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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055530
Article Type:	Protocol
Date Submitted by the Author:	15-Jul-2021
Complete List of Authors:	Logie, Carmen; University of Toronto, Factor-Inwentash Faculty of Social Work; Women's College Hospital, Women's College Research Institute Okumu, Moses ; University of Illinois at Urbana-Champaign Berry, Isha ; University of Toronto Dalla Lana School of Public Health, Hakiza , Robert ; Young African Refugees for Integral Development Kibuuka-Musoke , Daniel; International Research Consortium Kyambadde, Peter ; Mulago Hospital, Most at Risk Population Initiative Mwima, Simon; University of Illinois at Urbana-Champaign; Republic of Uganda Ministry of Health Lester, Richard; The University of British Columbia Perez-Brumer, Amaya; University of Toronto Baral, Stefan; Johns Hopkins University, Johns Hopkins Bloomberg School of Public Health Mbuagbaw, Lawrence; McMaster University, Department of Clinical Epidemiology & Biostatistics
Keywords:	COVID-19, PREVENTIVE MEDICINE, PUBLIC HEALTH

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title: 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

Author & Affiliations: Carmen H. Logie[1-3*], Moses Okumu[4], Isha Berry[5], Robert Hakiza[6], Daniel Kibuuka Musoke[7], Peter Kyambadde[8,9], Simon Mwima[4,8], Richard T. Lester[10], Amaya G. Perez-Brumer[5], Stefan D. Baral[11], Lawrence C. Mbuagbaw[12-14]

1: Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada
2: Women's College Research Institute, Women's College Hospital, Toronto, ON, Canada
3: Centre for Gender & Sexual Health Equity, Vancouver, BC, Canada
4: School of Social Work, University of Illinois Urbana-Champaign, Urbana, IL, United States
5: Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada
6: Young African Refugees for Integral Development (YARID), Kampala, Uganda
7: International Research Consortium, Kampala, Uganda
8: National AIDS Control Program, Ministry of Health, Kampala, Uganda
9: Most At Risk Population Initiative Clinic, Mulago Hospital, Kampala, Uganda
10: Department of Medicine, University of British Columbia, Vancouver, BC, Canada
11: Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, United States
12: Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada
13: Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada
14: Centre for Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Yaoundé, Cameroon

*Corresponding Author:
Carmen Logie
Factor-Inwentash Faculty of Social Work
246 Bloor St. West
University of Toronto
Toronto, Ontario, M5S 1V4
Canada
T: 416-946-3365
E: carmen.logie@utoronto.ca

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

completion, and findings will be communicated locally, nationally, and internationally through executive reports and conferences presentations.

Trial Registration: This pre-test/post-test study is registered at ClinicalTrials.gov (NCT04631367).

Key words: Adolescents and youth, COVID-19, mHealth, refugee, hygiene, vaccine acceptability, Uganda

Strengths and limitations of this study

- The Kukaa 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 effects 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]

Our study applies behavioural science to mHealth to increase COVID-19 preventive practice uptake with urban refugee youth. As Michie described, "behavioural science must be at the heart of the public health response" (p. 1) for COVID-19 mitigation.[23] We follow the RANAS approach to systematic behaviour change for Water and Sanitation and Hygiene (WASH) grounded in three contexts (social, physical, personal) and five behavioural factors: *risk* (e.g. risk and vulnerability awareness), *attitude* (e.g. costs/benefits of the behaviour), *norms* (e.g. behaviours others adopt), *ability* (e.g. efficacy, confidence), and *self-regulation* (e.g. action and barrier planning).[24,25] RANAS—a widely used framework for WASH interventions—provides behavioural change techniques to address behavioural factors.[26–29]

Mobile health (mHealth) is a cost-effective health information delivery approach that is aligned with how youth learn and socialize, and important for physical distancing. messaging services (SMS), or text messages, have been used to disseminate hygiene messaging in humanitarian contexts,[18] and by the Office of the United Nations High Commissioner for Refugees (UNHCR) for COVID-19 symptom reporting in Kenya.[5] Similarly, Singapore is using WhatsApp[30] to share COVID-19 updates with healthcare providers.[31] In particular, interactive mHealth interventions including multiple forms of media and engagement including SMS, WhatsApp, and group photo sharing could be more effective than one-way messages/reminders for changing behaviour.[32–36] The potential to implement mHealth solutions at scale is high given that most urban refugees in Uganda have access to mobile phones.[37] Yet, in 2021, the use of mHealth for RANAS-based behaviour change remains understudied among urban refugee youth.

Kukaa Salama, roughly translated from Swahili for 'staying safe', aims to address these knowledge gaps by evaluating an interactive informational mHealth intervention on COVID-19 prevention practices. This study is nested within a cluster randomized trial on HIV self-testing for which the primary outcomes are HIV testing frequency and status knowledge (Tushirikiane; clinicaltrial.gov registration NCT04504097), which recently completed data collection in Kampala, Uganda.[38] Findings from this study can be used to inform local and global response efforts with new knowledge of mHealth approaches for COVID-19 prevention with urban refugee youth in humanitarian contexts.

Methods

Study Aim and Objectives

The overarching goal of this study is to evaluate the effectiveness of an 8-week interactive informational mHealth intervention on increasing COVID-19 prevention practices among refugee and displaced youth aged 16-24 years in Kampala, Uganda. The primary objective is to evaluate the effectiveness of the intervention on participants' self-efficacy (e.g., ability confidence, and adherence) to practice hand and respiratory hygiene COVID-19 prevention

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

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

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

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

Outcomes

The primary outcome measured in this trial is:

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

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

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

2. *Changes in attitude towards COVID-19*, assessed by asking participants to report on their attitude (i.e., feelings, costs/benefits) towards COVID-19 prevention practices as well as towards COVID-19 testing and potential vaccines (Time 1, Time 2, Time 3).

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

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

Data Analysis

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

Discussion

There are knowledge gaps regarding efficacious strategies to increase COVID-19 preventive practices with urban refugee youth—despite calls for inclusion of migrants and refugees in COVID-19 responses.[1] The current study aims to address this knowledge gap by conducting an 8-week interactive and informational mHealth intervention to improve COVID-19 prevention practices among refugee youth in Kampala, Uganda. Study strengths are: the intervention is inclused within an existing community-based research cohort study that leverages trained peer navigators and engaged community and government collaborators; the design and foci were informed by qualitative research with urban refugee youth and key informants to address identified needs; and alignment with the well-established RANAS framework.[25] There are also study limitations due to the pre/post-test design with no control group; other study designs such as stepped wedge could be implemented in future iterations. In addition, given the COVID-19 pandemic we have seen higher rates of loss to follow-up as participants leave urban areas and return to their country of origin or to settlements/camps. Political instability and interruptions to internet access in Uganda in early 2021 also delayed study implementation.

This study will provide effectiveness data for a non-pharmaceutical intervention that is low cost, scalable, contextually specific, and rooted in behavioural science, which is essential with limited availability of COVID-19 vaccines in Uganda and other Sub-Saharan African context. If findings indicate that the intervention increases COVID-19 prevention practices in this population there is scope to scale-up this intervention for other urban-refugee populations in Uganda, and can be

adapted for other informal settlement populations as well as non-urban settlement-based refugees.

Ethics and Dissemination of Findings

Ethical Approval

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

Dissemination Plan

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

Trial Status

The Kukaa Salama study launched in April 2021 with pre-intervention data collection. The Intervention is currently underway. We anticipate data collection post-intervention to be conducted in August 2021, and the final follow-up survey to be conducted in October 2021.

Contributors: Study design: CHL, MO, RH, LM. Data collection: RH, DKM, RL, CHL, MO, IB. Data management: IB, CHL, DKM, RH, RL. Manuscript writing: IB, CHL. Manuscript editing and critical review: CHL, MO, IB, RH, LM, DKM, PK, SM, RL, APB, SDB.

Funding: This study is funded by the International Development Research Center (# 109549-001). Funding agencies played no role in the design or execution of the study. CL is also funded by the Canada Research Chairs program (#Tier 2), Canada Foundation for Innovation (#JELF), and the Ontario Ministry of Research and Innovation (ERA).

Acknowledgements: We would like to acknowledge the support and contributions of: Young African Refugees for Integral Development (YARID), Uganda Ministry of Health, Uganda National AIDS Control Program, Dr. Gabby Serafini (WelTel), Interaid Uganda, Mildmay Uganda, Organization for Gender Empowerment and Rights Advocacy (OGERA Uganda), Most At Risk Population Initiative (MARPI), Uganda Office of the Prime Minister Department of Refugees, Peer Navigators (Gabriella Nzulungi; Bibishe Hakiza Muruta; Sabrina Gamwanya; Hillary Nuwamanya; Justin Paluku; Bella Nshimirimana; Claudine Ndoole; Priscilla Asiimwe; Angelique Kipenda; Phiona Nattabi; Joyeux Mugisho; Pole Pole).

Competing Interests: RL is an academic physician-researcher and also has interests in a non-profit and private company social enterprise, WelTel Inc., that develops and provides digital health software. He is not being paid or otherwise compensated by WelTel for this project. No other authors declare a conflict of interest.

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

Provenance and peer review: Not commissioned, externally peer reviewed.

Data Sharing statement: The data collected during this study will not be made publicly available due to the possibility of identifying participants using a combination of common demographic and response characteristics. The data may be made available from the corresponding author on reasonable request and upon completing suitable data sharing agreements.

References

1. Orcutt M, Patel P, Burns R, Hiam L, Aldridge R, Devakumar D, et al. Global call to action for inclusion of migrants and refugees in the COVID-19 response. Lancet. 2020;395(10235):1482–3.
2. Orcutt M, Patel P, Burns R, Hiam L, Aldridge R, Devakumar D, et al. Global call to action for inclusion of migrants and refugees in the COVID-19 response. Lancet [Internet]. 2020 May 4;S0140673620309715. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673620309715
3. Singh L, Singh NS, Nezafat Maldonado B, Tweed S, Blanchet K, Graham WJ. What does 'leave no one behind' mean for humanitarian crises-affected populations in the COVID-19 pandemic? BMJ Glob Heal [Internet]. 2020 May 4;5(4):e002540. Available from: http://gh.bmj.com/lookup/doi/10.1136/bmjgh-2020-002540
4. Kluge HHP, Jakab Z, Bartovic J, D'Anna V, Severoni S. Refugee and migrant health in the COVID-19 response. Lancet [Internet]. 2020 May 4;395(10232):1237–9. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673620307911
5. Hargreaves S, Zenner D, Wickramage K, Deal A, Hayward SE. Targeting COVID-19 interventions towards migrants in humanitarian settings. Lancet Infect Dis [Internet]. 2020 May 4;0(0). Available from: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30292-9/abstract
6. UNHCR. Global Trends: Forced Displacement in 2020 [Internet]. UNHCR. Geneva, Switzerland; 2020. Available from: https://www.unhcr.org/60b638e37/unhcr-global-trends-2020
7. Rees M. Foreword : Time for cities to take centre stage on forced migration.

2020;(February):4–5.

8. Anzellini V, Leduc C. Urban internal displacement : data and evidence. 2020;(February):6–7.

9. Sabila S, Silver I. Cities as partners: the case of Kampala. Forced Migr Rev [Internet]. 2020;63(February):41–3. Available from: https://www.fmreview.org/cities/saliba-silver

10. UNHCR. Uganda - Refugee Statistics April 2021. 2021.

11. Bukuluki P, Mwenyango H, Katongole SP, Sidhva D, Palattiyil G. The socio-economic and psychosocial impact of Covid-19 pandemic on urban refugees in Uganda. Soc Sci Humanit Open. 2020;2(1).

12. World Health Organization (WHO). Coronavirus disease (COVID-10) Advice for the Public [Internet]. 2021. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public

13. Singh NS, Abrahim O, Altare C, Blanchet K, Favas C, Odlum A, et al. COVID-19 in humanitarian settings: documenting and sharing context-specific programmatic experiences. Confl Health [Internet]. 2020;14(1):79. Available from: https://conflictandhealth.biomedcentral.com/articles/10.1186/s13031-020-00321-w

14. Nasreen S, Azziz-Baumgartner E, Gurley ES, Winch PJ, Unicomb L, Sharker MAY, et al. Prevalent high-risk respiratory hygiene practices in urban and rural Bangladesh: **High-risk respiratory hygiene practices**. Trop Med Int Heal [Internet]. 2010 May 4;15(6):762–71. Available from: http://doi.wiley.com/10.1111/j.1365-3156.2010.02531.x

15. Sultana F, Nizame FA, Southern DL, Unicomb L, Winch PJ, Luby SP. Pilot of an elementary school cough etiquette intervention: acceptability, feasibility, and potential for sustainability. Am J Trop Med Hyg [Internet]. 2017 May 4;97(6):1876–85. Available

from: http://www.ajtmh.org/content/journals/10.4269/ajtmh.16-0914

16. Stebbins S, Cummings DAT, Stark JH, Vukotich C, Mitruka K, Thompson W, et al. Reduction in the incidence of influenza A but not influenza B associated with use of hand sanitizer and cough hygiene in schools: a randomized controlled trial. Pediatr Infect Dis J [Internet]. 2011 May 4;30(11):921–6. Available from: http://journals.lww.com/pidj/Fulltext/2011/11000/Reduction_in_the_Incidence_of_Influenza_A_But_Not.2.aspx

17. Phillips RM, Vujcic J, Boscoe A, Handzel T, Aninyasi M, Cookson ST, et al. Soap is not enough: handwashing practices and knowledge in refugee camps, Maban County, South Sudan. Confl Health [Internet]. 2015 May 4;9(1):39. Available from: https://doi.org/10.1186/s13031-015-0065-2

18. Vujcic J, Ram PK, Blum LS. Handwashing promotion in humanitarian emergencies: strategies and challenges according to experts. J Water, Sanit Hyg Dev [Internet]. 2015 May 4;5(4):574–85. Available from: https://iwaponline.com/washdev/article/5/4/574/30105/Handwashing-promotion-in-humanitarian-emergencies

19. Watson J, Cumming O, Aunger R, Deola C, Chase RP, Dreibelbis R. Child handwashing in an internally displaced persons camp in Northern Iraq: A qualitative multi-method exploration of motivational drivers and other handwashing determinants. PLoS One [Internet]. 2020 May 4;15(2):e0228482. Available from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0228482

20. Blum LS, Yemweni A, Trinies V, Kambere M, Tolani F, Allen J V, et al. Programmatic implications for promotion of handwashing behavior in an internally displaced persons

camp in North Kivu, Democratic Republic of Congo. Confl Health [Internet]. 2019 May 4;13(1):54. Available from: https://conflictandhealth.biomedcentral.com/articles/10.1186/s13031-019-0225-x

21. Subbaraman N. 'Distancing is impossible': refugee camps race to avert coronavirus catastrophe. Nature [Internet]. 2020 May 4; Available from: https://www.nature.com/articles/d41586-020-01219-6

22. Ramalingam B, Singh NS, Mahieu A, Blanchet K. Responding to COVID-19: Guidance for humanitarian agencies. London: ODI/ALNAP; 2020.

23. Behavioural science must be at the heart of the public health response to covid-19 [Internet]. The BMJ. 2020. Available from: https://blogs.bmj.com/bmj/2020/02/28/behavioural-science-must-be-at-the-heart-of-the-public-health-response-to-covid-19/

24. Mosler H-J. A systematic approach to behavior change interventions for the water and sanitation sector in developing countries: a conceptual model, a review, and a guideline. Int J Environ Health Res [Internet]. 2012;22(5):431–49. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22292899

25. Contzen N, Mosler HJ. The RANAS approach to systematic behavior change: Methodological Fact Sheet 1. Dübendorf, Switzerland: Eawag, Swiss Federal Institute of Aquatic Science and Technology; 2015.

26. Graf J, Meierhofer R, Wegelin M, Mosler H-J. Water disinfection and hygiene behaviour in an urban slum in Kenya: impact on childhood diarrhoea and influence of beliefs. Int J Environ Health Res [Internet]. 2008;18(5):335–55. Available from: https://www.dora.lib4ri.ch/eawag/islandora/object/eawag%3A12514/datastream/PDF/Graf

-2007-Water_disinfection_and_hygiene_behaviour-%28published_version%29.pdf

27. Contzen N, Meili IH, Mosler H-J. Changing handwashing behaviour in southern Ethiopia: A longitudinal study on infrastructural and commitment interventions. Soc Sci Med [Internet]. 2015 May 5;124:103–14. Available from: http://www.sciencedirect.com/science/article/pii/S0277953614007291

28. Contzen N, Mosler H-J. Impact of different promotional channels on handwashing behaviour in an emergency context: Haiti post-earthquake public health promotions and cholera response. J Public Health (Bangkok) [Internet]. 2013 May 5;21(6):559–73. Available from: https://doi.org/10.1007/s10389-013-0577-4

29. Friedrich MND, Binkert ME, Mosler H-J. Contextual and psychosocial determinants of effective handwashing technique: recommendations for interventions from a case study in Harare, Zimbabwe. Am J Trop Med Hyg [Internet]. 2017 May 5;96(2):430–6. Available from: http://www.ajtmh.org/lookup/doi/10.4269/ajtmh.16-0553

30. Connecting One Billion Users Every Day [Internet]. WhatsApp Blog. 2017. Available from: https://blog.whatsapp.com/connecting-one-billion-users-every-day

31. Legido-Quigley H, Asgari N, Teo YY, Leung GM, Oshitani H, Fukuda K, et al. Are high-performing health systems resilient against the COVID-19 epidemic? Lancet [Internet]. 2020 May 4;395(10227):848–50. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30551-1/abstract

32. Zotti F, Dalessandri D, Salgarello S, Piancino M, Bonetti S, Visconti L, et al. Usefulness of an app in improving oral hygiene compliance in adolescent orthodontic patients. Angle Orthod [Internet]. 2016 May 4;86(1):101–7. Available from: https://meridian.allenpress.com/angle-orthodontist/article/86/1/101/59317/Usefulness-of-

an-app-in-improving-oral-hygiene

33. Cheung YTD, Chan CHH, Lai C-KJ, Chan WFV, Wang MP, Li HCW, et al. Using WhatsApp and Facebook online social groups for smoking relapse prevention for recent quitters: a pilot pragmatic cluster randomized controlled trial. J Med Internet Res [Internet]. 2015 May 4;17(10):e238. Available from: http://www.jmir.org/2015/10/e238/

34. Alanzi TM, Bah S, Jaber F, Alshammari S, Alzahrani S. Evaluation of a mobile social networking application for glycaemic control and diabetes knowledge in patients with type 2 diabetes: a randomized controlled trial using WhatsApp. In: Qatar Foundation Annual Research Conference Proceedings [Internet]. Hamad bin Khalifa University Press (HBKU Press); 2016. Available from: https://www.qscience.com/content/papers/10.5339/qfarc.2016.HBPP2533

35. Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet [Internet]. 2010 May 7;376(9755):1838–45. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)61997-6/abstract

36. van der Kop ML, Muhula S, Nagide PI, Thabane L, Gelmon L, Awiti PO, et al. Articles Effect of an interactive text-messaging service on patient retention during the first year of HIV care in Kenya (WelTel Retain): an open-label , randomised parallel-group study. 2018;143–52. Available from: file:///Users/main/Desktop/Internet Usage - HIV Review/Effect of an interactive text-messaging service on patient retention during the first year of HIV care in Kenya (WelTel Retain): an open-label, randomised parallel-group study.pdf

37. Connecting Refugees: How Internet and Mobile Connectivity Can Improve Refugee Well-Being and Transform Humanitarian Action [Internet]. UN Refugee Agency; 2016. Available from: file::http://www.unhcr.org/connectivity-for-refugees.html.

38. Logie CH. Mobile Health-Supported HIV Self-Testing Strategy Among Urban Refugee and Displaced Youth in Kampala, Uganda: Protocol for a Cluster Randomized Trial (Tushirikiane, Supporting Each Other). 7. JMIR Res Protoc. 2021;4504097.

39. Smith M, Upshur R. Pandemic Disease, Public Health, and Ethics. In: The Oxford Handbook of Public Health Ethics. 2019.

40. Campbell AR, Kinvig K, Côté HCF, Lester RT, Qiu AQ, Maan EJ, et al. Health Care Provider Utilization and Cost of an mHealth Intervention in Vulnerable People Living With HIV in Vancouver, Canada: Prospective Study. JMIR mHealth uHealth [Internet]. 2018 May 7;6(7):e152. Available from: https://mhealth.jmir.org/2018/7/e152/

41. Rouhani SA, Marsh RH, Rimpel L, Edmond MC, Julmisse M, Checkett KA. Social messaging for global health: lessons from Haiti. J Glob Health [Internet]. 2019 May 4;9(1):10308. Available from: http://jogh.org/documents/issue201901/jogh-09-010308.pdf

42. Shen C, Wang MP, Wan A, Viswanath K, Chan SSC, Lam TH. Health information exposure from information and communication technologies and its associations with health behaviors: Population-based survey. Prev Med (Baltim) [Internet]. 2018 May 4;113:140–6. Available from: http://www.sciencedirect.com/science/article/pii/S0091743518301749

43. Dorwal P, Sachdev R, Gautam D, Jain D, Sharma P, Tiwari AK, et al. Role of WhatsApp Messenger in the laboratory management system: a boon to communication. J Med Syst [Internet]. 2016 May 4;40(1):14. Available from:

http://link.springer.com/10.1007/s10916-015-0384-2

44. Ellanti P, Moriarty A, Coughlan F, McCarthy T. The use of WhatsApp smartphone messaging improves communication efficiency within an orthopaedic surgery team. Cureus [Internet]. 2017 May 4;9(2):e1040. Available from: https://assets.cureus.com/uploads/original_article/pdf/6501/1566922100-20190827-1409-o3oksh.pdf

45. Gamma AE, Slekiene J, von Medeazza G, Asplund F, Cardoso P, Mosler H-J. Contextual and psychosocial factors predicting Ebola prevention behaviours using the RANAS approach to behaviour change in Guinea-Bissau. BMC Public Health [Internet]. 2017;17(1):446. Available from: https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/s12889-017-4360-2

46. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. J Gen Intern Med. 2001;16(9).

47. Des Jarlais DC, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND Statement. Am J Public Health [Internet]. 2004 May 5;94(3):361–6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448256/

Tables & Figures

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

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

Figure 1. Study design for Kukaa 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.

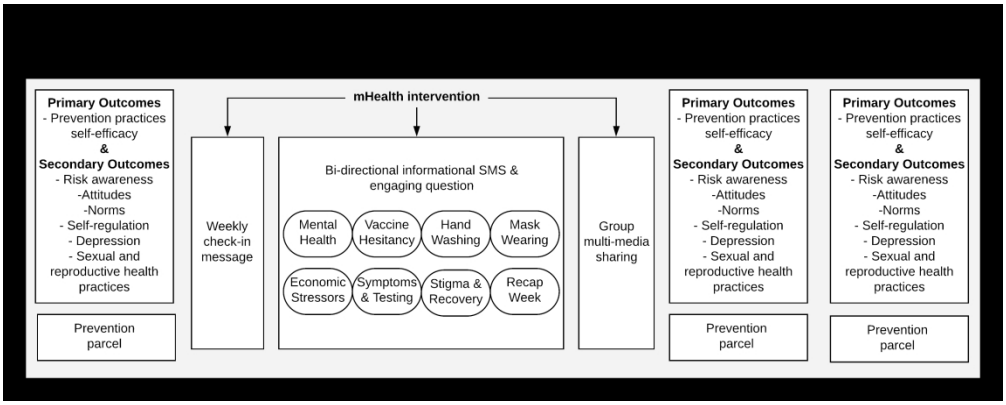

Figure 1. Study design for Kukaa Salama, a pre-test/post-test trial of an interactive and informational mobile health (mHealth) strategy among urban refugee and displaced youth in Kamala, Uganda.

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055530.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Oct-2021
Complete List of Authors:	Logie, Carmen; University of Toronto, Factor-Inwentash Faculty of Social Work; Women's College Hospital, Women's College Research Institute Okumu, Moses ; University of Illinois at Urbana-Champaign Berry, Isha ; University of Toronto Dalla Lana School of Public Health, Hakiza , Robert ; Young African Refugees for Integral Development Kibuuka-Musoke , Daniel; International Research Consortium Kyambadde, Peter ; Mulago Hospital, Most at Risk Population Initiative Mwima, Simon; University of Illinois at Urbana-Champaign; Republic of Uganda Ministry of Health Lester, Richard; The University of British Columbia Perez-Brumer, Amaya; University of Toronto Baral, Stefan; Johns Hopkins University, Johns Hopkins Bloomberg School of Public Health Mbuagbaw, Lawrence; McMaster University, Department of Clinical Epidemiology & Biostatistics
Primary Subject Heading:	Global health
Secondary Subject Heading:	Public health
Keywords:	COVID-19, PREVENTIVE MEDICINE, PUBLIC HEALTH

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title: 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

Author & Affiliations: Carmen H. Logie[1-3*], Moses Okumu[4], Isha Berry[5], Robert Hakiza[6], Daniel Kibuuka Musoke[7], Peter Kyambadde[8,9], Simon Mwima[4,8], Richard T. Lester[10], Amaya G. Perez-Brumer[5], Stefan D. Baral[11], Lawrence C. Mbuagbaw[12-14]

1: Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada
2: Women's College Research Institute, Women's College Hospital, Toronto, ON, Canada
3: Centre for Gender & Sexual Health Equity, Vancouver, BC, Canada
4: School of Social Work, University of Illinois Urbana-Champaign, Urbana, IL, United States
5: Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada
6: Young African Refugees for Integral Development (YARID), Kampala, Uganda
7: International Research Consortium, Kampala, Uganda
8: National AIDS Control Program, Ministry of Health, Kampala, Uganda
9: Most At Risk Population Initiative Clinic, Mulago Hospital, Kampala, Uganda
10: Department of Medicine, University of British Columbia, Vancouver, BC, Canada
11: Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, United States
12: Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada
13: Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada
14: Centre for Development of Best Practices in Health (CDBPH), Yaoundé Central Hospital, Yaoundé, Cameroon

*Corresponding Author:
Carmen Logie
Factor-Inwentash Faculty of Social Work
246 Bloor St. West
University of Toronto
Toronto, Ontario, M5S 1V4
Canada
T: 416-946-3365
E: carmen.logie@utoronto.ca

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 16-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, and findings communicated through reports and conferences presentations.

Trial Registration: This pre-test/post-test study is registered at ClinicalTrials.gov (NCT04631367). First posted date: 17 November 2020; latest update: 27 September 2021.

Key words: Adolescents and youth, COVID-19, mHealth, refugee, hygiene, vaccine acceptability, Uganda

Strengths and limitations of this study

- The Kukaa 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.
- We use a pre-test/post-test longitudinal design to examine changes over time and assess if the 8-week interactive informational mHealth intervention effects 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]

Our study applies behavioural science to mHealth to increase COVID-19 preventive practice uptake with urban refugee youth. As Michie described, "behavioural science must be at the heart of the public health response" (p. 1) for COVID-19 mitigation.[23] We follow the RANAS approach to systematic behaviour change for Water and Sanitation and Hygiene (WASH) grounded in three contexts (social, physical, personal) and five behavioural factors: *risk* (e.g. risk and vulnerability awareness), *attitude* (e.g. costs/benefits of the behaviour), *norms* (e.g. behaviours others adopt), *ability* (e.g. efficacy, confidence), and *self-regulation* (e.g. action and barrier planning).[24,25] RANAS—a widely used framework for WASH interventions—provides behavioural change techniques to address behavioural factors.[26–29]

Mobile health (mHealth) is a cost-effective health information delivery approach that is aligned with how youth learn and socialize, and important for physical distancing. messaging services (SMS), or text messages, have been used to disseminate hygiene messaging in humanitarian contexts,[18] and by the Office of the United Nations High Commissioner for Refugees (UNHCR) for COVID-19 symptom reporting in Kenya.[5] Similarly, Singapore is using WhatsApp[30] to share COVID-19 updates with healthcare providers.[31] In particular, interactive mHealth interventions including multiple forms of media and engagement including SMS, WhatsApp, and group photo sharing could be more effective than one-way messages/reminders for changing behaviour.[32–36] The potential to implement mHealth solutions at scale is high given that most urban refugees in Uganda have access to mobile phones.[37] Yet, in 2021, the use of mHealth for RANAS-based behaviour change remains understudied among urban refugee youth.

Kukaa Salama, roughly translated from Swahili for 'staying safe', aims to address these knowledge gaps by evaluating an interactive informational mHealth intervention on COVID-19 prevention practices. This study is nested within a cluster randomized trial on HIV self-testing for which the primary outcomes are HIV testing frequency and status knowledge (Tushirikiane; clinicaltrial.gov registration NCT04504097), which recently completed data collection in Kampala, Uganda.[38] Findings from this study can be used to inform local and global response efforts with new knowledge of mHealth approaches for COVID-19 prevention with urban refugee youth in humanitarian contexts.

Methods

Study Aim and Objectives

The overarching goal of this study is to evaluate the effectiveness of an 8-week interactive informational mHealth intervention on increasing COVID-19 prevention practices among refugee and displaced youth aged 16-24 years in Kampala, Uganda. The primary objective is to evaluate the effectiveness of the intervention on participants' self-efficacy (e.g., ability confidence, and adherence) to practice hand and respiratory hygiene COVID-19 prevention

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 16-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

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

Insert Table 1

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

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

Outcomes

The primary outcome measured in this trial is:

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

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

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

2. *Changes in attitude towards COVID-19*, assessed by asking participants to report on their attitude (i.e., feelings, costs/benefits) towards COVID-19 prevention practices as well as towards COVID-19 testing and potential vaccines (Time 1, Time 2, Time 3).

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).

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

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

Data Analysis

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

Discussion

There are knowledge gaps regarding efficacious strategies to increase COVID-19 preventive practices with urban refugee youth—despite calls for inclusion of migrants and refugees in COVID-19 responses.[1] The current study aims to address this knowledge gap by conducting an 8-week interactive and informational mHealth intervention to improve COVID-19 prevention practices among refugee youth in Kampala, Uganda. Study strengths are: the intervention is inclused within an existing community-based research cohort study that leverages trained peer navigators and engaged community and government collaborators; the design and foci were informed by qualitative research with urban refugee youth and key informants to address identified needs; and alignment with the well-established RANAS framework.[25] There are also study limitations due to the pre/post-test design with no control group; other study designs such as stepped wedge could be implemented in future iterations. In addition, given the COVID-19 pandemic we have seen higher rates of loss to follow-up as participants leave urban areas and return to their country of origin or to settlements/camps. Political instability and interruptions to internet access in Uganda in early 2021 also delayed study implementation.

This study will provide effectiveness data for a non-pharmaceutical intervention that is low cost, scalable, contextually specific, and rooted in behavioural science, which is essential with limited availability of COVID-19 vaccines in Uganda and other Sub-Saharan African context. If findings indicate that the intervention increases COVID-19 prevention practices in this population there is scope to scale-up this intervention for other urban-refugee populations in Uganda, and can be

adapted for other informal settlement populations as well as non-urban settlement-based refugees.

Ethics and Dissemination of Findings

Ethical Approval

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

Dissemination Plan

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

Trial Status

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

Insert Table 2

Contributors: Study design: CHL, MO, RH, LM. Data collection: RH, DKM, RL, CHL, MO, IB. Data management: IB, CHL, DKM, RH, RL. Manuscript writing: IB, CHL. Manuscript editing and critical review: CHL, MO, IB, RH, LM, DKM, PK, SM, RL, APB, SDB.

Funding: This study is funded by the International Development Research Center (# 109549-001). Funding agencies played no role in the design or execution of the study. CL is also funded by the Canada Research Chairs program (#Tier 2), Canada Foundation for Innovation (#JELF), and the Ontario Ministry of Research and Innovation (ERA).

Acknowledgements: We would like to acknowledge the support and contributions of: Young African Refugees for Integral Development (YARID), Uganda Ministry of Health, Uganda National AIDS Control Program, Dr. Gabby Serafini (WelTel), Interaid Uganda, Mildmay Uganda, Organization for Gender Empowerment and Rights Advocacy (OGERA Uganda), Most At Risk Population Initiative (MARPI), Uganda Office of the Prime Minister Department of Refugees, Peer Navigators (Gabriella Nzulungi; Bibishe Hakiza Muruta; Sabrina Gamwanya; Hillary Nuwamanya; Justin Paluku; Bella Nshimirimana; Claudine Ndoole; Priscilla Asiimwe; Angelique Kipenda; Phiona Nattabi; Joyeux Mugisho; Pole Pole).

Competing Interests: RL is an academic physician-researcher and also has interests in a non-profit and private company social enterprise, WelTel Inc., that develops and provides digital health software. He is not being paid or otherwise compensated by WelTel for this project. No other authors declare a conflict of interest.

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

Provenance and peer review: Not commissioned, externally peer reviewed.

Data Sharing statement: The data collected during this study will not be made publicly available due to the possibility of identifying participants using a combination of common demographic and response characteristics. The data may be made available from the corresponding author on reasonable request and upon completing suitable data sharing agreements.

References

1. Orcutt M, Patel P, Burns R, Hiam L, Aldridge R, Devakumar D, et al. Global call to action for inclusion of migrants and refugees in the COVID-19 response. Lancet. 2020;395(10235):1482–3.
2. Orcutt M, Patel P, Burns R, Hiam L, Aldridge R, Devakumar D, et al. Global call to action for inclusion of migrants and refugees in the COVID-19 response. Lancet [Internet]. 2020 May 4;S0140673620309715. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673620309715
3. Singh L, Singh NS, Nezafat Maldonado B, Tweed S, Blanchet K, Graham WJ. What does 'leave no one behind' mean for humanitarian crises-affected populations in the COVID-19 pandemic? BMJ Glob Heal [Internet]. 2020 May 4;5(4):e002540. Available from: http://gh.bmj.com/lookup/doi/10.1136/bmjgh-2020-002540
4. Kluge HHP, Jakab Z, Bartovic J, D'Anna V, Severoni S. Refugee and migrant health in the COVID-19 response. Lancet [Internet]. 2020 May 4;395(10232):1237–9. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673620307911
5. Hargreaves S, Zenner D, Wickramage K, Deal A, Hayward SE. Targeting COVID-19 interventions towards migrants in humanitarian settings. Lancet Infect Dis [Internet]. 2020 May 4;0(0). Available from: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30292-9/abstract
6. UNHCR. Global Trends: Forced Displacement in 2020 [Internet]. UNHCR. Geneva, Switzerland; 2020. Available from: https://www.unhcr.org/60b638e37/unhcr-global-trends-2020
7. Rees M. Foreword : Time for cities to take centre stage on forced migration.

2020;(February):4–5.

8. Anzellini V, Leduc C. Urban internal displacement : data and evidence. 2020;(February):6–7.

9. Sabila S, Silver I. Cities as partners: the case of Kampala. Forced Migr Rev [Internet]. 2020;63(February):41–3. Available from: https://www.fmreview.org/cities/saliba-silver

10. UNHCR. Uganda - Refugee Statistics April 2021. 2021.

11. Bukuluki P, Mwenyango H, Katongole SP, Sidhva D, Palattiyil G. The socio-economic and psychosocial impact of Covid-19 pandemic on urban refugees in Uganda. Soc Sci Humanit Open. 2020;2(1).

12. World Health Organization (WHO). Coronavirus disease (COVID-10) Advice for the Public [Internet]. 2021. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public

13. Singh NS, Abrahim O, Altare C, Blanchet K, Favas C, Odlum A, et al. COVID-19 in humanitarian settings: documenting and sharing context-specific programmatic experiences. Confl Health [Internet]. 2020;14(1):79. Available from: https://conflictandhealth.biomedcentral.com/articles/10.1186/s13031-020-00321-w

14. Nasreen S, Azziz-Baumgartner E, Gurley ES, Winch PJ, Unicomb L, Sharker MAY, et al. Prevalent high-risk respiratory hygiene practices in urban and rural Bangladesh: **High-risk respiratory hygiene practices**. Trop Med Int Heal [Internet]. 2010 May 4;15(6):762–71. Available from: http://doi.wiley.com/10.1111/j.1365-3156.2010.02531.x

15. Sultana F, Nizame FA, Southern DL, Unicomb L, Winch PJ, Luby SP. Pilot of an elementary school cough etiquette intervention: acceptability, feasibility, and potential for sustainability. Am J Trop Med Hyg [Internet]. 2017 May 4;97(6):1876–85. Available

from: http://www.ajtmh.org/content/journals/10.4269/ajtmh.16-0914

16. Stebbins S, Cummings DAT, Stark JH, Vukotich C, Mitruka K, Thompson W, et al. Reduction in the incidence of influenza A but not influenza B associated with use of hand sanitizer and cough hygiene in schools: a randomized controlled trial. Pediatr Infect Dis J [Internet]. 2011 May 4;30(11):921–6. Available from: http://journals.lww.com/pidj/Fulltext/2011/11000/Reduction_in_the_Incidence_of_Influenza_A_But_Not.2.aspx

17. Phillips RM, Vujcic J, Boscoe A, Handzel T, Aninyasi M, Cookson ST, et al. Soap is not enough: handwashing practices and knowledge in refugee camps, Maban County, South Sudan. Confl Health [Internet]. 2015 May 4;9(1):39. Available from: https://doi.org/10.1186/s13031-015-0065-2

18. Vujcic J, Ram PK, Blum LS. Handwashing promotion in humanitarian emergencies: strategies and challenges according to experts. J Water, Sanit Hyg Dev [Internet]. 2015 May 4;5(4):574–85. Available from: https://iwaponline.com/washdev/article/5/4/574/30105/Handwashing-promotion-in-humanitarian-emergencies

19. Watson J, Cumming O, Aunger R, Deola C, Chase RP, Dreibelbis R. Child handwashing in an internally displaced persons camp in Northern Iraq: A qualitative multi-method exploration of motivational drivers and other handwashing determinants. PLoS One [Internet]. 2020 May 4;15(2):e0228482. Available from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0228482

20. Blum LS, Yemweni A, Trinies V, Kambere M, Tolani F, Allen J V, et al. Programmatic implications for promotion of handwashing behavior in an internally displaced persons

camp in North Kivu, Democratic Republic of Congo. Confl Health [Internet]. 2019 May 4;13(1):54. Available from: https://conflictandhealth.biomedcentral.com/articles/10.1186/s13031-019-0225-x

21. Subbaraman N. 'Distancing is impossible': refugee camps race to avert coronavirus catastrophe. Nature [Internet]. 2020 May 4; Available from: https://www.nature.com/articles/d41586-020-01219-6

22. Ramalingam B, Singh NS, Mahieu A, Blanchet K. Responding to COVID-19: Guidance for humanitarian agencies. London: ODI/ALNAP; 2020.

23. Behavioural science must be at the heart of the public health response to covid-19 [Internet]. The BMJ. 2020. Available from: https://blogs.bmj.com/bmj/2020/02/28/behavioural-science-must-be-at-the-heart-of-the-public-health-response-to-covid-19/

24. Mosler H-J. A systematic approach to behavior change interventions for the water and sanitation sector in developing countries: a conceptual model, a review, and a guideline. Int J Environ Health Res [Internet]. 2012;22(5):431–49. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22292899

25. Contzen N, Mosler HJ. The RANAS approach to systematic behavior change: Methodological Fact Sheet 1. Dübendorf, Switzerland: Eawag, Swiss Federal Institute of Aquatic Science and Technology; 2015.

26. Graf J, Meierhofer R, Wegelin M, Mosler H-J. Water disinfection and hygiene behaviour in an urban slum in Kenya: impact on childhood diarrhoea and influence of beliefs. Int J Environ Health Res [Internet]. 2008;18(5):335–55. Available from: https://www.dora.lib4ri.ch/eawag/islandora/object/eawag%3A12514/datastream/PDF/Graf

-2007-Water_disinfection_and_hygiene_behaviour-%28published_version%29.pdf

27. Contzen N, Meili IH, Mosler H-J. Changing handwashing behaviour in southern Ethiopia: A longitudinal study on infrastructural and commitment interventions. Soc Sci Med [Internet]. 2015 May 5;124:103–14. Available from: http://www.sciencedirect.com/science/article/pii/S0277953614007291

28. Contzen N, Mosler H-J. Impact of different promotional channels on handwashing behaviour in an emergency context: Haiti post-earthquake public health promotions and cholera response. J Public Health (Bangkok) [Internet]. 2013 May 5;21(6):559–73. Available from: https://doi.org/10.1007/s10389-013-0577-4

29. Friedrich MND, Binkert ME, Mosler H-J. Contextual and psychosocial determinants of effective handwashing technique: recommendations for interventions from a case study in Harare, Zimbabwe. Am J Trop Med Hyg [Internet]. 2017 May 5;96(2):430–6. Available from: http://www.ajtmh.org/lookup/doi/10.4269/ajtmh.16-0553

30. Connecting One Billion Users Every Day [Internet]. WhatsApp Blog. 2017. Available from: https://blog.whatsapp.com/connecting-one-billion-users-every-day

31. Legido-Quigley H, Asgari N, Teo YY, Leung GM, Oshitani H, Fukuda K, et al. Are high-performing health systems resilient against the COVID-19 epidemic? Lancet [Internet]. 2020 May 4;395(10227):848–50. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30551-1/abstract

32. Zotti F, Dalessandri D, Salgarello S, Piancino M, Bonetti S, Visconti L, et al. Usefulness of an app in improving oral hygiene compliance in adolescent orthodontic patients. Angle Orthod [Internet]. 2016 May 4;86(1):101–7. Available from: https://meridian.allenpress.com/angle-orthodontist/article/86/1/101/59317/Usefulness-of-

an-app-in-improving-oral-hygiene

33. Cheung YTD, Chan CHH, Lai C-KJ, Chan WFV, Wang MP, Li HCW, et al. Using WhatsApp and Facebook online social groups for smoking relapse prevention for recent quitters: a pilot pragmatic cluster randomized controlled trial. J Med Internet Res [Internet]. 2015 May 4;17(10):e238. Available from: http://www.jmir.org/2015/10/e238/

34. Alanzi TM, Bah S, Jaber F, Alshammari S, Alzahrani S. Evaluation of a mobile social networking application for glycaemic control and diabetes knowledge in patients with type 2 diabetes: a randomized controlled trial using WhatsApp. In: Qatar Foundation Annual Research Conference Proceedings [Internet]. Hamad bin Khalifa University Press (HBKU Press); 2016. Available from: https://www.qscience.com/content/papers/10.5339/qfarc.2016.HBPP2533

35. Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet [Internet]. 2010 May 7;376(9755):1838–45. Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)61997-6/abstract

36. van der Kop ML, Muhula S, Nagide PI, Thabane L, Gelmon L, Awiti PO, et al. Articles Effect of an interactive text-messaging service on patient retention during the first year of HIV care in Kenya (WelTel Retain): an open-label , randomised parallel-group study. 2018;143–52. Available from: file:///Users/main/Desktop/Internet Usage - HIV Review/Effect of an interactive text-messaging service on patient retention during the first year of HIV care in Kenya (WelTel Retain): an open-label, randomised parallel-group study.pdf

37. Connecting Refugees: How Internet and Mobile Connectivity Can Improve Refugee Well-Being and Transform Humanitarian Action [Internet]. UN Refugee Agency; 2016. Available from: file::http://www.unhcr.org/connectivity-for-refugees.html.

38. Logie CH. Mobile Health-Supported HIV Self-Testing Strategy Among Urban Refugee and Displaced Youth in Kampala, Uganda: Protocol for a Cluster Randomized Trial (Tushirikiane, Supporting Each Other). 7. JMIR Res Protoc. 2021;4504097.

39. Smith M, Upshur R. Pandemic Disease, Public Health, and Ethics. In: The Oxford Handbook of Public Health Ethics. 2019.

40. Campbell AR, Kinvig K, Côté HCF, Lester RT, Qiu AQ, Maan EJ, et al. Health Care Provider Utilization and Cost of an mHealth Intervention in Vulnerable People Living With HIV in Vancouver, Canada: Prospective Study. JMIR mHealth uHealth [Internet]. 2018 May 7;6(7):e152. Available from: https://mhealth.jmir.org/2018/7/e152/

41. Rouhani SA, Marsh RH, Rimpel L, Edmond MC, Julmisse M, Checkett KA. Social messaging for global health: lessons from Haiti. J Glob Health [Internet]. 2019 May 4;9(1):10308. Available from: http://jogh.org/documents/issue201901/jogh-09-010308.pdf

42. Shen C, Wang MP, Wan A, Viswanath K, Chan SSC, Lam TH. Health information exposure from information and communication technologies and its associations with health behaviors: Population-based survey. Prev Med (Baltim) [Internet]. 2018 May 4;113:140–6. Available from: http://www.sciencedirect.com/science/article/pii/S0091743518301749

43. Dorwal P, Sachdev R, Gautam D, Jain D, Sharma P, Tiwari AK, et al. Role of WhatsApp Messenger in the laboratory management system: a boon to communication. J Med Syst [Internet]. 2016 May 4;40(1):14. Available from:

http://link.springer.com/10.1007/s10916-015-0384-2

44. Ellanti P, Moriarty A, Coughlan F, McCarthy T. The use of WhatsApp smartphone messaging improves communication efficiency within an orthopaedic surgery team. Cureus [Internet]. 2017 May 4;9(2):e1040. Available from: https://assets.cureus.com/uploads/original_article/pdf/6501/1566922100-20190827-1409-o3oksh.pdf

45. Gamma AE, Slekiene J, von Medeazza G, Asplund F, Cardoso P, Mosler H-J. Contextual and psychosocial factors predicting Ebola prevention behaviours using the RANAS approach to behaviour change in Guinea-Bissau. BMC Public Health [Internet]. 2017;17(1):446. Available from: https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/s12889-017-4360-2

46. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. J Gen Intern Med. 2001;16(9).

47. Des Jarlais DC, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND Statement. Am J Public Health [Internet]. 2004 May 5;94(3):361–6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448256/

Tables & Figures

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

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

Figure 1. Study design for Kukaa 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.

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

Data category	Information
Primary registry and trial identifying number: ClinicalTrials.gov NCT04631367	
Date of registration: 13 November 2020	
Source(s) of monetary support: International Development Research Center	
Primary sponsor: University of Toronto	
Contact for public and scientific queries: Carmen Logie, PhD [carmen.logie@utoronto.ca]	
Public and scientific title: mHealth Intervention for Increasing COVID-19 Prevention Practices With Urban Refugee and Displaced Youth in Uganda	
Countries of recruitment: Uganda	
Health condition(s) or problem(s) studied: COVID-19 prevention practices	
Intervention(s): Kukaa Salama: mHealth intervention; Face Mask + Soap	
Key inclusion criteria: 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.	
Study type: Interventional; Single group assignment pre-post trial; Primary purpose: behavioural change	
Date of first enrolment: June 2021	
Target sample size: 404	
Primary outcome(s): 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	
Key secondary outcomes: 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.	

655

656

657

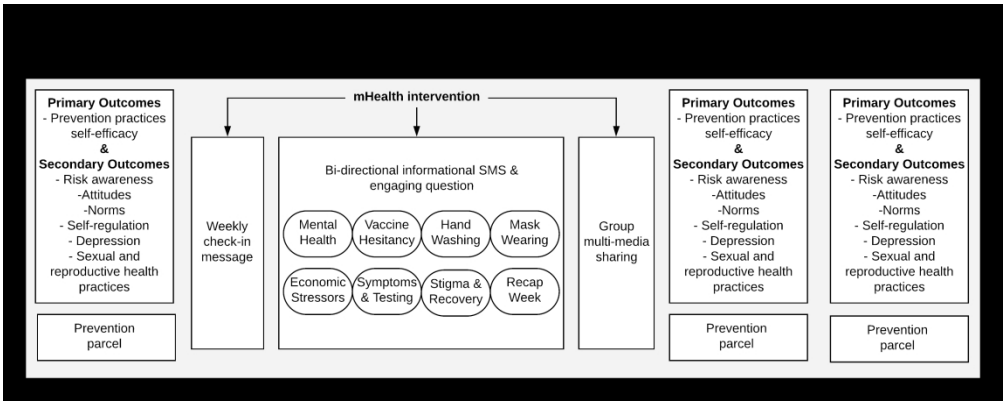

Figure 1. Study design for Kukaa Salama, a pre-test/post-test trial of an interactive and informational mobile health (mHealth) strategy among urban refugee and displaced youth in Kamala, Uganda.

1151x456mm (72 x 72 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	ItemNo	Description	Page (P); Line (L)
Administrative information			
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
Introduction			
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

	6b	Explanation for choice of comparators	N/A; pre-test/post-test trial all participants receive intervention
Objectives	7	Specific objectives or hypotheses	P8-9; L173-182
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P9; L184-192
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P9; L194-200
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P9; L 207-213
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P 10-11; L243-284
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A; low risk behaviour change intervention
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A; low risk behaviour change intervention
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A; low risk behaviour change intervention
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P 11-12; L 285-328

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			

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
	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
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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P 13; L48-368
	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
Methods: Monitoring			
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
	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
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

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
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P 14; L397-402
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
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
	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
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
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P 15; L450-453
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
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
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
	31b	Authorship eligibility guidelines and any intended use of professional writers	P 14; L 405-407

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P 15; L462-466
Appendices			
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

*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" license.