Reviewer’s report

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

Version: 0 Date: 09 Jan 2018

Reviewer: Evelyne Kestelyn

Reviewer’s report:

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.

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?

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?
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.

* 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?

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?

Participant selection criteria

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

Informed consent and baseline data collection

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

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

Intervention

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

* 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).

* 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?

* 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?

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

* 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?

* 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.

* 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.

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.

Data monitoring

* Line 579 - Nothing relevant in this section about monitoring or quality control. Please clarify.
Availability of data and materials

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

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