Author’s response to reviews

Title: Mobile Link - a theory-based messaging intervention for improving sexual and reproductive health of female entertainment workers in Cambodia: Study protocol of a randomized controlled trial

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Response to reviewers’ comments

Reviewer #1:

Thanks for giving me the opportunity to comment on the protocol: The Mobile Link: Using a theory-based messaging intervention to improve sexual and reproductive health of female entertainment workers in Cambodia - Study protocol of a randomized controlled trial. This was interesting reading. It would be informative for those who are involved in mobile linked innovative interventions to enhance the utilization of Sexual and Reproductive Health Services. Below are my comments;

1) Study design require more elaboration with rationale. A brief on Mobile Link conceptual framework will be apt here.

RESPONSE: The Theory of Change description and logic model provide a comprehensive rationale and conceptual framework. We are happy to provide more details if the reviewer can be more specific. Please see the description of the Theory of Change and logic model on lines 204-224.

2) Citation of influx of FEWs through different trades and other reasons and trends of mobile usership in Cambodia can be shortened/synthesized to reduce the length of manuscript.
RESPONSE: Thank you for this suggestion, we have tightened this paragraph. Please see lines 97-105 and 145-165.

3) It seems that study will adopt mix method to collect the information on primary and secondary outcome indicators throughout the study. The study tools also indicate the same, however, it does not get reflected in method section. Please correct if i have misunderstood.

RESPONSE: All outcome data will be self-reported and collected through surveys. We have clarified this where suitable. Please see line 375.

4) It is unclear as how the study will assurance the quality of data that would be collected by peer groups (collectors). No robust mechanism has been mentioned for data monitoring and management to ensure the reliability of data. This important as the majority of participant would be illiterate (as reported) and the method of data collection by peer data collector will be both oral and verbal.

RESPONSE: Thank you for your important comments. We have now come to a decision that all data will be collected by a team of independent trained data collectors. The peer data collectors (now called community health workers) will play coordination roles in recruiting, collecting contact information of, and follow up FEWs. Changes have made accordingly.

5) Contents given under Data monitoring subhead (pg line 571-573) are more suited to confidentiality.

RESPONSE: We have merged the two sections under the confidentiality section. Please see lines 583-595.

6) I could not see any mention about utilizing a witness (presence and signature) while taking the informed consent/the thumbprint from illiterate FEWs who wish to participate. It is a mandate as per the research Ethics. found this missing in informed consent format too.

RESPONSE: We have addressed this by adding information about witnesses to the manuscript (line 569-571) and the informed consent form.

7) Contents under subheadings, Participant selection criteria and Screening for eligibility can be merged, as these two getting repeated.

RESPONSE: Thank you we have merged these sections. Please see lines 196-202.
8) Difference between work in an entertainment venue and work in entertainment at venue (point 6 line 210) under Participant selection criteria should be clarified a bit? Also, please explain the participant whether these are separate or one should possess both in order to be eligible for the study? As Person working in an entertainment venue may not be directly involved in Entertainment work, though s/he could be prospective FEW.

RESPONSE: We have refined the selection criteria to avoid the confusion. Please see lines 196-202.

Reviewer #2:

This manuscript reports the protocol for a randomized controlled trial of 'Using a theory-based messaging intervention to improve sexual and reproductive health of female entertainment workers in Cambodia'. The trial will evaluate the efficacy and determine the cost-effectiveness of the Mobile Link intervention.

An interesting study in a difficult to reach population. Good contextualization of the work with relevant references to the existing literature. The protocol is well-written but at times repetitive. Following Spirit guidelines and adding the checklist is a Trials requirement.

Most of the comments are minor but clarifications around written versus oral consent and social harms documentation are crucial.

Abstract:

Methods section

Line 49 - The primary outcome measures include HIV testing, condom use, STI testing and treatment and contraceptive use. Please clarify this is self-reported data.

RESPONSE: We have made this clarification in the abstract. Please see line 49.

Discussion

Line 51 - If the Mobile Link trial is successful, an increase in condom use, screening and treatment for HIV and STI and contraception use is expected. These outcomes would lead to a reduction in the prevalence of HIV, STIs and unintended pregnancies. How will these reductions be measured; only through self-reported data?

RESPONSE: Yes, all expected outcomes will only be measured through self-reported data. We have clarified in the text. Please see line 51.
Line 57 - Third, we are working with is a hidden, hard-to-reach and dynamic population with which traditional methods of outreach have not been fully successful. What do the authors understand by 'traditional methods of outreach' and can they provide references to previous work showing they were unsuccessful?

RESPONSE: To avoid the confusion and due to a word count limit, we have changed the term ‘traditional methods’ to ‘existing methods.’ Please see line 57.

Background:

* Benefits and harms according to the SPIRIT checklist; No evaluation and/or documentation of potential social harm by identifying and contacting this population (which is described repeatedly as hidden and stigmatized). Please see below comments on Line 410 and 472.

* Line 142 - In addition, this intervention will determine if SMS/VM messaging can be a reliable source of monitoring and evaluation data. How? Not mentioned in the goals and objectives.

RESPONSE: We have softened the language as this is not meant to me a major goal or objective of this study. Please see lines 139-141.

* Line 130 - If using these services due to discrimination by providers is a known barrier and a preference for private providers is known, why is private providers use not included as well?
RESPONSE: This study does not dictate where FEWs get their services. They can chose to obtain HIV testing and other services at the provider of their choice. KHANA services and providers are tailored to FEWs and therefore patients report facing less or no discrimination, but they are not required to be restricted to services provided by KHANA, government, or any other NGOs as part of this study.

Goal and objectives:

* Line 194-199 - (2) evaluating the efficacy of the Mobile Link intervention at the individual and venue level … (3) determining the cost-effectiveness of the Mobile Link intervention for FEWs as compared to the standard outreach, care and treatment services provided by the national HIV program. How will this be done at venue level? How will data from the national HIV program be obtained?

RESPONSE: Because of the design of our sampling plan, we are using the venue as a unit of analyses. While we will evaluate on the individual level, the venue level is actually the most appropriate given the design. As for the standard that we will compare for cost, we meant this to indicate that we would compare to the KHANA’s standard for HIV programming. We have made this clarification. Please see lines 178.

Participant selection criteria
* Line 214 - Do the authors foresee any issues with self-identification as a FEW?

RESPONSE: This is a good question. Thus far, we have not had any issues with women identifying themselves as FEWs especially since we are approaching them at their place of work at entertainment venues, and we work closely with their peer outreach workers.

Informed consent and baseline data collection

* Line 280 - Please specify whether a witness independent from the study will be present.

RESPONSE: Yes, and we have clarified this on lines 569-571 and in the informed consent forms.

* Line 289 - Please specify whether informed consent is obtained for in person workplace visits to conduct follow-up. Is the amount of visits specified?

RESPONSE: The informed consent form details the follow-up protocol. Please see the consent form attached in the Additional file 2.

Intervention

* Line 296 - How are these 50 FEW selected and recruited?

RESPONSE: We believe the reviewer meant 15, not 50. They were selected by peer facilitators (community health workers) using eligibility criteria that will be used to select future study participants. We have clarified in the manuscript. Please see lines 311-313.

* Line 348, 369 and 376 - Please make clear that all outcomes are self-reported in the section 'The primary outcome measures will include: (1) HIV testing; (5) STI screening when experiencing symptoms; (6) STI treatment when diagnosed; etc…’ as self-reporting is prone to bias. (I feel it is not sufficient to mention it in line 382). Please consider offering an HIV test at the end of the study (in reference to the discussion section on line 666).

RESPONSE: Thank you. We have made this explicit in the text. Please see line 375.

* Line 363 - How will the authors determine the outcomes were not influenced by trial participation itself (regardless of being in intervention versus control group) as opposed to the messaging in itself?

RESPONSE: This is always a potential limitation in any trial and we do not think that this trial has any specific reason to be concerned that participation could affect results more than any other. But we are open to specific concerns.
* Line 410 - This is a behavioral intervention unlikely to produce adverse effects, so analysis will be undertaken once the six-month follow-up has been completed.

AND

Line 472 - Any participants raising a personal sexual issue or consequences arising from other people listening to voice messages (for example, an argument or violence) will be linked into appropriate existing services at local organizations. Please clarify whether social harms will be collected as part of the study procedures?

RESPONSE: This is an important point. We have added this question to the survey and we have an adverse outcomes protocol that all data collectors and field supervisors will have learned in their training. We have added language in line 477-481 and in the questionnaire (Q104-105).

* Line 452 - Qualitative interviews. How was the amount of interviews determined? Will data saturation be achieved?

RESPONSE: Yes. The data will be collected until the saturation has been reached. We have clarified this on line 459-460.

* Line 467 - Ethical Consideration. All participants will provide written informed consent before enrolling in the trial or commencing the follow-up interview. Please ensure a witness is present in case of illiterate participants. See comment line 280. Line 557 Verbal consent. Please clarify will the study team be obtaining written or verbal consent and was this approved by the ECs?

RESPONSE: Thank you. We have clarified that all consent will be verbal and any mention of written consent has been amended.

* Line 471 - Ethical Consideration. Participants will be able to withdraw from the study at any point but please clarify the criteria for discontinuing or modifying allocated interventions for a given trial participant as per the Spirit checklist.

RESPONSE: We have added additional language on withdrawal protocol at line 480-482.

* Line 475 - Reimbursements. References to reimbursements is not clear see line 337. Will personal costs be incurred or will air-time be provided to cover these costs? Line 583 refers to costs as well. Please centralize this information.

RESPONSE: Thank you for this information. We have clarified that participants will be compensated with $5 in cash after completion of the intervention. Please see lines 597-601.

Risks to human subjects.

* Line 535 - Does not specify how the risks of this specific study population will be mitigated by the study team. All responsibility is placed on the participants by referring to the informed consent. Please elaborate.
RESPONSE: We have elaborated in lines 578-581.

Data monitoring

* Line 579 - Nothing relevant in this section about monitoring or quality control. Please clarify.

RESPONSE: We have included information on the data monitoring protocol at line 592-595.

Availability of data and materials

* Line 698 - Please elaborate what ethical restrictions are referred to for sharing anonymised data?

RESPONSE: This is a protocol of the study, and no data are currently available. We have modified the statement as suggested. Please see lines 704-706.