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## **Kukaa Salama (Staying Safe): Study Protocol for a Pre-Post Trial of an Interactive mHealth Intervention for Increasing COVID-19 Prevention Practices with Urban Refugee Youth in Kampala, Uganda**

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3 **Title:** Kukaa Salama (Staying Safe): Study Protocol for a Pre-Post Trial of an Interactive  
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5 mHealth Intervention for Increasing COVID-19 Prevention Practices with Urban Refugee Youth  
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7 in Kampala, Uganda  
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## Abstract

**Introduction:** With over 82.4 million forcibly displaced persons worldwide there remains an urgent need to better describe culturally, contextually and age-tailored strategies for preventing COVID-19 in humanitarian contexts. Knowledge gaps are particularly pronounced for urban refugees who experience poverty, overcrowded living conditions, and poor sanitation access that constrain the ability to practice COVID-19 mitigation strategies such as physical distancing and frequent hand washing. With over 1.4 million refugees, Uganda is sub-Saharan Africa's largest refugee hosting nation. More than 90,000 of Uganda's refugees live in Kampala, most in informal settlements, and 27% are aged 15-24 years old. There is an urgent need for tailored COVID-19 responses with urban refugee adolescents and youth. This study aims to evaluate the effectiveness of an 8-week interactive informational mHealth intervention on COVID-19 prevention practices among refugee and displaced youth aged 16-24 years in Kampala, Uganda.

**Methods and Analysis:** We will conduct a pre-test/post-test study nested within a larger cluster randomized trial. Approximately 385 youth participants will be enrolled and followed for six months. Data will be collected at three-time points: before the intervention (Time 1); immediately after the intervention (Time 2); and at 12-week follow-up (Time 3). The primary outcome (self-efficacy to practice COVID-19 prevention measures) and secondary outcomes (COVID-19 risk awareness, attitudes, norms, and self-regulation practices; depression; sexual and reproductive health practices; food and water security; COVID-19 vaccine acceptability) will be evaluated using descriptive statistics and regression analyses.

**Ethics and Dissemination:** This study has been approved by the University of Toronto Research Ethics Board, the Mildmay Uganda Research Ethics Committee, and the Uganda National Council for Science & Technology. The results will be published in peer-reviewed journals upon

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3 completion, and findings will be communicated locally, nationally, and internationally through  
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5 executive reports and conferences presentations.  
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8 **Trial Registration:** This pre-test/post-test study is registered at ClinicalTrials.gov  
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10 (NCT04631367).  
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14 **Key words:** Adolescents and youth, COVID-19, mHealth, refugee, hygiene, vaccine  
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16 acceptability, Uganda  
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### Strengths and limitations of this study

- The Kuka Salama study is unique in exploring the use of mHealth technologies for improving COVID-19 prevention practices, including COVID-19 vaccine acceptance, among urban refugee and displaced youth in Kampala, Uganda. Little is known about effective strategies for advancing COVID-19 prevention with this population.
- We use a pre-test/post-test longitudinal design to examine changes over time and assess if the 8-week interactive informational mHealth intervention affects participants' self-efficacy to practice COVID-19 prevention measures.
- The primary study limitations are loss to follow-up and missing data points, as well as delays due to COVID-19.
- This research will inform us on the potential benefits of mHealth strategies in scaling up differentiated COVID-19 response efforts and messaging with urban refugee and displaced youth, and how this can be adapted for diverse contexts.

## Background

“This global public health emergency highlights the exclusion and multiple barriers to health care that are faced by migrants and refugees, among whom COVID-19 threatens to have rapid and devastating effects.” Global call to action for inclusion of migrants and refugees in the COVID-19 response.(p. 1482)[1]

Refugee and other forcibly displaced persons experience healthcare barriers that require urgent attention in the COVID-19 pandemic to ensure that no one is left behind in public health responses.[2] Poverty, overcrowded living conditions, and poor sanitation elevate forcibly displaced persons' COVID-19 risks while limiting the ability to practice mitigation strategies (e.g., physical distancing, hand washing).[3–5] There is a pressing need to better understand culturally, contextually and age-tailored strategies for preventing COVID-19 among the more than 82.4 million forcibly displaced persons worldwide.[6] Although adolescents and youth comprise 42% of the world's forcibly displaced persons [6] they have been understudied in pandemics, and this is true for urban refugee youth who are often overlooked in research and programming due to a focus on settlement-based refugees.[7–9] With over 1.4 million refugees, Uganda is sub-Saharan Africa's largest refugee hosting nation.[10] More than 90,000 of Uganda's refugees live in Kampala, most in informal settlements, and 27% are aged 15-24 years old.[10] Language and communication barriers have been identified as barriers to accessing COVID-19 information among urban refugees at large in Kampala, [11] and knowledge gaps persist regarding efficacious strategies to increase knowledge and uptake of COVID-19 prevention practices among urban refugee youth.

The World Health Organization's (WHO) recommended COVID-19 mitigation practices include hand hygiene (washing hands regularly and thoroughly with soap and water, avoiding touching mouth, eyes or nose); respiratory hygiene (covering mouth or nose when coughing or sneezing, then washing hands); physical distancing (maintaining at least 1-meter distance with others; in densely populated contexts this may involve household or community shielding); and wearing a mask (including appropriate storage and daily cleaning of cloth masks).[12] These calls for physical distancing, hand and respiratory hygiene, and mask wearing with daily cleaning practices may not be realized among those living in informal settlements due to overcrowded living conditions, poverty, and poor access to water and sanitation.[2,3,13]

There are knowledge gaps regarding some of these recommended hygiene practices with adolescents and youth in humanitarian contexts. For instance, we identified no respiratory hygiene intervention studies in humanitarian contexts.[14–16] Humanitarian context hand hygiene studies report that information is necessary—*but not sufficient*—to motivate hand hygiene [17–19] and call for behaviour change strategies.[18] No adolescent/youth hand hygiene studies were located in humanitarian contexts. A study with internally displaced children in Iraq identified hand hygiene determinants included hygiene promotion, social norms, and motivational drivers.[19] A hand hygiene study with displaced adults in the Democratic Republic of Congo highlighted the role of emotional and social motivators and a need for innovation.[20] Physical distancing is not feasible in crowded settlements,[21] yet limited research has assessed strategies to promote alternatives such as household or community shielding.[3,22]



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6 Our study applies behavioural science to mHealth to increase COVID-19 preventive practice  
7 uptake with urban refugee youth. As Michie described, “behavioural science must be at the heart  
8 of the public health response” (p. 1) for COVID-19 mitigation.[23] We follow the RANAS  
9 approach to systematic behaviour change for Water and Sanitation and Hygiene (WASH)  
10 grounded in three contexts (social, physical, personal) and five behavioural factors: *risk* (e.g. risk  
11 and vulnerability awareness), *attitude* (e.g. costs/benefits of the behaviour), *norms* (e.g.  
12 behaviours others adopt), *ability* (e.g. efficacy, confidence), and *self-regulation* (e.g. action and  
13 barrier planning).[24,25] RANAS—a widely used framework for WASH interventions—  
14 provides behavioural change techniques to address behavioural factors.[26–29]  
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18 Mobile health (mHealth) is a cost-effective health information delivery approach that is aligned  
19 with how youth learn and socialize, and important for physical distancing. messaging services  
20 (SMS), or text messages, have been used to disseminate hygiene messaging in humanitarian  
21 contexts,[18] and by the Office of the United Nations High Commissioner for Refugees  
22 (UNHCR) for COVID-19 symptom reporting in Kenya.[5] Similarly, Singapore is using  
23 WhatsApp[30] to share COVID-19 updates with healthcare providers.[31] In particular,  
24 interactive mHealth interventions including multiple forms of media and engagement including  
25 SMS, WhatsApp, and group photo sharing could be more effective than one-way  
26 messages/reminders for changing behaviour.[32–36] The potential to implement mHealth  
27 solutions at scale is high given that most urban refugees in Uganda have access to mobile  
28 phones.[37] Yet, in 2021, the use of mHealth for RANAS-based behaviour change remains  
29 understudied among urban refugee youth.  
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34 *Kukaa Salama*, roughly translated from Swahili for ‘staying safe’, aims to address these  
35 knowledge gaps by evaluating an interactive informational mHealth intervention on COVID-19  
36 prevention practices. This study is nested within a cluster randomized trial on HIV self-testing  
37 for which the primary outcomes are HIV testing frequency and status knowledge (Tushirikiane;  
38 clinicaltrial.gov registration NCT04504097), which recently completed data collection in  
39 Kampala, Uganda.[38] Findings from this study can be used to inform local and global response  
40 efforts with new knowledge of mHealth approaches for COVID-19 prevention with urban  
41 refugee youth in humanitarian contexts.  
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## 46 **Methods**

### 47 ***Study Aim and Objectives***

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50 The overarching goal of this study is to evaluate the effectiveness of an 8-week interactive  
51 informational mHealth intervention on increasing COVID-19 prevention practices among  
52 refugee and displaced youth aged 16-24 years in Kampala, Uganda. The primary objective is to  
53 evaluate the effectiveness of the intervention on participants’ self-efficacy (e.g., ability  
54 confidence, and adherence) to practice hand and respiratory hygiene COVID-19 prevention  
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measures. Secondary objectives include examining the impact of the intervention on 1) COVID-19 risk awareness; 2) attitudes towards COVID-19; 3) perceived COVID-19 norms; 4) COVID-19 self-regulation practices; 5) depression; 6) sexual and reproductive health practices; 7) food and water security perceptions; and 8) COVID-19 vaccine acceptability.

### ***Study Design***

To evaluate the intervention's effectiveness, we are conducting a single arm, pre-test/post-test trial design. A control group design is intentionally not used based on recommendations regarding ethical concerns over the potential withholding of any public health intervention benefits from a vulnerable group (i.e., refugee youth living in informal settlements) in the midst of a pandemic.[39] Data will be collected at three-time points: at enrollment before the intervention (Time 1); immediately after the completion of the mHealth intervention at 8-weeks (Time 2); and at a 12-week follow-up survey (Time 3). Participant demographic data will be linked from the Tushirikiane cohort, which collected baseline data in February 2020.

### ***Study Setting***

This trial is being conducted in five informal settlements in Kampala, Uganda (Kabalagala, Kansanga, Katwe, Nsyamba, Rubaga). Enrollment and clinical activities are based at the Young African Refugees for Integral Development (YARID) center, a youth-focused community-based non-governmental organization that implements economic empowerment programs for refugee youth. Full details regarding the trial site geography and population have been described elsewhere.[38]

### ***Participants and Recruitment***

All participants enrolled in the Tushirikiane trial are eligible for the Kukaa Salama sub-study. Tushirikiane participants were recruited using purposive methods, including peer-driven recruitment with the support of 12 peer navigators. Peer navigators are study staff who identify as refugees or displaced persons, aged 18-24 years, who have been engaged to help with recruitment and retention, as well as providing feedback on study designs and surveys. Inclusion criteria for participants into the Kukaa Salama study include: 1) being a Tushirikiane participant, 2) living in one of the five informal settlement sites (Kabalanga, Kansanga, Katwe, Nsambya, or Rubaga); 3) identifying as a refugee/displaced person of have been born to refugee/displaced persons; 4) aged 16-24 years; 5) speaking one of the study languages (English, French, Kinyarwanda/ Kirundi, Luganda, or Swahili); and 6) owning or having access to a mobile phone for the duration of the study.

Participants are informed of the Kukaa Salama sub-study at a clinical visit after enrollment into the original trial. We obtain separate written, informed consent for participation in Kukaa Salama. Participants are free to refuse participation or withdraw from Kukaa Salama while remaining in Tushirikiane. However, Tushirikiane participants who withdraw or are lost to follow-up are automatically withdrawn from the Kukaa Salama sub-study. Community

collaborators and peer navigators will facilitate participant retention using multiple study reminder strategies to maintain engagement.

### ***Patient and Public Involvement***

This study protocol was developed after the completion of a formative qualitative research phase. During this formative research, we engaged in in-depth interviews with youth participants from the Tushirikiane study as well as local key informants, who are professionals in various roles supporting health and well-being of refugee youth in Uganda, to identify key priorities and preferences. This qualitative component informed the development of the intervention and key themes for the COVID-19 prevention messaging; therefore, this study directly responds to refugee youth-identified needs. Additionally, this research is being conducted in collaboration with YARID, and study collaborators have been involved in all aspects of the research cycle, from development of the study question to implementation. In particular, the YARID peer navigators have been consulted regarding the study design and outcomes, supported participant recruitment and engagement, and have pilot-tested all study instruments to assess acceptability for the study population. All peer navigators' feedback has been integrated into the final intervention and study instruments, with modifications made to ensure appropriate delivery. The key study findings will be disseminated to participants and community members through an integrated knowledge translation approach, including infographics and community meetings developed in collaboration with local partners.

### ***Intervention Description***

This is a pre-test/post-test trial, therefore all participants will receive the Kukaa Salama intervention. Kukaa Salama is an 8-week mHealth program of COVID-19 prevention messaging, which includes sending weekly informational SMS and facilitated secure group interactions to share multimedia images. The intervention is hosted on a web-based SMS platform developed by WelTel [35,36,40] and accompanied by moderated group interactions and photo sharing using WhatsApp. WelTel is a non-profit agency developing the mHealth intervention, in which participants receive weekly supportive bidirectional text messages. WhatsApp is a no cost mobile phone application that allows users to share SMS, photos, videos, and voice messages with end-to-end encryption; requires minimal data; and is widely used to share health information.[32,33,41–44] The intervention involves three linked mHealth components and a prevention parcel, which are described below and summarized in **Figure 1**.

*Check-in messaging:* Each week, participants will receive a message asking how they are doing and are requested to reply “fine” or “not fine;” those responding “not fine” will be contacted for support by a peer navigator. The WelTel system will manage the SMS intervention on a structured mobile phone platform (all SMS interactions are logged).

*COVID-19 prevention messaging:* Participants will also receive a weekly themed COVID-19 informational SMS and an accompanying question to enhance engagement. Content topics address the themes identified during our formative qualitative research phase and apply BCT

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3 approaches following the RANAS [25] framework. Weekly themed topics include information  
4 on COVID-19 symptoms and transmission; encouragement on the use of handwashing,  
5 respiratory hygiene, and face masks; COVID-19 vaccines and testing; and stigma and recovery  
6 (**Table 1**). All messages will be translated into the five study languages; in the pre-intervention  
7 survey participants indicate their language preference for receiving health-related SMS, and the  
8 preferred language will be programmed for each participant. The peer navigators will review the  
9 responses to the engagement question and the top response will be sent out to all participants to  
10 incentivize engagement. Participants can also respond to the SMS with any questions about  
11 COVID-19, and the study team will respond with further information and/or additional  
12 resources.  
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17 *COVID-19 multimedia sharing*: Finally, within the peer navigator-facilitated secure and  
18 encrypted WhatsApp groups, participants are able to share multimedia images related to the  
19 weekly theme. These can include photos, memes, GIFs, and other multimedia options; this  
20 provides an opportunity for participants to display their application and practice of the weekly  
21 COVID-19 prevention topics in their daily lives. This aligns with calls for hygiene  
22 communication in humanitarian contexts to include information and images.[18]  
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26 *COVID-19 prevention parcel*: At each survey time point, participants will also be offered the  
27 opportunity to pick up a parcel that contains a face mask, bar of soap, and a small parcel of food  
28 to support the prevention messaging.  
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### 31 **Outcomes**

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33 The primary outcome measured in this trial is:

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35 *Changes in COVID-19 prevention practices*, assessed by asking participants to report on their  
36 self-efficacy (i.e., ability, confidence, and adherence) to practice hand and respiratory hygiene  
37 (e.g., hand washing with soap, face mask usage) and physical distancing. Questions utilize the  
38 RANAS framework questions [25,27,45] applied to these preventive practices. This measure is  
39 assessed at all three study time points (pre-intervention [Time 1], post-intervention [Time 2], and  
40 follow-up [Time 3]).  
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43 Secondary outcomes are below; secondary outcomes 1-4 follow the RANAS questionnaire items  
44 [25,27,45] adapted for COVID-19 preventive practices:  
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- 47 1. *Changes in COVID-19 risk awareness*, assessed by asking participants to report on their  
48 perceived risk and vulnerabilities to COVID-19 as well as their knowledge of symptoms  
49 and severity (Time 1, Time 2, Time 3).  
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- 51 2. *Changes in attitude towards COVID-19*, assessed by asking participants to report on their  
52 attitude (i.e., feelings, costs/benefits) towards COVID-19 prevention practices as well as  
53 towards COVID-19 testing and potential vaccines (Time 1, Time 2, Time 3).  
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3. *Changes in COVID-19 norms*, assessed by asking participants to report on the perceived behaviours approved by others (i.e., social pressures) towards COVID-19 prevention practices, transmission, and stigma (Time 1, Time 2, Time 3).
4. *Changes in COVID-19 self-regulation*, assessed by asking participants about their action plan for implementing COVID-19 prevention practices (Time 1, Time 2, Time 3).
5. *Changes in depression*, assessed using the Patient Health Questionnaire-9 item (PHQ-9) [46] (Time 1, Time 2, Time 3). Scores range from 0 to 27; higher scores mean a worse outcome.
6. *Changes in sexual and reproductive health practices*, assessed by asking participants to report on personal experiences (e.g., intimate partner violence) as well as perceived changes in the community (e.g., violence, access to sexual and reproductive health services) (Time 1, Time 2, Time 3).
7. *Changes in food and water insecurity*, which is assessed by asking participants to report on frequency of insufficient food (i.e., going to bed hungry) and inadequate clean water (Time 1, Time 2, Time 3).
8. *Changes in COVID-19 vaccine acceptability*, which is assessed by asking participants to report how likely they would be to accept a COVID-19 vaccine that was shown to be effective and available using a four-point Likert scale (very likely, likely, somewhat likely, not at all likely) (Time 1, Time 2, Time 3).

### ***Sample Size and Power***

We estimate that a sample size of 52 participants (104 data points) is required to detect an effect size of 0.4 between pairs with a power of 80% and type 1 error rate of 5%, and assuming a correlation between pre-test/post-test responses of 0.5. For a correlation as low as 0.1 we estimate that 91 participants will be required, and if the effect size is larger we will require fewer participants. Based on current participant retention rates, we anticipate that at least 85% (n=340) of the Tushirkiane cohort (n=404) will participate in Kukaa Salama. This will give us sufficient power for conducting this analysis, as well as for covariate adjustment.

### ***Data Collection and Management***

Participant outcome data will be collected at three-time points (pre-intervention, Time 1; post-intervention, Time 2; follow-up, Time 3) using structured questionnaires administered by trained research assistants. Interviews will be conducted in all study languages and data will be collected in-person or by mobile telephone, depending on local COVID-19 guidelines. All data will be recorded on tablets using SurveyCTO (Dobility Inc., Cambridge, USA). Data collection tools include branching logic for efficiency and have range and consistency checks built-in to provide immediate feedback to research assistants regarding errors and inconsistencies. Tablet based data collected will be automatically encrypted and uploaded to a password-protected project team server on a daily basis using an SSL certificate. To maintain confidentiality, all participants have

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3 been given a unique Case ID, and no personal identifying information will be stored with the  
4 study data.  
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### 6 ***Data Analysis***

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9 All analyses and reporting will be conducted following the TREND checklist.[47] Descriptive  
10 analyses of socio-demographic variables will be conducted to characterize the participant sample  
11 using counts or means and standard deviations or medians and interquartile ranges, as  
12 appropriate. Outcome scale items will be summed to calculate overall and sub-scale scores, and  
13 novel scales will be assessed for reliability (i.e., Cronbach's alpha). To assess pre-post outcomes  
14 differences in RANAS scores we will use linear or logistic generalized estimating equation  
15 (GEE) regression models, depending on which outcome is being evaluated, with an  
16 exchangeable correlation matrix to account for clustering by participant. To assess the  
17 moderating effect of engagement with the intervention we will examine interactions between  
18 mean outcome pre-post score changes and intervention usage (e.g., WelTel data regarding  
19 frequency of interaction, number of days used, length of time, etc.). We will conduct adjusted  
20 analyses to examine the role of covariates on the relative effect. Covariates (e.g., age, gender)  
21 will be entered as a block. The level of significance will be set at  $\alpha=0.05$ , and we will report  
22 odds ratios or mean differences as appropriate, and corresponding 95% confidence intervals and  
23 p-values.  
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### 28 **Discussion**

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31 There are knowledge gaps regarding efficacious strategies to increase COVID-19 preventive  
32 practices with urban refugee youth—despite calls for inclusion of migrants and refugees in  
33 COVID-19 responses.[1] The current study aims to address this knowledge gap by conducting an  
34 8-week interactive and informational mHealth intervention to improve COVID-19 prevention  
35 practices among refugee youth in Kampala, Uganda. Study strengths are: the intervention is  
36 included within an existing community-based research cohort study that leverages trained peer  
37 navigators and engaged community and government collaborators; the design and foci were  
38 informed by qualitative research with urban refugee youth and key informants to address  
39 identified needs; and alignment with the well-established RANAS framework.[25] There are also  
40 study limitations due to the pre/post-test design with no control group; other study designs such  
41 as stepped wedge could be implemented in future iterations. In addition, given the COVID-19  
42 pandemic we have seen higher rates of loss to follow-up as participants leave urban areas and  
43 return to their country of origin or to settlements/camps. Political instability and interruptions to  
44 internet access in Uganda in early 2021 also delayed study implementation.  
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50 This study will provide effectiveness data for a non-pharmaceutical intervention that is low cost,  
51 scalable, contextually specific, and rooted in behavioural science, which is essential with limited  
52 availability of COVID-19 vaccines in Uganda and other Sub-Saharan African context. If findings  
53 indicate that the intervention increases COVID-19 prevention practices in this population there is  
54 scope to scale-up this intervention for other urban-refugee populations in Uganda, and can be  
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3 adapted for other informal settlement populations as well as non-urban settlement-based  
4 refugees.  
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## 8 **Ethics and Dissemination of Findings**

### 9 *Ethical Approval*

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12 The Kuka Salama intervention study was approved as an amendment to the Tushirikiane trial by  
13 the University of Toronto Research Ethics Board (reference 37496); the Mildmay Uganda  
14 Research Ethics Committee (reference 0806-2019); and the Uganda National Council for  
15 Science & Technology (reference HS 2716). All participants have provided written, informed  
16 consent for inclusion in this study.  
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### 19 *Dissemination Plan*

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21 Irrespective of study findings, results will be published in peer-reviewed scientific journals and  
22 will be presented to academics and researchers at key scientific conferences. Study results will  
23 also be shared as executive summaries, reports and technical policy briefs with national and  
24 international collaborating organizations, including our collaborators, the Uganda Ministry of  
25 Health, and UNHCR. Engaging, pictorial research summaries with highlights of study findings  
26 in all five languages will also be shared with participants and study collaborators.  
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### 30 **Trial Status**

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33 The Kuka Salama study launched in April 2021 with pre-intervention data collection. The  
34 Intervention is currently underway. We anticipate data collection post-intervention to be  
35 conducted in August 2021, and the final follow-up survey to be conducted in October 2021.  
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## Tables & Figures

**Table 1.** Topics on COVID-19 prevention included in the Kuka Salama mobile health (mHealth) intervention

Scenario	Description
<b>Mental health</b>	Explores strategies for managing stress and supporting mental health and well-being during COVID-19, including peers can support each other.
<b>Vaccine hesitancy</b>	Presents the importance of taking a COVID-19 vaccine to protect oneself and their community.
<b>Hand washing</b>	Explains the importance of hand washing for COVID-19 prevention, and provides tips on when one should wash their hands.
<b>Mask wearing</b>	Explains the importance of wearing masks to reduce COVID-19 transmission, and provides tips on when one should wear a mask.
<b>Economic stressors</b>	Acknowledges the personal and community hardships caused by COVID-19, and elicits peer support for overcoming hardship.
<b>Symptoms &amp; testing</b>	Provides a reminder of key COVID-19 symptoms and addresses the importance of COVID-19 testing as a pathway to care.
<b>Stigma &amp; recovery</b>	Addresses stigma associated with COVID-19 and COVID-19 recovery, and encourages peer support during and after recovery.
<b>Recap week</b>	Reviews the key themes and encourages peer and community support.

**Figure 1.** Study design for Kuka Salama, a pre-test/post-test trial of an interactive and informational mobile health (mHealth) strategy among urban refugee and displaced youth in Kamala, Uganda.

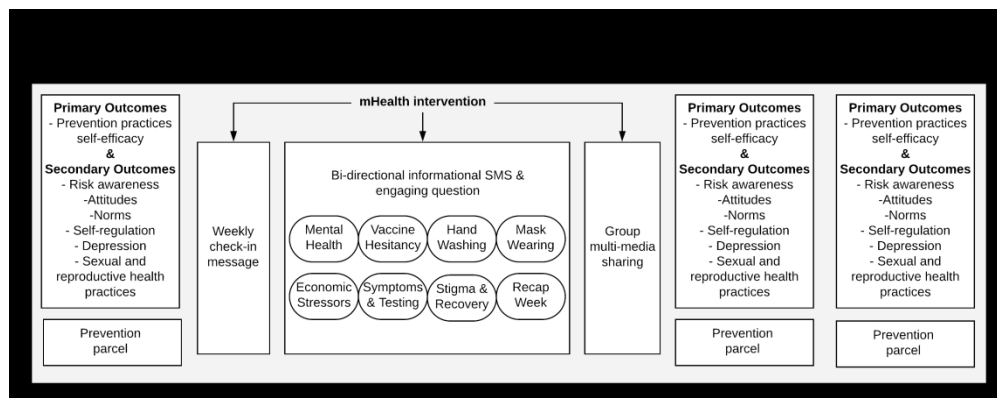


Figure 1. Study design for Kuka Salama, a pre-test/post-test trial of an interactive and informational mobile health (mHealth) strategy among urban refugee and displaced youth in Kamala, Uganda.

1151x456mm (72 x 72 DPI)

# BMJ Open

## Kukaa Salama (Staying Safe): Study Protocol for a Pre-Post Trial of an Interactive mHealth Intervention for Increasing COVID-19 Prevention Practices with Urban Refugee Youth in Kampala, Uganda

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Date Submitted by the Author:	02-Oct-2021
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<b>Primary Subject Heading</b>:	Global health
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Keywords:	COVID-19, PREVENTIVE MEDICINE, PUBLIC HEALTH

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3 **40 Abstract**

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5 **41 Introduction:** With over 82.4 million forcibly displaced persons worldwide there remains an  
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8 **43** urgent need to better describe culturally, contextually and age-tailored strategies for preventing  
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10 **44** COVID-19 in humanitarian contexts. Knowledge gaps are particularly pronounced for urban  
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12 **45** refugees who experience poverty, overcrowded living conditions, and poor sanitation access that  
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14 **46** constrain the ability to practice COVID-19 mitigation strategies such as physical distancing and  
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16 **47** frequent hand washing. With over 1.4 million refugees, Uganda is sub-Saharan Africa's largest  
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18 **48** refugee hosting nation. More than 90,000 of Uganda's refugees live in Kampala, most in  
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20 **49** informal settlements, and 27% are aged 15-24 years old. There is an urgent need for tailored  
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22 **50** COVID-19 responses with urban refugee adolescents and youth. This study aims to evaluate the  
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24 **51** effectiveness of an 8-week interactive informational mHealth intervention on COVID-19  
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26 **52** prevention practices among refugee and displaced youth aged 16-24 years in Kampala, Uganda.

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29 **53 Methods and Analysis:** We will conduct a pre-test/post-test study nested within a larger cluster  
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32 **54** randomized trial. Approximately 385 youth participants will be enrolled and followed for six  
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34 **55** months. Data will be collected at three-time points: before the intervention (Time 1);  
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36 **56** immediately after the intervention (Time 2); and at 16-week follow-up (Time 3). The primary  
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38 **57** outcome (self-efficacy to practice COVID-19 prevention measures) and secondary outcomes  
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40 **58** (COVID-19 risk awareness, attitudes, norms, and self-regulation practices; depression; sexual  
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42 **59** and reproductive health practices; food and water security; COVID-19 vaccine acceptability)  
43  
44 **60** will be evaluated using descriptive statistics and regression analyses.

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47 **61 Ethics and Dissemination:** This study has been approved by the University of Toronto Research  
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50 **62** Ethics Board, the Mildmay Uganda Research Ethics Committee, and the Uganda National  
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3 63 Council for Science & Technology. The results will be published in peer-reviewed journals, and  
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5 64 findings communicated through reports and conferences presentations.  
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8 65 **Trial Registration:** This pre-test/post-test study is registered at ClinicalTrials.gov  
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10 66 (NCT04631367). First posted date: 17 November 2020; latest update: 27 September 2021.  
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12 67  
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14 68 **Key words:** Adolescents and youth, COVID-19, mHealth, refugee, hygiene, vaccine  
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16 69 acceptability, Uganda  
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### 74 **Strengths and limitations of this study**

- 75 • The Kuka Salama study is unique in exploring the use of mHealth technologies for  
76 improving COVID-19 prevention practices, including COVID-19 vaccine acceptance,  
77 among urban refugee and displaced youth in Kampala, Uganda.
- 78 • We use a pre-test/post-test longitudinal design to examine changes over time and assess if  
79 the 8-week interactive informational mHealth intervention effects participants' self-  
80 efficacy to practice COVID-19 prevention measures.
- 81 • The primary study limitations are loss to follow-up and missing data points, as well as  
82 delays due to COVID-19.
- 83 • This research will inform us on the potential benefits of mHealth strategies in scaling up  
84 differentiated COVID-19 response efforts and messaging with urban refugee and  
85 displaced youth, and how this can be adapted for diverse contexts.



## 90 Background

91 “This global public health emergency highlights the exclusion and multiple barriers to health care  
92 that are faced by migrants and refugees, among whom COVID-19 threatens to have rapid and  
93 devastating effects.” Global call to action for inclusion of migrants and refugees in the COVID-  
94 19 response.(p. 1482)[1]

95  
96 Refugee and other forcibly displaced persons experience healthcare barriers that require urgent  
97 attention in the COVID-19 pandemic to ensure that no one is left behind in public health  
98 responses.[2] Poverty, overcrowded living conditions, and poor sanitation elevate forcibly  
99 displaced persons’ COVID-19 risks while limiting the ability to practice mitigation strategies  
100 (e.g., physical distancing, hand washing).[3–5] There is a pressing need to better understand  
101 culturally, contextually and age-tailored strategies for preventing COVID-19 among the more  
102 than 82.4 million forcibly displaced persons worldwide.[6] Although adolescents and youth  
103 comprise 42% of the world’s forcibly displaced persons [6] they have been understudied in  
104 pandemics, and this is true for urban refugee youth who are often overlooked in research and  
105 programming due to a focus on settlement-based refugees.[7–9] With over 1.4 million refugees,  
106 Uganda is sub-Saharan Africa’s largest refugee hosting nation.[10] More than 90,000 of  
107 Uganda’s refugees live in Kampala, most in informal settlements, and 27% are aged 15-24 years  
108 old.[10] Language and communication barriers have been identified as barriers to accessing  
109 COVID-19 information among urban refugees at large in Kampala, [11] and knowledge gaps  
110 persist regarding efficacious strategies to increase knowledge and uptake of COVID-19  
111 prevention practices among urban refugee youth.  
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113 The World Health Organization’s (WHO) recommended COVID-19 mitigation practices include  
114 hand hygiene (washing hands regularly and thoroughly with soap and water, avoiding touching  
115 mouth, eyes or nose); respiratory hygiene (covering mouth or nose when coughing or sneezing,  
116 then washing hands); physical distancing (maintaining at least 1-meter distance with others; in  
117 densely populated contexts this may involve household or community shielding); and wearing a  
118 mask (including appropriate storage and daily cleaning of cloth masks).[12] These calls for  
119 physical distancing, hand and respiratory hygiene, and mask wearing with daily cleaning  
120 practices may not be realized among those living in informal settlements due to overcrowded  
121 living conditions, poverty, and poor access to water and sanitation.[2,3,13]  
122

123 There are knowledge gaps regarding some of these recommended hygiene practices with  
124 adolescents and youth in humanitarian contexts. For instance, we identified no respiratory  
125 hygiene intervention studies in humanitarian contexts.[14–16] Humanitarian context hand  
126 hygiene studies report that information is necessary—*but not sufficient*—to motivate hand  
127 hygiene [17–19] and call for behaviour change strategies.[18] No adolescent/youth hand hygiene  
128 studies were located in humanitarian contexts. A study with internally displaced children in Iraq  
129 identified hand hygiene determinants included hygiene promotion, social norms, and  
130 motivational drivers.[19] A hand hygiene study with displaced adults in the Democratic Republic  
131 of Congo highlighted the role of emotional and social motivators and a need for innovation.[20]  
132 Physical distancing is not feasible in crowded settlements,[21] yet limited research has assessed  
133 strategies to promote alternatives such as household or community shielding.[3,22]

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6 135 Our study applies behavioural science to mHealth to increase COVID-19 preventive practice  
7 136 uptake with urban refugee youth. As Michie described, “behavioural science must be at the heart  
8 137 of the public health response” (p. 1) for COVID-19 mitigation.[23] We follow the RANAS  
9 138 approach to systematic behaviour change for Water and Sanitation and Hygiene (WASH)  
10 139 grounded in three contexts (social, physical, personal) and five behavioural factors: *risk* (e.g. risk  
11 140 and vulnerability awareness), *attitude* (e.g. costs/benefits of the behaviour), *norms* (e.g.  
12 141 behaviours others adopt), *ability* (e.g. efficacy, confidence), and *self-regulation* (e.g. action and  
13 142 barrier planning).[24,25] RANAS—a widely used framework for WASH interventions—  
14 143 provides behavioural change techniques to address behavioural factors.[26–29]  
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18 145 Mobile health (mHealth) is a cost-effective health information delivery approach that is aligned  
19 146 with how youth learn and socialize, and important for physical distancing. messaging services  
20 147 (SMS), or text messages, have been used to disseminate hygiene messaging in humanitarian  
21 148 contexts,[18] and by the Office of the United Nations High Commissioner for Refugees  
22 149 (UNHCR) for COVID-19 symptom reporting in Kenya.[5] Similarly, Singapore is using  
23 150 WhatsApp[30] to share COVID-19 updates with healthcare providers.[31] In particular,  
24 151 interactive mHealth interventions including multiple forms of media and engagement including  
25 152 SMS, WhatsApp, and group photo sharing could be more effective than one-way  
26 153 messages/reminders for changing behaviour.[32–36] The potential to implement mHealth  
27 154 solutions at scale is high given that most urban refugees in Uganda have access to mobile  
28 155 phones.[37] Yet, in 2021, the use of mHealth for RANAS-based behaviour change remains  
29 156 understudied among urban refugee youth.  
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34 158 *Kukaa Salama*, roughly translated from Swahili for ‘staying safe’, aims to address these  
35 159 knowledge gaps by evaluating an interactive informational mHealth intervention on COVID-19  
36 160 prevention practices. This study is nested within a cluster randomized trial on HIV self-testing  
37 161 for which the primary outcomes are HIV testing frequency and status knowledge (Tushirikiane;  
38 162 clinicaltrial.gov registration NCT04504097), which recently completed data collection in  
39 163 Kampala, Uganda.[38] Findings from this study can be used to inform local and global response  
40 164 efforts with new knowledge of mHealth approaches for COVID-19 prevention with urban  
41 165 refugee youth in humanitarian contexts.  
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## 45 167 **Methods**

### 46 168 ***Study Aim and Objectives***

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50 169 The overarching goal of this study is to evaluate the effectiveness of an 8-week interactive  
51 170 informational mHealth intervention on increasing COVID-19 prevention practices among  
52 171 refugee and displaced youth aged 16-24 years in Kampala, Uganda. The primary objective is to  
53 172 evaluate the effectiveness of the intervention on participants’ self-efficacy (e.g., ability  
54 173 confidence, and adherence) to practice hand and respiratory hygiene COVID-19 prevention  
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174 measures. Secondary objectives include examining the impact of the intervention on 1) COVID-  
175 19 risk awareness; 2) attitudes towards COVID-19; 3) perceived COVID-19 norms; 4) COVID-  
176 19 self-regulation practices; 5) depression; 6) sexual and reproductive health practices; 7) food  
177 and water security perceptions; and 8) COVID-19 vaccine acceptability.  
178

### 179 ***Study Design***

180 To evaluate the intervention's effectiveness, we are conducting a single arm, pre-test/post-test  
181 trial design. A control group design is intentionally not used based on recommendations  
182 regarding ethical concerns over the potential withholding of any public health intervention  
183 benefits from a vulnerable group (i.e., refugee youth living in informal settlements) in the midst  
184 of a pandemic.[39] Data will be collected at three-time points: at enrollment before the  
185 intervention (Time 1); immediately after the completion of the mHealth intervention at 8-weeks  
186 (Time 2); and at a 16-week follow-up survey (Time 3). Participant demographic data will be  
187 linked from the Tushirikiane cohort, which collected baseline data in February 2020.  
188

### 189 ***Study Setting***

190 This trial is being conducted in five informal settlements in Kampala, Uganda (Kabalagala,  
191 Kansanga, Katwe, Nsyamba, Rubaga). Enrollment and clinical activities are based at the Young  
192 African Refugees for Integral Development (YARID) center, a youth-focused community-based  
193 non-governmental organization that implements economic empowerment programs for refugee  
194 youth. Full details regarding the trial site geography and population have been described  
195 elsewhere.[38]  
196

### 197 ***Participants and Recruitment***

198 All participants enrolled in the Tushirikiane trial are eligible for the Kukaa Salama sub-study.  
199 Tushirikiane participants were recruited using purposive methods, including peer-driven  
200 recruitment with the support of 12 peer navigators. Peer navigators are study staff who identify  
201 as refugees or displaced persons, aged 18-24 years, who have been engaged to help with  
202 recruitment and retention, as well as providing feedback on study designs and surveys. Inclusion  
203 criteria for participants into the Kukaa Salama study include: 1) being a Tushirikiane participant,  
204 2) living in one of the five informal settlement sites (Kabalanga, Kansanga, Katwe, Nsambya, or  
205 Rubaga); 3) identifying as a refugee/displaced person of have been born to refugee/displaced  
206 persons; 4) aged 16-24 years; 5) speaking one of the study languages (English, French,  
207 Kinyarwanda/ Kirundi, Luganda, or Swahili); and 6) owning or having access to a mobile phone  
208 for the duration of the study.  
209

210 Participants are informed of the Kukaa Salama sub-study at a clinical visit after enrollment into  
211 the original trial. We obtain separate written, informed consent for participation in Kukaa  
212 Salama. Participants are free to refuse participation or withdraw from Kukaa Salama while  
213 remaining in Tushirikiane. However, Tushirikiane participants who withdraw or are lost to  
214 follow-up are automatically withdrawn from the Kukaa Salama sub-study. Community  
215

215 collaborators and peer navigators will facilitate participant retention using multiple study  
216 reminder strategies to maintain engagement.

217

### 218 ***Patient and Public Involvement***

219 This study protocol was developed after the completion of a formative qualitative research phase.  
220 During this formative research, we engaged in in-depth interviews with youth participants from  
221 the Tushirikiane study as well as local key informants, who are professionals in various roles  
222 supporting health and well-being of refugee youth in Uganda, to identify key priorities and  
223 preferences. This qualitative component informed the development of the intervention and key  
224 themes for the COVID-19 prevention messaging; therefore, this study directly responds to  
225 refugee youth-identified needs. Additionally, this research is being conducted in collaboration  
226 with YARID, and study collaborators have been involved in all aspects of the research cycle,  
227 from development of the study question to implementation. In particular, the YARID peer  
228 navigators have been consulted regarding the study design and outcomes, supported participant  
229 recruitment and engagement, and have pilot-tested all study instruments to assess acceptability  
230 for the study population. All peer navigators' feedback has been integrated into the final  
231 intervention and study instruments, with modifications made to ensure appropriate delivery. The  
232 key study findings will be disseminated to participants and community members through an  
233 integrated knowledge translation approach, including infographics and community meetings  
234 developed in collaboration with local partners.

235

### 236 ***Intervention Description***

237 This is a pre-test/post-test trial, therefore all participants will receive the Kuka Salama  
238 intervention. Kuka Salama is an 8-week mHealth program of COVID-19 prevention messaging,  
239 which includes sending weekly informational SMS and facilitated secure group interactions to  
240 share multimedia images. The intervention is hosted on a web-based SMS platform developed by  
241 WelTel [35,36,40] and accompanied by moderated group interactions and photo sharing using  
242 WhatsApp. WelTel is a non-profit agency developing the mHealth intervention, in which  
243 participants receive weekly supportive bidirectional text messages. WhatsApp is a no cost  
244 mobile phone application that allows users to share SMS, photos, videos, and voice messages  
245 with end-to-end encryption; requires minimal data; and is widely used to share health  
246 information.[32,33,41–44] The intervention involves three linked mHealth components and a  
247 prevention parcel, which are described below and summarized in **Figure 1**.

248

249 Check-in messaging: Each week, participants will receive a message asking how they are doing  
250 and are requested to reply “fine” or “not fine;” those responding “not fine” will be contacted for  
251 support by a peer navigator. The WelTel system will manage the SMS intervention on a  
252 structured mobile phone platform (all SMS interactions are logged).

253

254 COVID-19 prevention messaging: Participants will also receive a weekly themed COVID-19  
255 informational SMS and an accompanying question to enhance engagement. Content topics  
256 address the themes identified during our formative qualitative research phase and apply BCT

257 approaches following the RANAS [25] framework. Weekly themed topics include information  
258 on COVID-19 symptoms and transmission; encouragement on the use of handwashing,  
259 respiratory hygiene, and face masks; COVID-19 vaccines and testing; and stigma and recovery  
260 (**Table 1**). All messages will be translated into the five study languages; in the pre-intervention  
261 survey participants indicate their language preference for receiving health-related SMS, and the  
262 preferred language will be programmed for each participant. The peer navigators will review the  
263 responses to the engagement question and the top response will be sent out to all participants to  
264 incentivize engagement. Participants can also respond to the SMS with any questions about  
265 COVID-19, and the study team will respond with further information and/or additional  
266 resources.

268 Insert Table 1

269 *COVID-19 multimedia sharing*: Finally, within the peer navigator-facilitated secure and  
270 encrypted WhatsApp groups, participants are able to share multimedia images related to the  
271 weekly theme. These can include photos, memes, GIFs, and other multimedia options; this  
272 provides an opportunity for participants to display their application and practice of the weekly  
273 COVID-19 prevention topics in their daily lives. This aligns with calls for hygiene  
274 communication in humanitarian contexts to include information and images.[18]

276 *COVID-19 prevention parcel*: At each survey time point, participants will also be offered the  
277 opportunity to pick up a parcel that contains a face mask, bar of soap, and a small parcel of food  
278 to support the prevention messaging.

### 280 **Outcomes**

281 The primary outcome measured in this trial is:

283 *Changes in COVID-19 prevention practices*, assessed by asking participants to report on their  
284 self-efficacy (i.e., ability, confidence, and adherence) to practice hand and respiratory hygiene  
285 (e.g., hand washing with soap, face mask usage) and physical distancing. Questions utilize the  
286 RANAS framework questions [25,27,45] applied to these preventive practices. This measure is  
287 assessed at all three study time points (pre-intervention [Time 1], post-intervention [Time 2], and  
288 follow-up [Time 3]).

290 Secondary outcomes are below; secondary outcomes 1-4 follow the RANAS questionnaire items  
291 [25,27,45] adapted for COVID-19 preventive practices:

- 293 1. *Changes in COVID-19 risk awareness*, assessed by asking participants to report on their  
294 perceived risk and vulnerabilities to COVID-19 as well as their knowledge of symptoms  
295 and severity (Time 1, Time 2, Time 3).

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3 297 2. *Changes in attitude towards COVID-19*, assessed by asking participants to report on their  
4 298 attitude (i.e., feelings, costs/benefits) towards COVID-19 prevention practices as well as  
5 299 towards COVID-19 testing and potential vaccines (Time 1, Time 2, Time 3).  
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8 301 3. *Changes in COVID-19 norms*, assessed by asking participants to report on the perceived  
9 302 behaviours approved by others (i.e., social pressures) towards COVID-19 prevention  
10 303 practices, transmission, and stigma (Time 1, Time 2, Time 3).  
11 304 4. *Changes in COVID-19 self-regulation*, assessed by asking participants about their action  
12 305 plan for implementing COVID-19 prevention practices (Time 1, Time 2, Time 3).  
13 306  
14 307 5. *Changes in depression*, assessed using the Patient Health Questionnaire-9 item (PHQ-9)  
15 308 [46] (Time 1, Time 2, Time 3). Scores range from 0 to 27; higher scores mean a worse  
16 309 outcome.  
17 310  
18 311 6. *Changes in sexual and reproductive health practices*, assessed by asking participants to  
19 312 report on personal experiences (e.g., intimate partner violence) as well as perceived  
20 313 changes in the community (e.g., violence, access to sexual and reproductive health  
21 314 services) (Time 1, Time 2, Time 3).  
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23 315  
24 316 7. *Changes in food and water insecurity*, which is assessed by asking participants to report  
25 317 on frequency of insufficient food (i.e., going to bed hungry) and inadequate clean water  
26 318 (Time 1, Time 2, Time 3).  
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### 321 **Sample Size and Power**

322 We estimate that a sample size of 52 participants (104 data points) is required to detect an effect  
323 size of 0.4 between pairs with a power of 80% and type 1 error rate of 5%, and assuming a  
324 correlation between pre-test/post-test responses of 0.5. For a correlation as low as 0.1 we  
325 estimate that 91 participants will be required, and if the effect size is larger we will require fewer  
326 participants. Based on current participant retention rates, we anticipate that at least 85% (n=340)  
327 of the Tushirkiane cohort (n=404) will participate in Kukaa Salama. This will give us sufficient  
328 power for conducting this analysis, as well as for covariate adjustment.  
329

### 330 **Data Collection and Management**

331 Participant outcome data will be collected at three-time points (pre-intervention, Time 1; post-  
332 intervention, Time 2; follow-up, Time 3) using structured questionnaires administered by trained  
333 research assistants. Interviews will be conducted in all study languages and data will be collected  
334 in-person or by mobile telephone, depending on local COVID-19 guidelines. All data will be  
335 recorded on tablets using SurveyCTO (Dobility Inc., Cambridge, USA). Data collection tools  
336 include branching logic for efficiency and have range and consistency checks built-in to provide  
337 immediate feedback to research assistants regarding errors and inconsistencies. Tablet based data  
338 collected will be automatically encrypted and uploaded to a password-protected project team  
339 server on a daily basis using an SSL certificate. To maintain confidentiality, all participants have

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3 340 been given a unique Case ID, and no personal identifying information will be stored with the  
4 341 study data.

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6 343 **Data Analysis**

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9 344 All analyses and reporting will be conducted following the TREND checklist.[47] Descriptive  
10 345 analyses of socio-demographic variables will be conducted to characterize the participant sample  
11 346 using counts or means and standard deviations or medians and interquartile ranges, as  
12 347 appropriate. Outcome scale items will be summed to calculate overall and sub-scale scores, and  
13 348 novel scales will be assessed for reliability (i.e., Cronbach's alpha). To assess pre-post outcomes  
14 349 differences in RANAS scores we will use linear or logistic generalized estimating equation  
15 350 (GEE) regression models, depending on which outcome is being evaluated, with an  
16 351 exchangeable correlation matrix to account for clustering by participant. To assess the  
17 352 moderating effect of engagement with the intervention we will examine interactions between  
18 353 mean outcome pre-post score changes and intervention usage (e.g., WelTel data regarding  
19 354 frequency of interaction, number of days used, length of time, etc.). We will conduct adjusted  
20 355 analyses to examine the role of covariates on the relative effect. Covariates (e.g., age, gender)  
21 356 will be entered as a block. The level of significance will be set at  $\alpha=0.05$ , and we will report  
22 357 odds ratios or mean differences as appropriate, and corresponding 95% confidence intervals and  
23 358 p-values. Given this pre-post trial is of short duration with minimal risks, a data monitoring  
24 359 committee was not deemed necessary.  
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29 361 **Discussion**

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32 362 There are knowledge gaps regarding efficacious strategies to increase COVID-19 preventive  
33 363 practices with urban refugee youth—despite calls for inclusion of migrants and refugees in  
34 364 COVID-19 responses.[1] The current study aims to address this knowledge gap by conducting an  
35 365 8-week interactive and informational mHealth intervention to improve COVID-19 prevention  
36 366 practices among refugee youth in Kampala, Uganda. Study strengths are: the intervention is  
37 367 included within an existing community-based research cohort study that leverages trained peer  
38 368 navigators and engaged community and government collaborators; the design and foci were  
39 369 informed by qualitative research with urban refugee youth and key informants to address  
40 370 identified needs; and alignment with the well-established RANAS framework.[25] There are also  
41 371 study limitations due to the pre/post-test design with no control group; other study designs such  
42 372 as stepped wedge could be implemented in future iterations. In addition, given the COVID-19  
43 373 pandemic we have seen higher rates of loss to follow-up as participants leave urban areas and  
44 374 return to their country of origin or to settlements/camps. Political instability and interruptions to  
45 375 internet access in Uganda in early 2021 also delayed study implementation.  
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50 377 This study will provide effectiveness data for a non-pharmaceutical intervention that is low cost,  
51 378 scalable, contextually specific, and rooted in behavioural science, which is essential with limited  
52 379 availability of COVID-19 vaccines in Uganda and other Sub-Saharan African context. If findings  
53 380 indicate that the intervention increases COVID-19 prevention practices in this population there is  
54 381 scope to scale-up this intervention for other urban-refugee populations in Uganda, and can be  
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382 adapted for other informal settlement populations as well as non-urban settlement-based  
383 refugees.

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## 385 **Ethics and Dissemination of Findings**

### 386 *Ethical Approval*

387 The Kukaa Salama intervention study was approved as an amendment to the Tushirikiane trial by  
388 the University of Toronto Research Ethics Board (reference 37496); the Mildmay Uganda  
389 Research Ethics Committee (reference 0806-2019); and the Uganda National Council for  
390 Science & Technology (reference HS 2716). All participants have provided written, informed  
391 consent for inclusion in this study.

392

### 393 *Dissemination Plan*

394 Irrespective of study findings, results will be published in peer-reviewed scientific journals  
395 following international authorship guidelines, and will be presented to academics and researchers  
396 at key scientific conferences. Study results will also be shared as executive summaries, reports  
397 and technical policy briefs with national and international collaborating organizations, including  
398 our collaborators, the Uganda Ministry of Health, and UNHCR. Engaging, pictorial research  
399 summaries with highlights of study findings in all five languages will also be shared with  
400 participants and study collaborators.

401

### 402 **Trial Status**

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404 The Kukaa Salama study launched in April 2021 with pre-intervention data collection. The  
405 Intervention is currently underway. We anticipate data collection post-intervention to be  
406 conducted in August 2021, and the final follow-up survey to be conducted in October 2021. Any  
407 important protocol modifications will be included as amendments in REB and updated on the  
408 clinical trials registry, as and when needed. Table 2 details the information on the clinical trial  
409 registry.

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8 421 **Contributors:** Study design: CHL, MO, RH, LM. Data collection: RH, DKM, RL, CHL, MO,  
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30 443

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36 449

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41 454 demographic and response characteristics. The data may be made available from the  
42 455 corresponding author on reasonable request and upon completing suitable data sharing  
43 456 agreements.

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640 **Tables & Figures**641 **Table 1.** Topics on COVID-19 prevention included in the Kuka Salama mobile health  
642 (mHealth) intervention

Scenario	Description
<b>Mental health</b>	Explores strategies for managing stress and supporting mental health and well-being during COVID-19, including peers can support each other.
<b>Vaccine hesitancy</b>	Presents the importance of taking a COVID-19 vaccine to protect oneself and their community.
<b>Hand washing</b>	Explains the importance of hand washing for COVID-19 prevention, and provides tips on when one should wash their hands.
<b>Mask wearing</b>	Explains the importance of wearing masks to reduce COVID-19 transmission, and provides tips on when one should wear a mask.
<b>Economic stressors</b>	Acknowledges the personal and community hardships caused by COVID-19, and elicits peer support for overcoming hardship.
<b>Symptoms &amp; testing</b>	Provides a reminder of key COVID-19 symptoms and addresses the importance of COVID-19 testing as a pathway to care.
<b>Stigma &amp; recovery</b>	Addresses stigma associated with COVID-19 and COVID-19 recovery, and encourages peer support during and after recovery.
<b>Recap week</b>	Reviews the key themes and encourages peer and community support.

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647 **Figure 1.** Study design for Kuka Salama, a pre-test/post-test trial of an interactive and  
648 informational mobile health (mHealth) strategy among urban refugee and displaced youth in  
649 Kamala, Uganda.

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654 **Table 2.** Items from the United States National Institutes of Health Trial Registry

Data category	Information
<b>Primary registry and trial identifying number:</b>	ClinicalTrials.gov NCT04631367
<b>Date of registration:</b>	13 November 2020
<b>Source(s) of monetary support:</b>	International Development Research Center
<b>Primary sponsor:</b>	University of Toronto
<b>Contact for public and scientific queries:</b>	Carmen Logie, PhD [carmen.logie@utoronto.ca]
<b>Public and scientific title:</b>	mHealth Intervention for Increasing COVID-19 Prevention Practices With Urban Refugee and Displaced Youth in Uganda
<b>Countries of recruitment:</b>	Uganda
<b>Health condition(s) or problem(s) studied:</b>	COVID-19 prevention practices
<b>Intervention(s):</b>	Kukaa Salama: mHealth intervention; Face Mask + Soap
<b>Key inclusion criteria:</b>	Enrolled within the Tushirikiane HIV-self Testing cluster randomized trial; Live in one of the 5 slum/informal settlement sites (Kabalanga, Kasanga, Katwe, Nsambya Rubaga); Identify as a refugee/displaced person or have refugee parents; Age 16-24 years; Speak English, Luganda, French, Swahili, or Kinyarwanda; Own or have access to a mobile phone for the duration of the study.
<b>Study type:</b>	Interventional; Single group assignment pre-post trial; Primary purpose: behavioural change
<b>Date of first enrolment:</b>	June 2021
<b>Target sample size:</b>	404
<b>Primary outcome(s):</b>	Changes in COVID-19 Prevention Practices assessed by asking participants to report on their self-efficacy to practice hand and respiratory hygiene and physical distancing
<b>Key secondary outcomes:</b>	1) Changes in COVID-19 risk awareness. 2) Changes in attitude towards COVID-19. 3) Changes in COVID-19 norms. 4) Changes in COVID-19 self-regulation. 5) Changes in depression. 6) Changes in sexual and reproductive health practices. 7) Changes in food and water insecurity. 8) Changes in COVID-19 vaccine acceptability.

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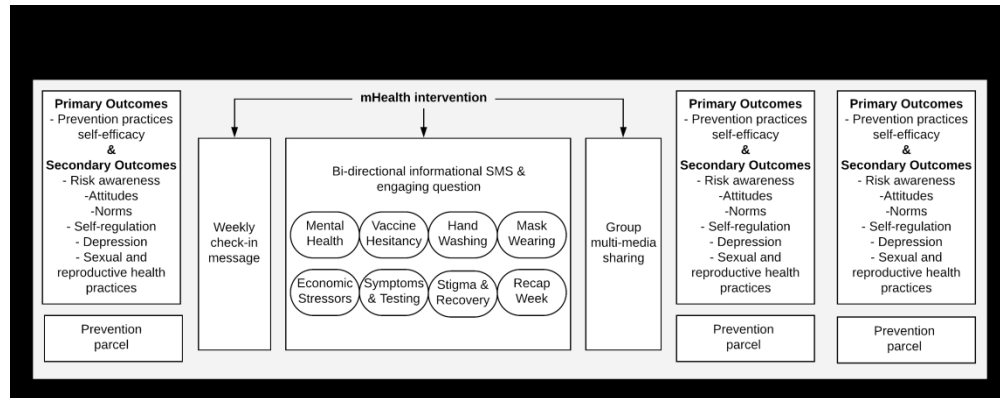


Figure 1. Study design for Kuka Salama, a pre-test/post-test trial of an interactive and informational mobile health (mHealth) strategy among urban refugee and displaced youth in Kamala, Uganda.

1151x456mm (72 x 72 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	ItemNo	Description	Page (P); Line (L)
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1; L1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	P3; L67-68
	2b	All items from the World Health Organization Trial Registration Data Set	P3-5
Protocol version	3	Date and version identifier	P3; L68
Funding	4	Sources and types of financial, material, and other support	P15; L 436-439
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P15; L432-434
	5b	Name and contact information for the trial sponsor	P1; L28-36
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P 15; L437
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P 7-8

1				
2		6b	Explanation for choice of comparators	N/A; pre-
3				test/post-test
4				trial all
5				participants
6				receive
7				intervention
8				
9				
10	Objectives	7	Specific objectives or hypotheses	P8-9; L173-
11				182
12				
13	Trial design	8	Description of trial design including type of trial (eg, parallel	P9; L184-192
14			group, crossover, factorial, single group), allocation ratio, and	
15			framework (eg, superiority, equivalence, noninferiority,	
16			exploratory)	
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20	<b>Methods: Participants, interventions, and outcomes</b>			
21	Study setting	9	Description of study settings (eg, community clinic, academic	P9; L194-200
22			hospital) and list of countries where data will be collected.	
23			Reference to where list of study sites can be obtained	
24				
25				
26	Eligibility	10	Inclusion and exclusion criteria for participants. If applicable,	P9; L 207-213
27	criteria		eligibility criteria for study centres and individuals who will	
28			perform the interventions (eg, surgeons, psychotherapists)	
29				
30	Interventions	11a	Interventions for each group with sufficient detail to allow	P 10-11;
31			replication, including how and when they will be administered	L243-284
32				
33		11b	Criteria for discontinuing or modifying allocated interventions for	N/A; low risk
34			a given trial participant (eg, drug dose change in response to	behaviour
35			harms, participant request, or improving/worsening disease)	change
36				intervention
37				
38				
39		11c	Strategies to improve adherence to intervention protocols, and	N/A; low risk
40			any procedures for monitoring adherence (eg, drug tablet return,	behaviour
41			laboratory tests)	change
42				intervention
43				
44				
45		11d	Relevant concomitant care and interventions that are permitted	N/A; low risk
46			or prohibited during the trial	behaviour
47				change
48				intervention
49				
50	Outcomes	12	Primary, secondary, and other outcomes, including the specific	P 11-12; L
51			measurement variable (eg, systolic blood pressure), analysis	285-328
52			metric (eg, change from baseline, final value, time to event),	
53			method of aggregation (eg, median, proportion), and time point	
54			for each outcome. Explanation of the clinical relevance of	
55			chosen efficacy and harm outcomes is strongly recommended	
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Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P 12; L326-333
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P 9-10; L219-222

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A; pre-test/post-test trial all participants receive intervention
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A; pre-test/post-test trial all participants receive intervention
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A; pre-test/post-test trial all participants receive intervention
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A; pre-test/post-test trial all participants receive intervention
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A; pre-test/post-test trial all participants receive intervention

### Methods: Data collection, management, and analysis

1				
2	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P 12; L335-346
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11		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P 9-10; L219-222 & P 12; L335-346
12				
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15	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P 12; L335-346
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22	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P 13; L352-368
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27		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P 13; L48-368
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30		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P 13; L352-370
31				
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35	<b>Methods: Monitoring</b>			
36	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P 13; L369-370
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45		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A; low risk behaviour change intervention for a short duration
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53	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A; low risk behaviour change intervention for a short duration
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2	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A; low risk behaviour change intervention for a short duration
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10	<b>Ethics and dissemination</b>			
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12	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P 14; L397-402
13				
14				
15	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	P 14; L417-419
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21	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P 9-10; L215-222
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24		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A; no biological specimens collected
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30	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P 12-13; L344-346
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34	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 15; L450-453
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38	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P 15; L462-466
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42	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A; low risk behaviour change intervention for a short duration
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50	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P 14; L404-411
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57		31b	Authorship eligibility guidelines and any intended use of professional writers	P 14; L 405-407
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## Appendices

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 15; L462-466
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A; no biological specimens collected

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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.