

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.
<b>AUTHORS</b>	Roux, Felicity; Burns, Sharyn; Chih, Hui; Hendriks, Jacqueline

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Youness EL ACHHAB Laboratory of Epidemiology, Faculty of Medicine and Pharmacy of Fez, Morocco CRMEF Fez-Meknes, Morocco
<b>REVIEW RETURNED</b>	19-Jul-2018

<b>GENERAL COMMENTS</b>	This manuscript is a very interesting topic focusing on developing a school-based ovulatory-menstrual health literacy program for adolescent females. It is well designed (triangulation) and presented. I would like to wonder if the intervention (program) will be delivered via Online or In-class. If in-class, this program/course will be integrated independently with regard to the curriculum or integrated into the health, physical education, science and religious subjects or will be delivered by school healthcare professionals. I suggest that the authors have more descriptions of how the program will be delivered.
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<b>REVIEWER</b>	Ruth Holman Ayrshire Central Hospital UK
<b>REVIEW RETURNED</b>	08-Aug-2018

<b>GENERAL COMMENTS</b>	Well written and thorough. A few minor suggestions. I think the abstract introduction should make it clearer that the paper is a protocol . In my opinion Line 5 would be better as "This paper describes the protocol for a study that aims to develop and trial an intervention for 13-16 year old adolescent females which enhances positive attitudes towards OM health, coupled with developing skills to monitor and self-report OM health." Abstract includes term molimina (which is a great word that I have never come across before) but is not used elsewhere in the paper- premenstrual syndrome( PMS) is used, which is the commoner term. I suggest change molimina to PMS for consistency and understandability. page 5, paragraph 1, line 4 " This raises questions about girls developing their own OM health literacy": I don't feel this is a logical statement based on the sentence before. I suggest e.g.
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	<p>"...not all teachers may have received this training which could negatively impact on supporting girls to develop their OM health literacy"</p> <p>page 6 ,paragraph 3, line 7 " The school will be single sex to eliminate study burden that a co-educational school may experience" I don't understand what this means- clarification would be useful to readers like me.</p> <p>Page 8 . last paragraph, line 4 - what is 'gynaecological age'? Do you mean "will have menstruated for up to three years"?</p>
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<b>REVIEWER</b>	Wen-Hsuan Hou School of Gerontology Health Management, College of Nursing, Taipei Medical University, Taiwan
<b>REVIEW RETURNED</b>	12-Oct-2018

<b>GENERAL COMMENTS</b>	<p>This is a study aims to develop and trial an ovulatory-menstrual (OM) health literacy intervention for delivery to female students aged 13-16 years. The study will be completed in both development and intervention trial phases from a quasi-experimental mixed method study. Several areas in the paper can be improved as follows:</p> <ol style="list-style-type: none"> <li>1. Please address the rationale of authors' using grounded theory approach to qualitatively analyze and evaluate the intervention.</li> <li>2. Please elaborate the sequence for processing the data analysis for both qualitative and quantitative research, as well as the strategies how this study merging together various data collection and answering the research questions.</li> <li>3. Pre-consider and mention expected outcomes even from the systematic literature review process will be more specific and practical.</li> </ol>
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<b>REVIEWER</b>	Moshtagh Farokhi University of Texas Health Science Center at San Antonio, Texas, USA
<b>REVIEW RETURNED</b>	22-Oct-2018

<b>GENERAL COMMENTS</b>	<p>Overall, this is a very interesting body of research. It is well written. Regarding your: Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.</p> <p>Perhaps, it is better stated: Developing a school-based ovulatory-menstrual health literacy program for adolescent females: a validated quasi-experimental mixed method approach?</p> <p>Page 2 Line 37 instead of consumer-empowered perhaps a consumer-centered will be more appropriate?</p> <p>Page 5 line 3, If the teachers cannot express OM literacy one can only imagine how unequipped the parents might be, this pilot is extremely valuable to empower young girls about calibrated learning regarding their body's OM cycles. Do you have any data</p>
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	<p>about parental OM training or lack of to include in your literature review? Currently there are many forms of online parental advice but there are not any published research regarding OM literacy for the teenage female population. When you succeed at this research, you will contribute greatly to this body of knowledge and more important the female teenage health literacy outcome that is much needed.</p> <p>Page 7 Line 25, under the primary target; Did you consider asking the teenagers about their social determinant of health barriers regarding OM? The religious, cultural, family aspects that shape a young girl's approach to OM self management? Is this part of the Delphi Study process?</p> <p>Page 7 Line 48, excellent use of Delphi study with your project</p> <p>Page 7 Line 40 as the secondary target population: A general comment, have you thought of querying the parents of the young girls regarding their attitudes and beliefs since they are the enabler and/or barrier to the provision of health care as your secondary target population? If not, should that be a component of your exclusion factors or future studies?</p> <p>Also, are these schools a mixture of private and public single sex schools? Throughout the manuscript, it is not clear if public schools are involved even though the socioeconomic levels are documented? Do you need to conduct a background check prior to accessing these schools? If so, please indicate that as your protocol.</p> <p>Is this the entire publication or will you report on the finding? The scoring above reflects the planning stage of this protocol or the development of a survey/protocol while the findings are yet to be determined. The indication of NA means that at this stage it was not disseminated.</p>
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1 - Youness EL ACHHAB - Institution and Country: Laboratory of Epidemiology, Faculty of Medicine and Pharmacy of Fez, Morocco CRMEF Fez-Meknes, Morocco

<p>This manuscript is a very interesting topic focusing on developing a school-based ovulatory-menstrual health literacy program for adolescent females. It is well designed (triangulation) and presented. I would like to wonder if the intervention (program) will be delivered via Online or In-class. If in-class, this program/course will be integrated independently with regard to the curriculum or integrated into the health, physical education, science and religious subjects or will be delivered by school healthcare professionals. I suggest that the authors have more descriptions of how the program will be delivered.</p>	
<p>FROM Page 10 Line 34</p>	<p>TO Page 10 Line 34</p>
<p>One single sex school in Perth WA will be purposively selected. The trial will run within a complete school year to reduce the risk of participant loss. Both primary and secondary target populations will be recruited from the same school:</p> <ol style="list-style-type: none"> <li>1. The primary target population will be adolescent females aged 13-16 years.</li> </ol>	<p>One single-sex private school in Perth WA will be purposively selected. The trial will be offered in-class at the school's convenience. Whilst the intervention will be mapped to the Australian curriculum for Health &amp; Physical Education, the school's preference for its delivery in other classes will be observed. For the purpose of the trial, the intervention will be delivered by the first</p>

<p>This age range falls in Grade 9, at which the intervention is targeted and which also provides the likeliest opportunity to recruit given curriculum time restrictions in more senior years. All Grade 9 girls will be invited. The intervention will be provided at the school's convenience and delivered by the student researcher.</p>	<p>author who has expertise in the facilitation of RSE programs to 13-16 year old students. It is anticipated that the trial will run for 6 to 8 weekly sessions during one school term which reduces the risk of participant loss. Both primary and secondary target populations will be recruited from the same school:</p> <ol style="list-style-type: none"> <li>1. The primary target population will be adolescent females aged 13-16 years. This age range falls in Grade 9, at which the intervention is targeted and which also provides the likeliest opportunity to recruit given curriculum time restrictions in more senior years. All Grade 9 girls will be invited.</li> </ol>
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Reviewer: 2 - Ruth Holman - Institution and Country: Ayrshire Central Hospital UK

<p>Well written and thorough. A few minor suggestions. I think the abstract introduction should make it clearer that the paper is a protocol . In my opinion Line 5 would be better as "This paper describes the protocol for a study that aims to develop and trial an intervention for 13-16 year old adolescent females which enhances positive attitudes towards OM health, coupled with developing skills to monitor and self-report OM health."</p>	
<p>FROM Page 1 Line 38</p>	<p>TO Page 1 Line 38</p>
<p>This study aims to develop and trial an intervention for 13-16-year old adolescent females. Enhancing positive attitudes towards OM health will be coupled with developing skills to monitor and self-report OM health.</p>	<p>This paper describes the protocol for a study that aims to develop and trial an intervention for 13-16 year old adolescent females which enhances positive attitudes towards OM health, coupled with developing skills to monitor and self-report OM health.</p>
<p>Abstract includes term molimina (which is a great word that I have never come across before) but is not used elsewhere in the paper- premenstrual syndrome( PMS) is used, which is the commoner term. I suggest change molimina to PMS for consistency and understandability.</p>	
<p>FROM Page 1 Line 46</p>	<p>TO Page 1 Line 46</p>
<p>(namely, dysmenorrhoea, abnormal uterine bleeding and premenstrual molimina)</p>	<p>(namely, dysmenorrhoea, abnormal uterine bleeding and premenstrual syndrome)</p>
<p>page 5, paragraph 1, line 4 " This raises questions about girls developing their own OM health literacy": I don't feel this is a logical statement based on the sentence before. I suggest e.g. "....not all teachers may have received this training which could negatively impact on supporting girls to develop their OM health literacy"</p>	
<p>FROM Page 5 Line 4</p>	<p>TO Page 5 Line 4</p>
<p>In Australia, RSE training is not mandatory for pre-service teachers, and so not all teachers may have received this training.<sup>35</sup> This raises questions about girls developing their OM health literacy.</p>	<p>In Australia, RSE training is not mandatory for pre-service teachers, and so not all teachers may have received this training.<sup>35</sup> This could negatively impact on supporting girls to develop their OM health literacy.</p>
<p>page 6 ,paragraph 3, line 7 " The school will be single sex to eliminate study burden that a co-educational school may experience" I don't understand what this means- clarification would be useful to readers like me.</p>	
<p>FROM Page 6 Line 30</p>	<p>TO Page 6 Line 30</p>
<p>The school will be single-sex to eliminate study burden that a co-educational school may experience.</p>	<p>The school will be single-sex rather than co-educational of mixed sexes in order to eliminate any study burden of occupying male students. Subsequent studies may explore the efficacy of this intervention in a co-educational setting.</p>
<p>Page 8 . last paragraph, line 4 - what is 'gynaecological age'? Do you mean "will have menstruated for up to three years"?</p>	
<p>FROM Page 8 Line 53</p>	<p>TO Page 8 Line 53</p>

...most will have already attained up to three years of gynaecological age	...most will have already been menstruating for up to three years
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Reviewer: 3 - Wen-Hsuan Hou - Institution and Country: School of Gerontology Health Management, College of Nursing, Taipei Medical University, Taiwan

This is a study aims to develop and trial an ovulatory-menstrual (OM) health literacy intervention for delivery to female students aged 13-16 years. The study will be completed in both development and intervention trial phases from a quasi-experimental mixed method study. Several areas in the paper can be improved as follows:	
1. Please address the rationale of authors' using grounded theory approach to qualitatively analyze and evaluate the intervention.	
FROM Page 12 Line 35	TO Page 12 Line 35
Using a grounded theory approach, <sup>80</sup> the data will be analysed by constant comparison, whereby ...	A grounded theory approach has been selected because it aims to make theoretical assumptions that can be verified. <sup>71 80</sup> This systematic approach accentuates the mixed methods approach. <sup>82</sup> The theory developed should explain variations in behaviour while representing the main concerns and ideas of the participants. <sup>83</sup> Accordingly, the data will be analysed by constant comparison, whereby ...  <sup>82</sup> Bluff R. Grounded Theory: The Methodology. In: Holloway I, editor. Qualitative Research in Health Care. Berkshire, UK: Open University Press, McGraw-Hill; 2005. <sup>83</sup> Glaser B. Basics of Grounded Theory Analysis. Mill Valley, CA: Sociology Press; 1992.
2. Please elaborate the sequence for processing the data analysis for both qualitative and quantitative research, as well as the strategies how this study merging together various data collection and answering the research questions.	
FROM Page 12 Line 47	TO
Using a mixed-method approach gives depth and breadth to findings using the above qualitative and quantitative instruments. A triangulation of data sources cross-check to inform the refinement of the intervention.	In summary, the qualitative and quantitative instruments used in this study's mixed-method approach offers a triangulation of data sources to cross-check and inform the development and trialling of the intervention. Each step in Phase One will inform the next step in order to progress the intervention's development and to validate the questionnaire as the measurement tool. In turn, Phase One provides the intervention and its validated questionnaire for trial in Phase Two. The final outcome expected at the end of Phase Two is a more nuanced and refined intervention for wider testing. A subsequent large intervention-based trial would include focus on generalisability and sustainability.
3. Pre-consider and mention expected outcomes even from the systematic literature review process will be more specific and practical.	
FROM Page 7 Line 45	TO Page 7 Line 45
...delivery in school-based settings, dissemination and program evaluation.	...delivery in school-based settings, dissemination and program evaluation.  The expected outcome from conducting the SLR is that it will inform the draft development of the

	intervention which will then be submitted to the Delphi panel for further development.
FROM Page 9 Line 48	TO Page 9 Line 48
The key findings based on the SLR, Delphi Panel and COREQ-32 will inform the refinement of the intervention in preparation for its trial.	The key findings based on the SLR, Delphi Panel and COREQ-32 will inform the refinement of the intervention. The expected outcomes are improvements in the intervention's feasibility and acceptability for its delivery in Phase Two.
FROM Page 10 Line 7	TO Page 10 Line 7
The research team will use the findings of the test-retest process to refine the questionnaire for use in Phase Two.	The research team will use the findings of the test-retest process to refine the questionnaire. The expected outcome is established validity and reliability for the questionnaire to be administered in Phase Two.
FROM Page 11 Line 37	TO Page 11 Line 37
Statistical significance will be achieved at 0.05. Data will be analysed using STATA version 14 (StataCorp LP).	Statistical significance will be achieved at 0.05. Data will be analysed using STATA version 14 (StataCorp LP). The expected outcomes are that the OM health knowledge and attitudes of participants will have improved, and they will have gained confidence in communicating OM cycle health by being able to recognise OM cycle phases.
FROM Page 12 Line 46	TO Page 12 Line 46
...interpretations of the qualitative studies. <sup>72</sup>	...interpretations of the qualitative studies. <sup>72</sup> The expected outcome is that the qualitative findings will provide a richer understanding of the intervention from the perspective of the students, teachers and school healthcare professionals. These data will be triangulated with the quantitative findings to further refine the intervention.

Reviewer: 4 - Moshtagh Farokhi - Institution and Country: University of Texas Health Science Center at San Antonio, Texas, USA

Overall, this is a very interesting body of research. It is well written. Regarding your: Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study. Perhaps, it is better stated: Developing a school-based ovulatory-menstrual health literacy program for adolescent females: a validated quasi-experimental mixed method approach?	
FROM Page 1 Line 5 and Page 3 Line 3	TO Page 1 Line 5 and Page 3 Line 3
Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.	Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.
Page 2 Line 37 instead of consumer-empowered perhaps a consumer-centered will be more appropriate?	
FROM Page 2 Line 37	TO Page 2 Line 37
➤ A consumer-empowered study that engages multiple stakeholders.	➤ A consumer-centred study that engages multiple stakeholders.
Page 5 line 3, If the teachers cannot express OM literacy one can only imagine how unequipped the parents might be, this pilot is extremely valuable to empower young girls about calibrated learning regarding their body's OM cycles. Do you have any data about parental OM training or lack of to include in your literature review? Currently there are many forms of online parental advice but there are not any published research regarding OM literacy for the teenage female population. When you succeed at this research, you will contribute greatly to this body of knowledge and more important the female teenage health literacy outcome that is much needed.	

<p>The authors regret to advise that they do not have any data regarding parental training in OM cycles, or any known published research regarding the OM literacy of adolescent females. An approximation would be an Australian study that showed 87% of women (n=282) motivated to conceive could not identify their ovulatory window (Hampton, Mazza, &amp; Newton, 2013).</p>	
<p>Page 7 Line 25, under the primary target; Did you consider asking the teenagers about their social determinant of health barriers regarding OM? The religious, cultural, family aspects that shape a young girl's approach to OM self management? Is this part of the Delphi Study process?</p>	
<p>FROM Page 8 Line 57 (in response to Page 7 Line 25)</p>	<p>TO Page 8 Line 57 (in response to Page 7 Line 25)</p>
<p>Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. Each of the five socio-demographically diverse schools will be asked ...</p>	<p>Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. This creates the opportunity to explore socio-ecological influences<sup>66</sup> that may shape an adolescent's approach to OM self-management. Each of the five socio-demographically diverse schools will be asked ...</p> <p><sup>66</sup> Bronfenbrenner U. The Ecology of Human Development. Cambridge, MA Harvard University Press; 1979.</p>
<p>Page 7 Line 48, excellent use of Delphi study with your project</p>	
<p>The authors thank A/Prof Farokhi for this affirmation.</p>	
<p>Page 7 Line 40 as the secondary target population: A general comment, have you thought of querying the parents of the young girls regarding their attitudes and beliefs since they are the enabler and/or barrier to the provision of health care as your secondary target population? If not, should that be a component of your exclusion factors or future studies?</p>	
<p>FROM Page 8 Line 57 (in response to Page 7 Line 40)</p>	<p>TO Page 8 Line 57 (in response to Page 7 Line 40)</p>
<p>Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. Each of the five socio-demographically diverse schools will be asked ...</p>	<p>Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. This creates the opportunity to appreciate any socio-ecological influences<sup>66</sup> that may shape an adolescent's approach to OM self-management. Exploration of girls' parents or guardians as enablers or barriers to OM health literacy lies however outside the scope of this study. Each of the five socio-demographically diverse schools will be asked ...</p>
<p>Also, are these schools a mixture of private and public single sex schools? Throughout the manuscript, it is not clear if public schools are involved even though the socioeconomic levels are documented? Do you need to conduct a background check prior to accessing these schools? If so, please indicate that as your protocol.</p>	
<p>FROM Page 6 Line 21</p>	<p>TO Page 6 Line 21</p>
<p>The study will be based in Perth, Western Australia. In Phase One, five schools will be approached to offer female students, teachers and healthcare professionals the opportunity to participate in focus groups. Representation ...</p>	<p>The study will be based in Perth, Western Australia. In Phase One, five schools will be invited to offer female students, teachers and school healthcare professionals the opportunity to participate in focus groups. Both private and public schools will be approached. Representation ...</p> <p>Representation across various sociodemographic backgrounds will be sought based on schools' Index of Community Socio-Educational Advantage values.<sup>43</sup> Both private and public schools will be approached. The setting for Phase Two will be one purposively</p>

	selected single-sex school in the Perth metropolitan area. Only private schools will be approached in this phase because there are no single-sex public schools in Perth.
Is this the entire publication or will you report on the finding? The scoring above reflects the planning stage of this protocol or the development of a survey/protocol while the findings are yet to be determined. The indication of NA means that at this stage it was not disseminated.	
This paper describes the protocol for an intended study. A series of publications at key milestones are planned once the study is underway: a systematic literature review, findings from the Delphi panel, validation of the OM health literacy questionnaire and mixed method findings from the final pilot.	

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Wenhsuan Hou School of Gerontology Health Management & Master Program in Long-Term Care, College of Nursing, Taipei Medical University, Taiwan Department of Physical Medicine and Rehabilitation, School of Medicine, Taipei Medical University, Taipei, Taiwan Department of Physical Medicine and Rehabilitation, Taipei Medical University Hospital, Taipei, Taiwan
<b>REVIEW RETURNED</b>	14-Dec-2018

<b>GENERAL COMMENTS</b>	1. Please provide the trial registration number after completing the registration. 2. In the section of Systematic Literature Review (SLR) of OM health programs for adolescent, please add the search date, included time period, and search databases plan to use in this research.
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<b>REVIEWER</b>	Moshtagh Farokhi University of Texas Health San Antonio, USA
<b>REVIEW RETURNED</b>	29-Nov-2018

<b>GENERAL COMMENTS</b>	Upon the current revisions and clarifications, this manuscript is now more cohesive and to the point as a protocol centered at the adolescent females OM health literacy. School-Based Prevention Programs are effective approaches to address social determinants of health and student empowerment. Additionally the response to questions 7, 9, 10, and 13 were NA since the manuscript is at the protocol stage where results will be reported upon the completion of the project and survey development.
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### VERSION 2 – AUTHOR RESPONSE

**Reviewer: 3 - Wen-Hsuan Hou - Institution and Country: School of Gerontology Health Management, Taipei Medical University, Taiwan**



*1. Please provide the trial registration number after completing the registration.*

This project is registered with the “Australian and New Zealand Clinical Trials Registry”. The trial registration number is ACTRN12619000031167.

*2. In the section of Systematic Literature Review (SLR) of OM health programs for adolescent, please add the search date, included time period, and search databases plan to use in this research.*

FROM Page 8 Line 7-22

TO Page 8 Line 7-22

The SLR will include an assessment of previous reviews of OM health programs and primary studies published in English using the PRISMA flow diagram and check list.<sup>44</sup> The inclusion dates extend from the present back to 1980, which is when a mainstream book that used Odeblad’s findings<sup>45</sup> to describe OM cycle phases was published.<sup>46</sup> The key search words will include: [adolescen\* OR teen?age\*] AND [menstrua\* OR menarch\*, ovulat\* OR fertil\* OR reproduc\*] AND [educat\* OR teach\* OR school\*] AND [chart\* OR record\* OR track\* OR diary] AND [knowledge OR aware\* OR “health literacy”] AND [attitude OR opinion OR “body image” OR confidence]. Initial databases to be used are CINAHL, Informit, Ovid, Proquest, Science Direct, Medline and Web of Science.

The SLR will include an assessment of previous reviews of OM health programs and primary studies published in English using the PRISMA flow diagram and check list.<sup>44</sup> The search time period spans 39 years, dating from 1<sup>st</sup> January 1980 to 31<sup>st</sup> December 2018. The year 1980 marks the publication of a mainstream book which used Odeblad’s findings<sup>45</sup> to describe OM cycle phases.<sup>46</sup> The key search words will include: [adolescen\* OR teen?age\*] AND [menstrua\* OR menarch\*, ovulat\* OR fertil\* OR reproduc\*] AND [educat\* OR teach\* OR school\*] AND [chart\* OR record\* OR track\* OR diary] AND [knowledge OR aware\* OR “health literacy”] AND [attitude OR opinion OR “body image” OR confidence]. The databases to be searched are CINAHL, Informit, Ovid, Proquest, Science Direct, Medline, Web Scopus. of Science and

**Reviewer: 4 - Moshtagh Farokhi - Institution and Country: University of Texas Health Science Center at San Antonio, Texas, USA**

*Upon the current revisions and clarifications, this manuscript is now more cohesive and to the point as a protocol centered at the adolescent females OM health literacy. School-Based Prevention Programs are effective approaches to address social determinants of health and student empowerment.*

The authors thank A/Prof Farokhi for this feedback. We look forward to contributing to adolescent health literacy.

*Additionally the response to questions 7, 9, 10, and 13 were NA since the manuscript is at the protocol stage where results will be reported upon the completion of the project and survey development.*

The authors understand that the changes to items on pages 7, 9, 10, 11 and 12 (from the original manuscript) could be interpreted as not applicable since results will only be reported once the project is finished. However, we were mindful that another reviewer requested explicit mention of expected outcomes on these pages. Their continued inclusion were subsequently agreed to in the previous manuscript resubmission.