CONSORT-EHEALTH (V 1.6.1) -Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be a) a guide for reporting for authors of RCTs, b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (nonpharmacologic treatment) items. Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED). Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption): Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126 URL: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name * First Last

Carinne Brody

Primary Affiliation (short), City, Country * University of Toronto, Toronto, Canada

Touro University California

Your e-mail address *

abc@gmail.com

carinne.brody@gmail.com

Title of your manuscript * Provide the (draft) title of your manuscript.

A Mobile Intervention to link Female Entertainment Workers in Cambodia to Health and Gender-based Violence Services: Randomized controlled trial

Name of your App/Software/Intervention * If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Mobile Link

Evaluated Version (if any) e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

v1

Language(s) * What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

Khmer (Cambodian Langauge)

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

Your answer

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?

access is free and open

access only for special usergroups, not open

access is open to everyone, but requires payment/subscription/in-app purchases

O app/intervention no longer accessible

O Other:

Primary Medical Indication/Disease/Condition *

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

sexual and reproductive health

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

self-reported HIV and STI testing, condom use,

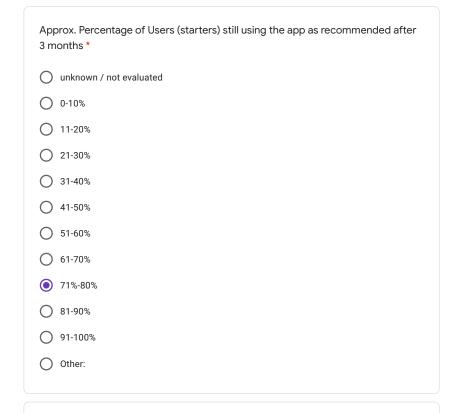
Secondary/other outcomes Are there any other outcomes the intervention is expected to affect?

contact with outreach workers, escorted referral services use, forced drinking, and GBV experiences

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- O Approximately Monthly
- O Approximately Yearly
- O "as needed"
- O Other:



Overall, was the app/intervention effective? *

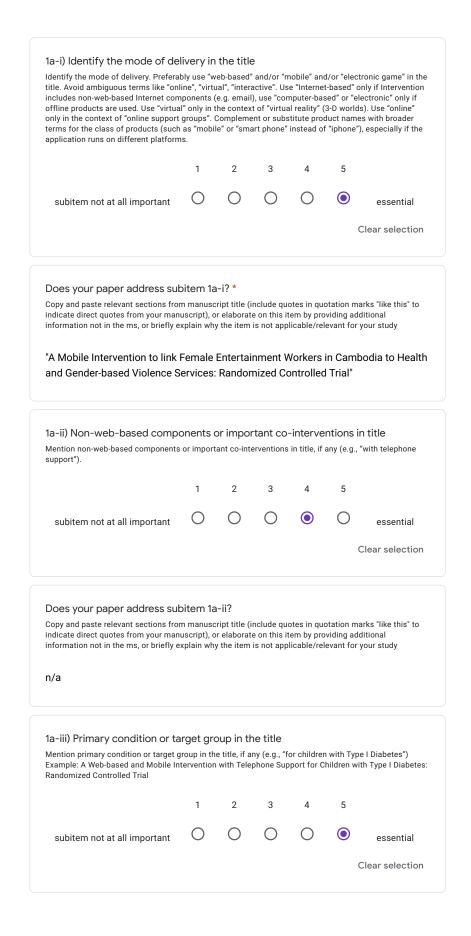
- O yes: all primary outcomes were significantly better in intervention group vs control
- \bigcirc no statistically significant difference between control and intervention
- $O_{\rm outcomes}^{\rm potentially harmful: control was significantly better than intervention in one or more <math display="inline">_{\rm outcomes}^{\rm potentially}$
- O inconclusive: more research is needed
- () Other: no primary outcomes were significantly better, three secondary outcom

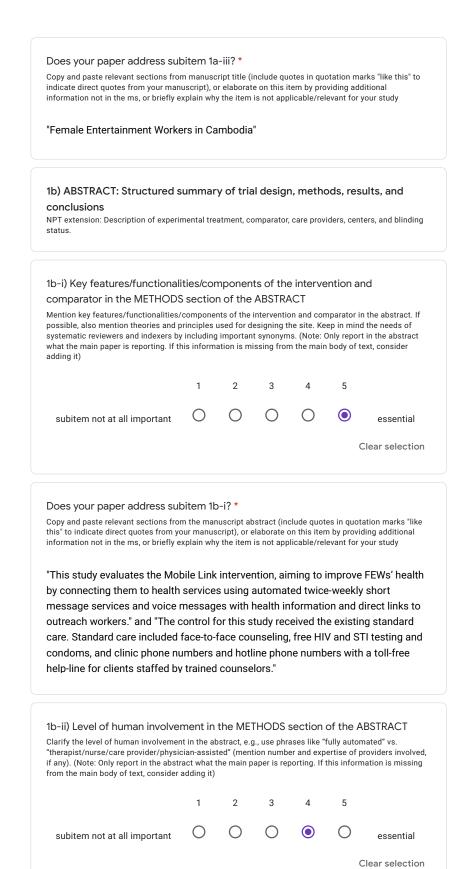
Article Preparation Status/Stage *

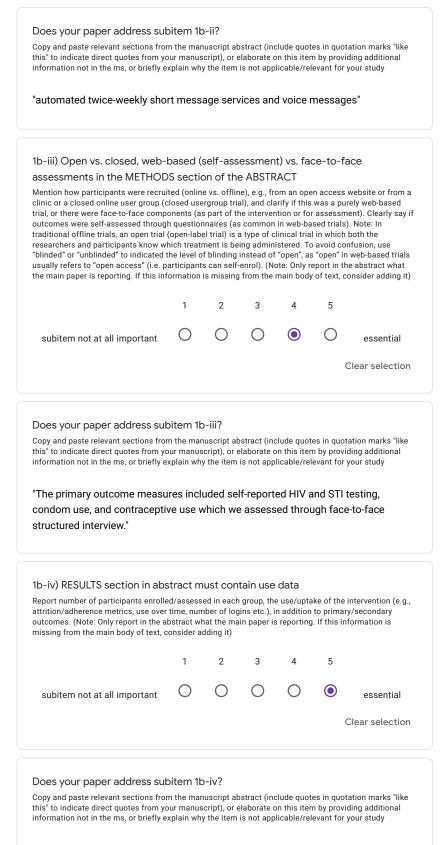
At which stage in your article preparation are you currently (at the time you fill in this form)

- onot submitted yet in early draft status
- o not submitted yet in late draft status, just before submission
- O submitted to a journal but not reviewed yet
- O submitted to a journal and after receiving initial reviewer comments
- O submitted to a journal and accepted, but not published yet
- published
- O Other:

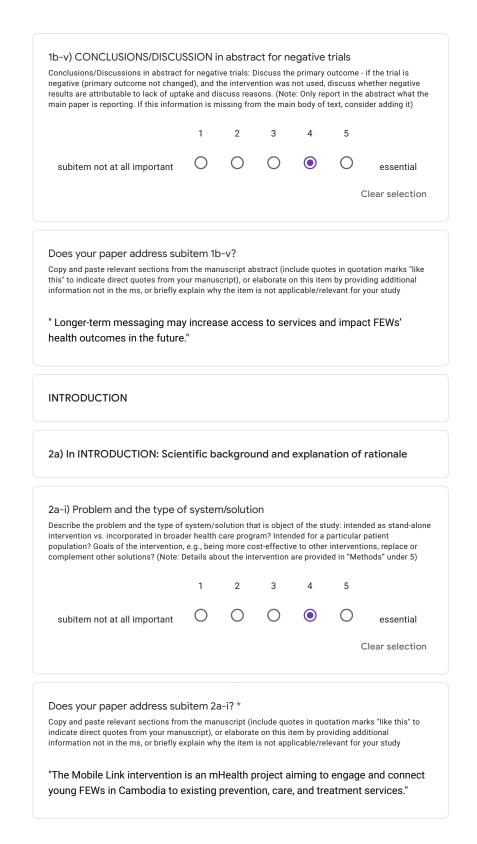
Journal * If you already know where you will submit this paper (or if it is already submitted), please provide the journal name under 'other' not submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR melaelth and UHealth JMIR Serious Games JMIR Public Health JMIR Formative Research Other JMIR sister journal Other i Is this a full powered effectiveness trial or a pilot/feasibility trial? * Pilot/feasibility Fully powered Manuscript tracking number * If the submitted to / published article in JMIR of the public health health Other: It is a JMIR powered effectiveness trial or a pilot/feasibility trial? * Fully powered Manuscript tracking number * If the submitted to / published article in JMIR of the submitted to / published in JMIR Of the r: If the submitted to / published in JMIR If the submitted to / published in JMIR Of ther: It LE AND ABSTRACT 1a) Druck work of the controlled Trial? (If not, explain the reason under 'other') Is yes of ther:	
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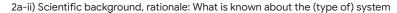






"We included 218 FEWs in intervention and 170 FEWs in control arms in the perprotocol analyses after 212 removing dropouts."





Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.



Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Health interventions using mobile phones – referred to as mobile health (mHealth) – presents a viable solution for connecting hard-to-reach, stigmatized, and criminalized populations such as FEWs to health services. In recent years, mHealth has received widespread attention due to its applicability in low-resource settings. mHealth has been used effectively in low- and middle-income countries to collect and report community health data [17], disperse health education information [17], raise health awareness [18], and conduct routine check-ins with patients and trigger follow-ups by nurses [19]. However, knowledge gaps persist in mHealth research. Fewer mHealth interventions have been rigorously evaluated. Much of the existing literature comprises small pilot studies lacking established health indicators and generalizability [20–22]. Additionally, there is a deficiency in mHealth research on interventions targeted towards behavior change and sexual and reproductive health (SRH) [21] "

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This study aims to evaluate the efficacy of the Mobile Link intervention in engaging FEWs, connecting them to existing HIV, SRH, and GBV services, and ultimately improving their health."

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The Mobile Link intervention study is a two-arm multisite 60-week randomized controlled trial (RCT). The trial was conducted in two sites in Phnom Penh and one site each in Banteay Meanchey, Battambang, and Siem Reap."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Protocol adaptations

There are several protocol deviations to note. The original protocol called for a 12month (52 week) trial. However, due to high dropout rates at the midterm, we extended the trial to 60 weeks to recruit and enroll more participants who would have the chance to be exposed to the intervention for at least 30 weeks.

We did not anticipate the level of loss to follow-up that occurred and, therefore, did not have a plan in place for replacement recruitment in our original protocol. We decided to recruit replacement participants at the midline by randomly selecting FEWs from our master list from the same venue and age group. In our analyses, we defined exposure as having had at least 30 weeks of exposure to the intervention.

Another deviation occurred in our group assignment plan. Initially, we planned to randomize at the entertainment venue level to conduct a cluster RCT. Before the implementation, we changed our trial design to randomize at the individual level due to the high level of movement of FEWs between venues. As a result, we modeled intervention effects using the individual rather than the venue as the analysis unit. We computed clustered standard errors based on the venue rather than including the venue as a level in the mixed-effects outcome models. Finally, we included the venue type (e.g., karaoke bar, beer garden, etc.) as a covariate in all our models.

In our protocol, we planned to send out weekly survey questions to intervention participants on various health topics. During intervention development, we heard from pilot participants that they felt reluctant to give that type of information through the phone. We were also concerned about message fatigue, privacy, and literacy and decided to omit that part of the intervention.

Finally, in our protocol, we stated that we would present an ITT analysis. Because the ITT and per-protocol findings were the same, we decided to present

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].



Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

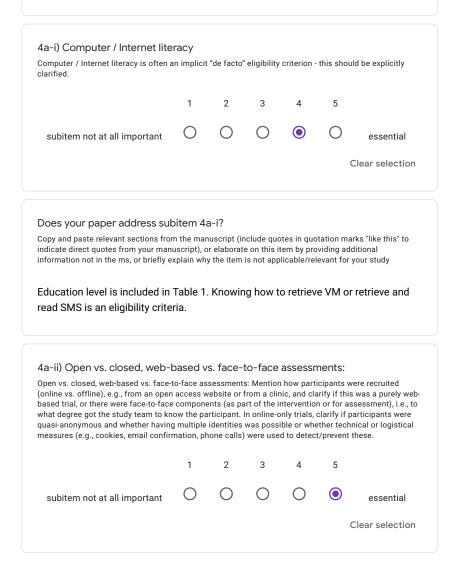
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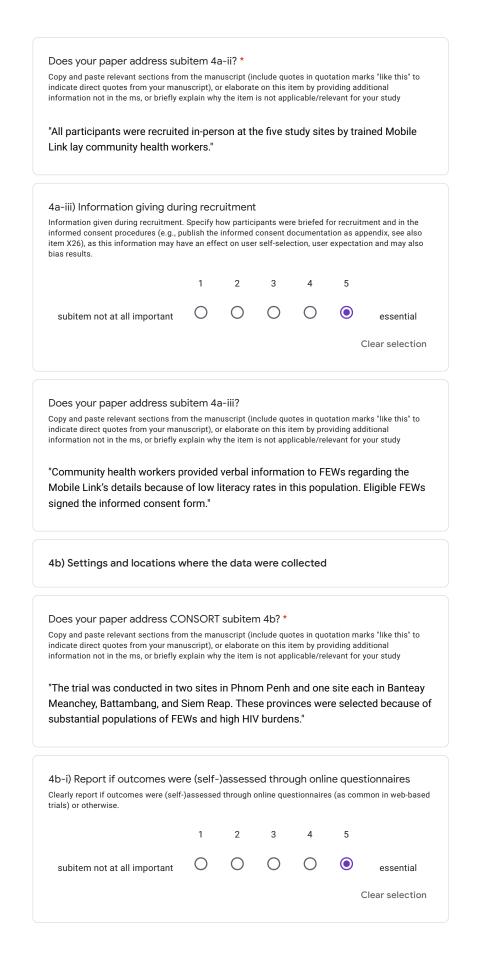
4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The intervention's participant inclusion criteria included: (1) working at an entertainment venue in the study sites; (2) being currently sexually active, defined as having engaged in oral, vaginal, or anal sex in the past three months; (3) owning a mobile phone; (4) knowing how to retrieve VM or retrieve and read SMS; (5) self-identifying as a FEW; (6) willing to receive two SMS/VM per week for one year; (7) providing written informed consent; and (8) agreeing to a follow-up visit after six months and 12 months."





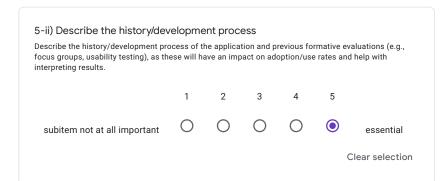
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Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Development of the message-based intervention was conducted with the support of local partners, InSTEDD iLab and the Women's Media Center (WMC). InSTEDD developed the mobile platform for interactive message delivery and data management using an open-source software program. The WMC helped translate messages into Khmer and tailor the contents to be specific, relevant, and engaging, given the cultural context. Example messages included can be found in a previously published paper [23]."



Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"We conducted a series of formative research activities using participatory methods to create appropriate and relevant health-related messages for FEWs and inform the intervention's development. The formative research process occurred over six months. We collected data through focus group discussions (FGDs), indepth interviews (IDIs), and key informant interviews (KIIs) with the venue- and nonvenue-based FEWs in addition to outreach workers and field staff that routinely work with this population [23]. Findings from the formative research revealed that FEWs were generally knowledgeable about HIV and STI prevention and transmission. However, they faced many structural barriers to optimal health, such as pressure to drink alcohol at work and complicated dynamics of negotiating condom use with clients in a criminalized environment [25, 26]. Furthermore, we found that many FEWs faced barriers to accessing medical care and services due to stigma discrimination and mistreatment from healthcare workers."

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

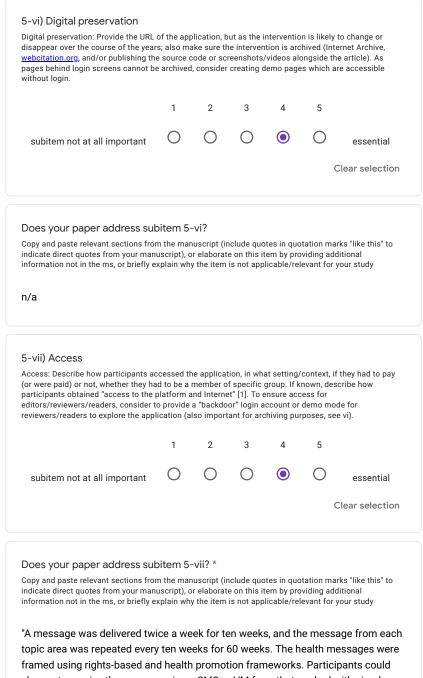
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 Clear selection

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5-iv) Quality assurance meth	nods					
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subitem not at all important	0	0	0	0	۲	essential
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The message bank is available upon request and has been given to the Ministry of Health.



framed using rights-based and health promotion frameworks. Participants could choose to receive the messages in an SMS or VM form that worked with simple and smartphone devices. Those who chose the SMS message option could further personalize their choice by selecting Khmer characters or Romanized Khmer. Each health topic message was followed by a message providing FEWs with the option to be linked to an outreach worker for free. Participants who selected this option were called by the Mobile Link's staff, who would provide individualized information via telephone or face-to-face and, if needed, would escort the participant to services."

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].



Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The Mobile Link intervention was informed by both behavior change theories and extensive formative research. The intervention provided FEWs with information, resources, and reminders. By utilizing an SMS/VM platform, these services were provided in a convenient, accessible, inexpensive, and confidential manner. Therefore, we theorized that this delivery mechanism would improve FEWs' knowledge of existing resources, risks, risk behaviors, and positive attitudes related to these topics. Increasing knowledge and positive attitudes will contribute to skill acquisition and positive behavior change."

5-ix) Describe use parameters

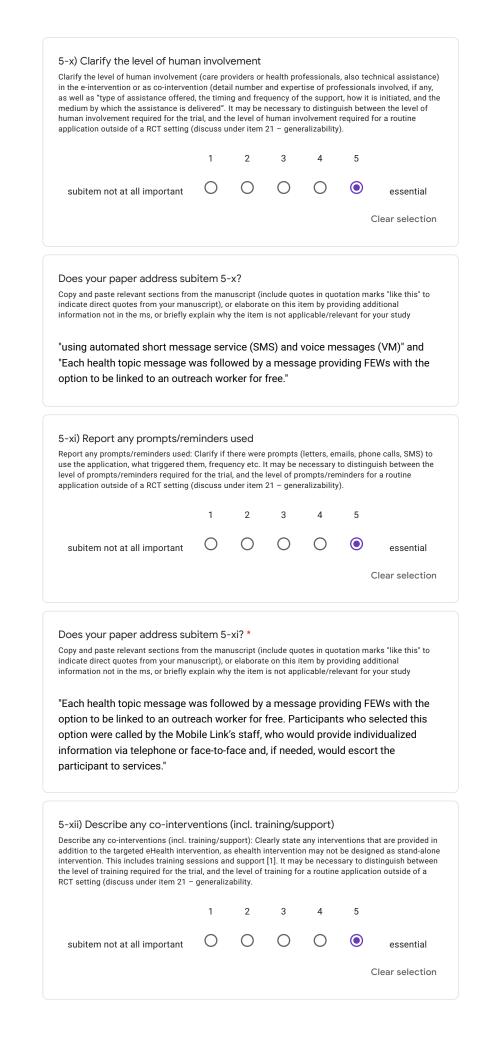
Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.



Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A message was delivered twice a week for ten weeks, and the message from each topic area was repeated every ten weeks for 60 weeks."



Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

n/a

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The primary outcome measures of the Mobile Link intervention were: (1) HIV testing, (2) STI testing when experiencing symptoms, (3) contraceptive use, (4) always use condoms with non-paying partners, and (5) always use condoms with paying partners. The secondary outcome measures were: (1) contact with outreach workers, (2) utilization of escorted referrals, (3) forced drinking at work, and (4) responses to GBV and GBV acceptance.

The primary and secondary outcomes were tracked and measured using self-reported data from the baseline, midline, and endline surveys. "

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

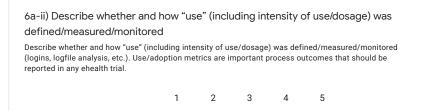
If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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Does your paper address subitem 6a-i? Copy and paste relevant sections from manuscript text

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Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The sample size was 600 based on a significance level of .05, with 80% power and accounting for 30% attrition.

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

n/a - we had no specified stopping rules.

8a) Method used to generate the random allocation sequence NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"At each site, 60 FEWs were randomly selected using a random number generator (30 in the age group of 18–24 and 30 in the age group of 25–30) for each arm (300 FEWs in the intervention and 300 FEWs in the control arm) for a total of 600 study participants."

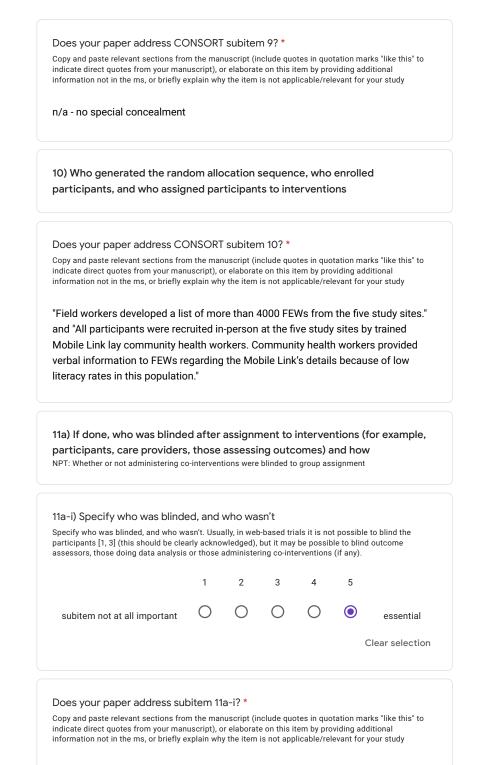
8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

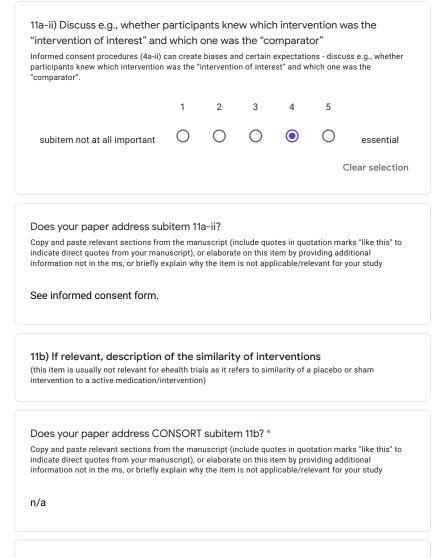
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

" At each site, 60 FEWs were randomly selected using a random number generator in a 1:1 ratio. There were 30 in the age group of 18–24 and 30 in the age group of 25–30 for each arm at each site (300 FEWs in the intervention and 300 FEWs in the control arm) for a total of 600 study participants."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned



"Reruited FEWs were assigned a unique identification number to protect their privacy and blind the researchers from their treatment arm assignment."



12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

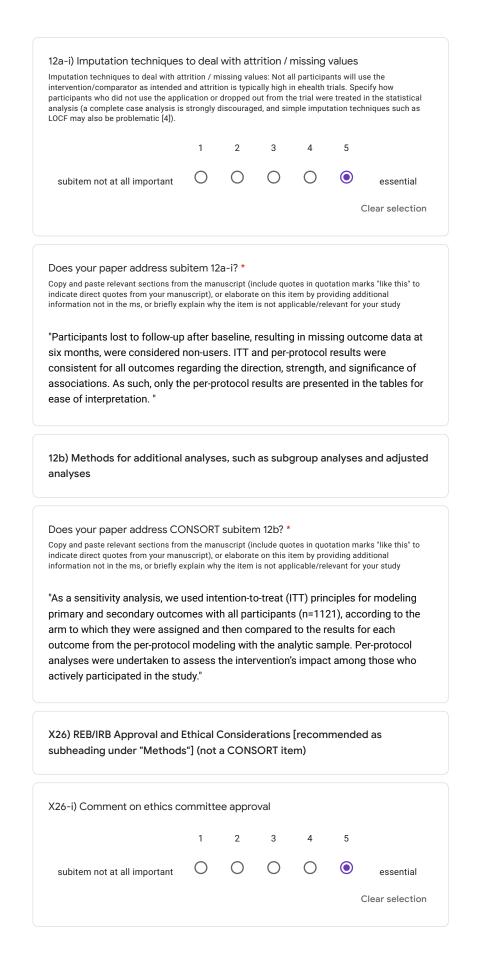
"Statistical analyses

STATA/SE 15.1 (College Station, TX, USA) was used for statistical analyses. We tabulated participants' baseline characteristics and distributions of primary and secondary outcome variables for intervention versus control arms for the analytic sample – participants with at least two observations – using frequencies and proportions for categorical variables and means and standard deviations (SDs) for continuous variables. These characteristics were compared by group using tests of association, including Pearson's Chi-squared tests of homogeneity for categorical variables and paired Student's t-tests for continuous variables to ensure the balance between the study arms. We conducted both crude and cluster-adjusted pooled tests of association to account for clustering within workplace venues. Participant characteristics were then compared for the analytic sample (n=388) versus non-analytic sample (n=733) to assess significant differences within and between groups for those retained in the study per protocol for at least two survey assessments (i.e., analytic sample) versus those lost to follow up after the baseline assessment (i.e., non-analytic sample).

Intervention effects were assessed using multilevel mixed-effects logistic regression to model all binary outcomes accounting for within-subject correlation from taking repeated measures on the same participants over time (two-level models with observations nested within individuals). Clustered standard errors were computed to account for the similarity of characteristics and behaviors among participants in the same venues. Separate models were conducted for each primary and secondary outcome. Model fit was assessed for each outcome using the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC).

Predictors in each simple unadjusted two-level mixed-effects logistic regression model included: group, time, and group by time interaction terms. Intervention effects for each outcome were determined by group by time interaction terms at endline with a significant p-value <0.05. Odds ratios (ORs) and 95% confidence intervals (CIs) for intervention effects at endline are displayed in Tables 2 and 3 (group by time interactions at time 3). Significant interactions indicating intervention effects were graphed using the marginsplot command (Figures 1–3). Midline effects (significant group by time interactions at time 2) are displayed in the figures but not in the tables. For the fully adjusted primary and secondary outcome models, the following covariates were included to control for alternative explanations: entertainment job venue type, province, cohabitation, age, and education. For primary outcomes, contact with outreach workers in the last six months was also included as a covariate to assess the impact of linkage support on HIV and STI testing, contraceptive use, and condom use.

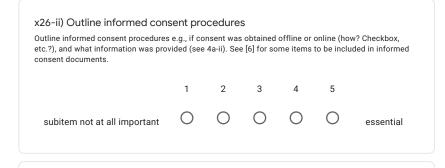
As a sensitivity analysis, we used intention-to-treat (ITT) principles for modeling primary and secondary outcomes with all participants (n=1121), according to the arm to which they were assigned and then compared to the results for each outcome from the per-protocol modeling with the analytic sample. Per-protocol analyses were undertaken to assess the intervention's impact among those who actively participated in the study. Participants lost to follow-up after baseline, resulting in missing outcome data at six months, were considered nonusers. ITT and per-protocol results were consistent for all outcomes regarding the direction strength and significance of associations. As such only the per-protocol



Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The Mobile Link intervention engaged community and public health stakeholders to ensure that the study incorporates best practices and strong ethical standards. Due to the sensitive nature of HIV, SRH, and GBV topics presented in the surveys and questionnaires, additional steps were taken to ensure participants' safety and well-being. First, all data collectors received training related to asking sensitive questions. Second, upon obtaining informed consent, community health workers disclosed information, making clear the sensitive topics discussed in the data collection process. Third, participants were offered escorted referrals to counseling services and provided with services upon request. Participants could be connected to services in the event of an adverse outcome through the SMS/VM platform. Also, participants could leave the study at any time. Furthermore, participants' identities were kept confidential and stored securely in password-protected files. Coded identifiers were given to participants after obtaining informed consent. No participants' personal identifiers were used in analyses or report writing. Participants received \$5 in compensation and transportation reimbursement for their participation. This study was approved by the National Ethics Committee for Health Research (NECHR, No. 142NECHR) within the Ministry of Health in Cambodia and the Toure College Institutional Poview Poard (No. DH 0117)



Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Community health workers provided verbal information to FEWs regarding the Mobile Link's details because of low literacy rates in this population. Eligible FEWs signed the informed consent form."

X26-iii) Safety and security procedures

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Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

" First, all data collectors received training related to asking sensitive questions. Second, upon obtaining informed consent, community health workers disclosed information, making clear the sensitive topics discussed in the data collection process. Third, participants were offered escorted referrals to counseling services and provided with services upon request. Participants could be connected to services in the event of an adverse outcome through the SMS/VM platform. Also, participants could leave the study at any time. Furthermore, participants' identities were kept confidential and stored securely in password-protected files. Coded identifiers were given to participants after obtaining informed consent. No participants' personal identifiers were used in analyses or report writing. Participants received \$5 in compensation and transportation reimbursement for their participation. "

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Before the intervention started, 3295 FEWs were assessed for eligibility, of whom 828 FEWs did not meet the eligibility criteria, 134 declined to participate, and 325 FEWs were excluded because of other reasons. Of the included FEWs, 435 FEWs were allocated to the intervention group and 683 FEWs to the control group. By the end of 30 weeks, 217 FEWs in the intervention and 513 FEWs in the control group discontinued the study and were replaced. We included 435 FEWs in the intervention and 683 FEWs in the intervention and 518 FEWs in the intervention and 218 FEWs in the intervention and 170 FEWs in the control group in the per-protocol analyses."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

See CONSORT Flow Diagram

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Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

n/a

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Table 1 and "Participant characteristics were then compared for the analytic sample (n=388) versus non-analytic sample (n=733) to assess significant differences within and between groups for those retained in the study per protocol for at least two survey assessments (i.e., analytic sample) versus those lost to follow up after the baseline assessment (i.e., non-analytic sample)." and "We compared the characteristics of the analytic (retained) vs. non-analytic (lost to follow-up) samples and identified significant baseline differences in believing that something can be done if someone experiences abuse and forced drinking at work. Participants in the analytic sample were more likely to believe that something can be done if a person experiences abuse and to report ever being forced to drink at work. No other baseline differences were identified between analytic and non-analytic samples. "

15-i) Report demographics a	ssociate	ed with	digital d	ivide iss	sues	
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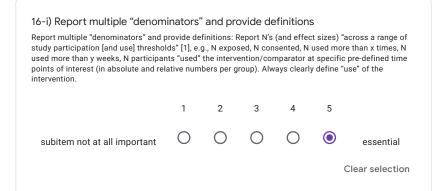
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Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Table 1 and associated narrative: "Table 1 displays characteristics of the sample stratified by intervention vs. control group with crude and cluster-adjusted pooled association tests. When accounting for clustering by the venue, there were no differences in sample characteristics by the group at baseline except a significantly lower proportion of currently married participants in the intervention than in the control group (19% vs. 28%, p=0.047). There were crude differences identified by province and entertainment job venue type when not accounting for clustering within venues. The intervention group had a higher proportion of participants from Battambang than the control group (16% vs. 9%, p=0.04). There were marginal but not significant crude differences in the proportions of intervention vs. control participants in each of the other three provinces. The intervention group had a higher proportion of participants working in karaoke bars (67% vs. 55%, p=0.01). In contrast, the control group had a higher proportion of participants working in beer gardens (12% vs. 22%, p=0.009). All other characteristics were successfully matched between arms with no statistically significant differences between intervention and control aroune "

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups



Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Tables 1-3

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
					C	Clear selection

Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"ITT and per-protocol results were consistent for all outcomes regarding the direction, strength, and significance of associations. As such, only the per-protocol results are presented in the tables for ease of interpretation."

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Tables 1-3

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
					C	lear selection

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

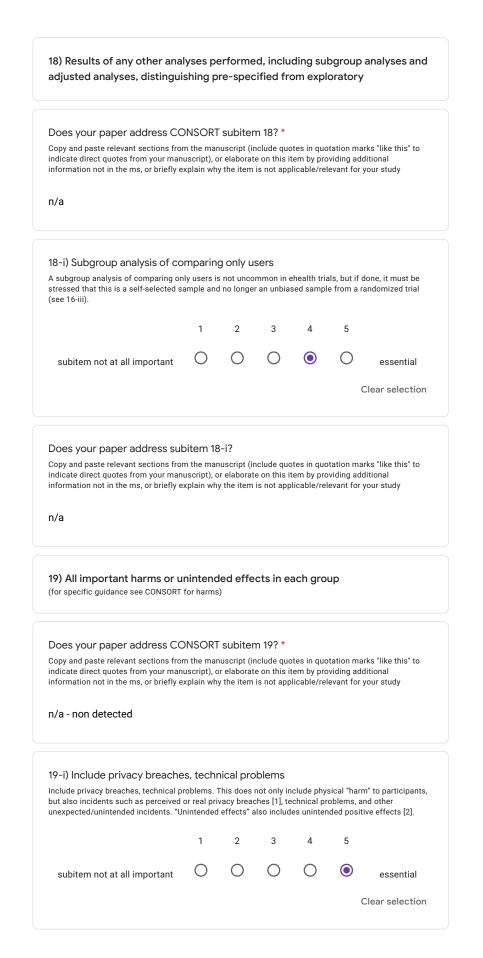
n/a

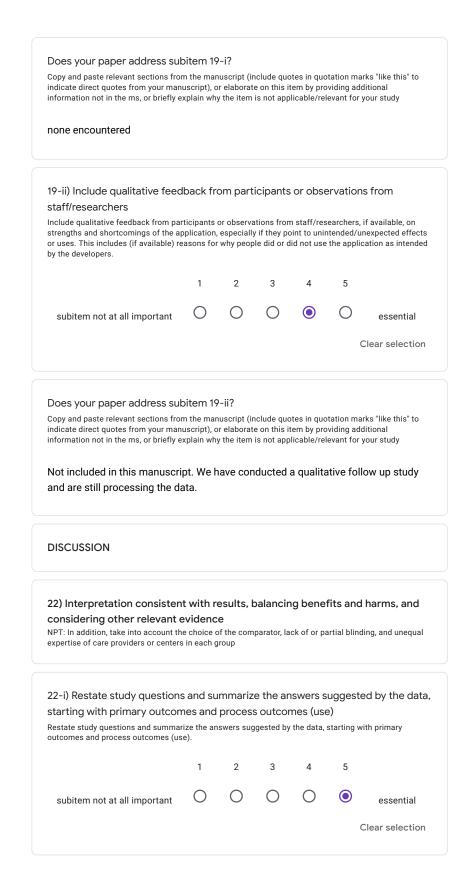
17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Tables 2 and 3 presents ORs and AORs





Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Our findings suggest that the Mobile Link intervention effectively connected FEWs with outreach workers for health information and escorted referrals. However, the findings do not indicate an impact on HIV and STI testing, condom use, and contraceptive use. Reductions in forced drinking at work were significantly larger in the intervention group than in the control group."

22-ii) Highlight unanswered new questions, suggest future research Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	0	0	0	۲	0	essential
					С	lear selection

Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Our study did not detect changes in health outcomes, perhaps because these changes take longer to occur. It is also possible that several trial implementation challenges may have limited ability to detect health outcomes changes, including the high loss to follow-up, which was identified as an issue for other mHealth studies in Cambodia."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in eh	ealth tri	als				
Typical limitations in ehealth trials: P look at a multiplicity of outcomes, ind intervention/usability issues, biases t	creasing ri	sk for a Ty	pe I error.	Discuss b	oiases due	to non-use of the
	1	2	3	4	5	
subitem not at all important	0	0	0	0	۲	essential
					(Clear selection

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Limitations

These findings should be interpreted with regard to study limitations. First, differential loss to follow-up was observed between intervention and control groups, and attrition was particularly high among control and replacement participants. Second, recruiting new participants to replace those lost to follow-up was conducted according to the initially intended distribution of participants per province rather than where participants were lost, resulting in an overrepresentation of control participants in smaller provinces. Third, high levels of movement between venues among FEWs led to a protocol change resulting in individual-level rather than venue-level sampling and non-random assignment to intervention and control groups. Finally, the participant were not blinded to the intervention. As such, the findings should be interpreted with caution. However, a balance between study arms at baseline was achieved on all primary and secondary outcomes, in both the analytic sample and full sample, suggesting that intervention and control participants were appropriately matched based on participant characterietics and health behaviors."

21) Generalisability (external validity, applicability) of the trial findings NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

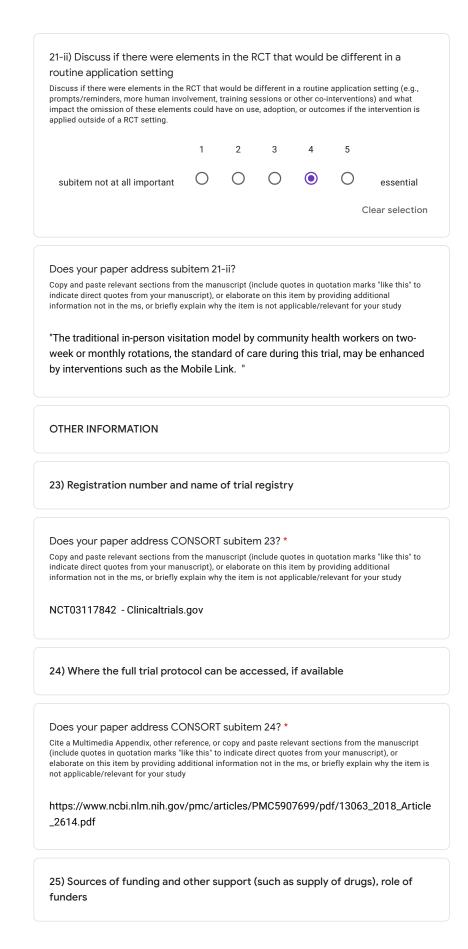
Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

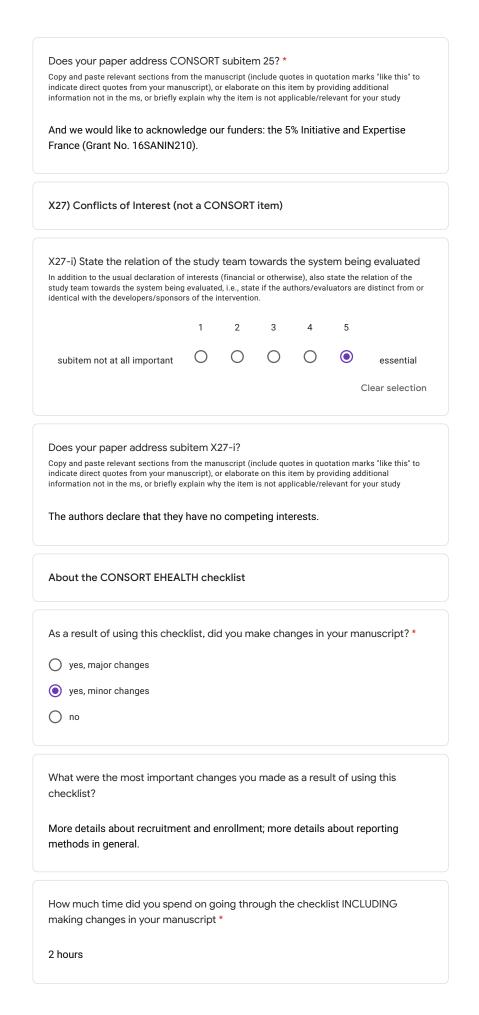


Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Given the positive findings on service linkages for this intervention, we will consider using the Mobile Link model with other key populations in Cambodia and the region. "





As a result of using this checklist, do you think your manuscript has improved? *
() yes
O no
O Other:
Would you like to become involved in the CONSORT EHEALTH group? This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document
• yes
O no
O Other:
Clear selection
Any other comments or questions on CONSORT EHEALTH
It would be nice to have the ability to save and come back later since this is a very long process.
STOP - Save this form as PDF before you click submit To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.
When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.
Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!
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