survival benefit found in more than one study), we suggest that the authors break down this sentence and cite their claims accordingly.

Once these issues have been addressed we recommend that this manuscript be considered for publication, pending the editor's approval.