Mobile phone based confidential social network referrals for HIV testing (CONSORT): protocol for a randomized controlled trial

Jan Ostermann, Bernard Njau, Marco van Zwetselaar, Thespina Yamanis, Leah McClimans, Rose Mwangi, Meky Beti, Amy Hobbie, Salomé-Joelle Gass, Tara Mtuy, Nathan Thielman

Submitted to: JMIR Research Protocols
on: December 01, 2023

Table of Contents

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Abstract

Background: The ubiquity of mobile phones across many high HIV prevalence settings has created opportunities to leverage mobile health (mHealth) technologies to engage social networks for HIV prevention and treatment.

Objective: This study seeks to evaluate the acceptability and efficacy of a novel mHealth intervention, Confidential Social Network Referrals for HIV Testing (CONSORT), to nudge at-risk individuals to test for HIV.

Methods: The study will be conducted in Moshi, Tanzania. After qualitative formative work and pilot testing, 400 clients presenting for HIV counseling and testing, and 200 persons living with HIV (PWH) and receiving care at HIV care and treatment centers will be enrolled as inviters into a randomized controlled trial. Inviters will be asked to complete a survey of their HIV risk behaviors and their social networks and then randomized into one of two study arms. Arm 1 participants will be offered to extend automated CONSORT invitations in the form of confidential Short Messaging System (SMS) messages or physical invitation cards to any of their network contacts. Arm 2 participants will be offered physical invitation cards only. The primary outcome will be uptake of HIV testing among network contacts within 30 days. Secondary outcomes will include the acceptability of CONSORT among inviters and the number of new HIV diagnoses among network contacts presenting for HIV testing.

Results: Enrollment into the randomized controlled trial is expected to start in September 2024. Findings will be disseminated to stakeholders and published in peer-reviewed journals.

Conclusions: If CONSORT is acceptable and effective, mobile-phone supported chain-referral methods could greatly improve the reach of HIV testing efforts. Clinical Trial: The protocol was registered in ClinicalTrials.gov (NCT05967208) on July 25, 2023.

(JMIR Preprints 01/12/2023:55068)
DOI: https://doi.org/10.2196/preprints.55068

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Mobile phone based confidential social network referrals for HIV testing (CONSORT): protocol for a randomized controlled trial

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Mobile phone-based confidential social network referrals for HIV testing (CONSORT): protocol for a randomized controlled trial

Abstract

Background. Critical to efforts to end the HIV epidemic is the identification of persons living with HIV who have yet to be diagnosed and engaged in care. Expanded HIV testing outreach efforts need to be both efficient and ambitious, targeting the social networks of persons living with HIV and those at above average risk of undiagnosed HIV infection**.** The ubiquity of mobile phones across many high HIV prevalence settings has created opportunities to leverage mobile health (mHealth) technologies to engage social networks for HIV testing outreach, prevention, and treatment.
Objective. The purpose of this study is to evaluate the acceptability and efficacy of a novel mHealth intervention, *Confidential Social Network Referrals for HIV Testing (CONSORT)*, to nudge at-risk individuals to test for HIV using Short Messaging System (SMS) messages.
Methods. The study will be conducted in Moshi, Tanzania, the commercial center and administrative capital of the Kilimanjaro Region in Northern Tanzania. After qualitative formative work and pilot testing, 400 clients presenting for HIV counseling and testing, and 200 persons living with HIV and receiving care at HIV care and treatment centers will be enrolled as “inviters” into a randomized controlled trial and randomized into one of two study arms. Eligible participants will be ages 18 years or older and live, work, or regularly receive care in Moshi. All inviters will be asked to complete a survey of their HIV testing and risk behaviors and to think of social network contacts who would benefit from HIV testing. They will then be asked to whom they would prefer to extend an HIV testing invitation via a physical invitation card. Arm 1 participants will also be given the opportunity to extend CONSORT invitations in the form of automated, confidential SMS messages to any of their social network contacts. Arm 2 participants will be offered physical invitation cards alone. The primary outcome will be counselor-documented uptake of HIV testing by invitees within 30 days of the enrollment of the inviter. Secondary outcomes will include (a) the acceptability of CONSORT among inviters, (b) the number of new HIV diagnoses among network contacts presenting for HIV testing, and (c) the HIV risk of invitees who present for testing.
Results: Enrollment into the randomized controlled trial is expected to start in September 2024. Findings will be disseminated to stakeholders and published in peer-reviewed journals.
Conclusion. If CONSORT is acceptable and effective for increasing the uptake of HIV testing, given the minimal costs of SMS reminders and potential for exponential but targeted growth using chain referrals, it may shift current practices for HIV testing programs in the area.
Registration. The protocol was registered in ClinicalTrials.gov (NCT05967208) on July 25, 2023.

Strengths and limitations of this study

- The randomized controlled trial will include as inviters clients who are presenting for HIV testing and persons who are living with HIV, ensuring that the intervention reaches network contacts at above-average risk of HIV infection.
- Potential exponential growth of network referral systems and the low cost of sending SMS messages indicate that even moderate acceptability and efficacy of CONSORT could result in a highly cost-effective intervention.
- Confidential chain referrals using secure, open-source mHealth technology may be applied to other contexts and health conditions, and lead to the development of new approaches for engaging hard-to-reach populations.
- Potential limitations include constraints on the amount of information that can be shared via SMS messages, high but non-universal rates of literacy and mobile phone ownership, and unknown generalizability of study findings to other populations and settings.

Keywords

HIV counseling and testing; mHealth; social networks; confidential referrals; stigma; Tanzania; sub-Saharan Africa

Word count: 4204

Mobile phone-based confidential social network referrals for HIV testing (CONSORT): protocol for a randomized controlled trial

Protocol version and date

Version 2.0. 27-November-2023

Background

UNAIDS set for 2030 the ambitious 95-95-95 target: diagnosing 95% of all persons living with HIV (PWH), initiating antiretroviral therapy for 95% of those diagnosed, and achieving viral suppression for 95% of those treated. Traditional testing approaches have linked countless PWH to treatment, however, the cost-effectiveness of these approaches for reaching incrementally harder-to-reach PWH is declining. The 2022 Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) found that only 79.6% of Tanzanian women and 64% of Tanzanian men had tested for HIV during their lifetime.[1] Further, despite the recommendation that those in the general population who test negative re-test annually, only 36.5% of women and 30.6% of men reported testing for HIV in the previous 12 months. Thus, novel approaches that efficiently reach at-risk individuals are urgently needed.

Social and sexual networks play a critical role in HIV transmission,[2] testing decisions,[3, 4] linkage to care,[5] and adherence.[6] However, numerous barriers, including HIV-related stigma, legal concerns, and the risk of unwanted serostatus disclosure can impede HIV-related communication within social and sexual networks.[7, 8] The ubiquity of mobile phones across many high HIV prevalence settings, including those in low- and middle-income countries (LMICs), has created opportunities to leverage mobile health (mHealth) technologies to engage social networks along the HIV care continuum, e.g., for contact tracing, partner notification, clinic engagement, adherence reminders, and support for PWH.[9-11] The privacy and confidentiality afforded by novel applications of mHealth technologies can help to address stigma, legal concerns, and disclosure, and broadly improve uptake of testing.

This paper describes the study protocol for a randomized controlled trial (RCT) to evaluate the acceptability and efficacy of mobile phone-based ‘nudges’ in the form of *confidential social network referrals for HIV testing* (*CONSORT*) to reach high-risk individuals and prompt them to test for HIV. The study will adapt and use an existing, highly versatile *mobile phone-based appointment reminder and incentive system (mParis)*.[12-14] mParis resides in Tanzania and can autonomously receive and respond to large numbers of Short Message Service (SMS) text messages according to pre-specified algorithms, making it a low-cost tool that can easily be adapted and scaled. In prior work we explored the hypothetical acceptability and efficacy of CONSORT.[15] The survey results from this work suggested high feasibility and moderate acceptability of CONSORT. The present study will explore the actual acceptability and efficacy of the intervention.

This study aligns with Tanzania’s 2017-22 *Health Sector HIV and AIDS Strategic Plan (HSHSP-IV)*, which listed as its first challenge that HIV testing services need to be more efficient and ambitious.[16] Acknowledging the unfinished business from HSHSP-IV, the *Health Sector Strategic Plan July 2021 – June 2026* highlights persistently low rates of HIV testing for some groups, particularly men and young people.[17] If CONSORT is shown to be acceptable and effective, confidential, digital, chain-referral methods could greatly improve the reach and cost-effectiveness of HIV testing efforts. While the CONSORT system will be developed and tested using SMS functionality in a low-resource setting, the confidential chain-referral approach and the system’s open-source, “low-code” architecture may be extended to promote other health behaviors across varied social networks, app-based technologies, health conditions, and geographic settings.

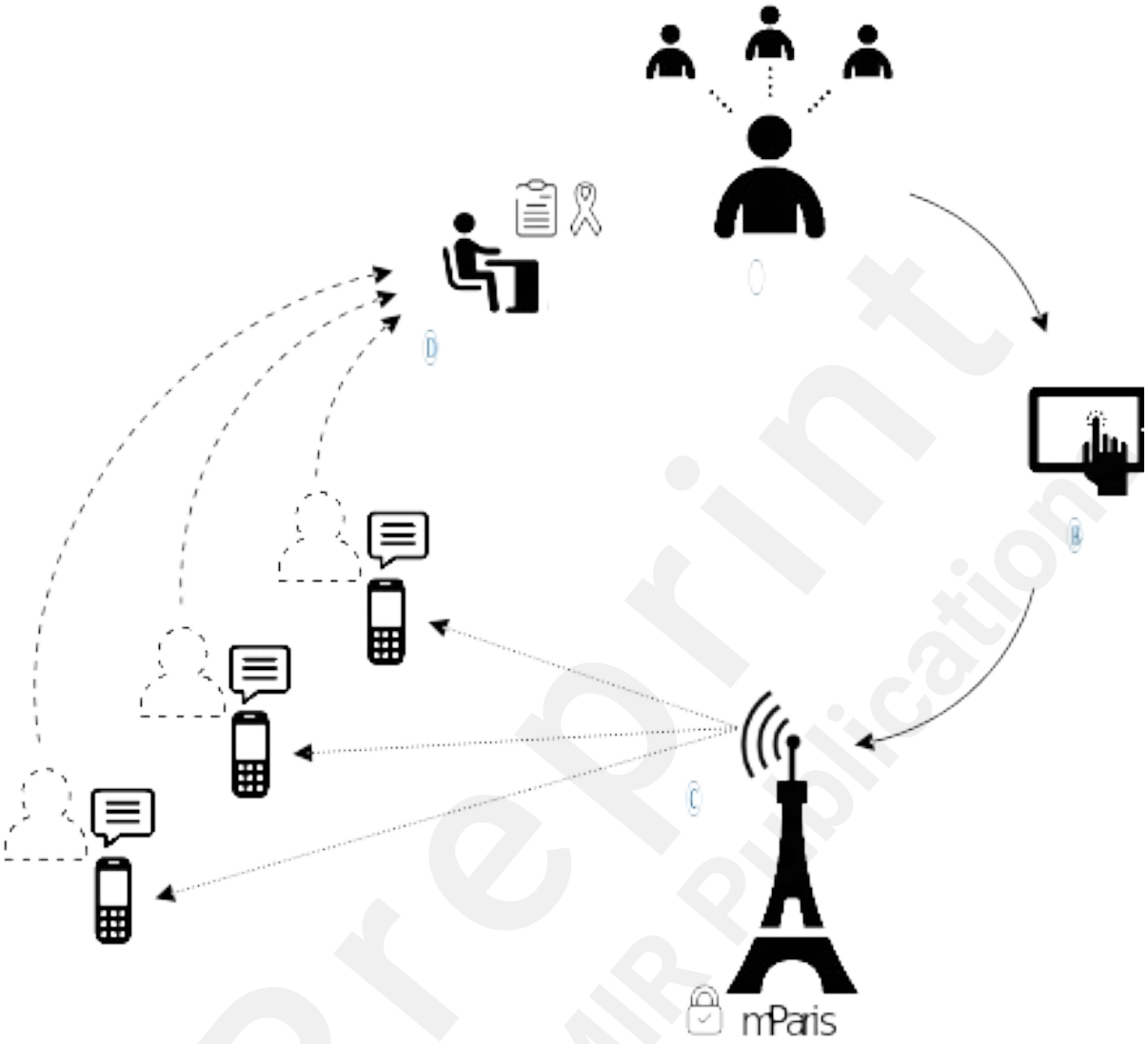
Study aims and hypothesis

The study aims to evaluate the acceptability and efficacy of automated, confidential, SMS-based HIV testing invitations as a means of 'nudging' individuals to test for HIV. The overall study hypothesis is that that an automated, confidential referral system, developed and deployed in the Kilimanjaro Region of Tanzania, will be acceptable to both index participants ("inviters") and their referrals ("invitees") and it will be effective for increasing uptake of HIV testing.

The CONSORT intervention

The CONSORT process is shown in **Figure 1**. A consented inviter completes an HIV risk assessment and a survey of their social and sexual network contacts **(A)**. Next, the inviter selects invitation messages from a menu of options to send to any of their network contacts who they think could benefit from HIV testing **(B)**. Invitee phone numbers and message texts are transferred securely to *mParis*. *mParis* autonomously sends the invitation message with a unique *referral code* to each invitee phone number **(C)**. Invitees presenting for HIV testing with a referral code ("invitee testers") will be offered the opportunity to become inviters **(D)**.

Figure 1. The Confidential Social Network Referrals for HIV testing (*CONSORT*) process



(A) A consented “inviter” volunteers phone numbers of social network contacts and **(B)** selects the invitation message. **(C)** A secure, autonomous digital health system sends the selected message to each “invitee” phone number. **(D)** An invitee responding to the invitation presents for HIV testing (”invitee tester”) and is offered the opportunity to become an inviter. Abbreviations: mParis: mobile phone assisted appointment reminder and incentive system

Methods and analysis

Study setting

The study will be conducted in Moshi, Tanzania. Moshi is the commercial center and administrative capital of the Kilimanjaro Region in Northern Tanzania and has an estimated population of about 535,000.[18] Moshi has 25 HIV counseling and testing (HCT) facilities which offer free HIV testing; many of these function as HIV care and treatment centers (CTCs), providing free HIV care to persons living with HIV.[19] HCT and CTC facilities with adequate volume to support the proposed study activities will be eligible to participate in the recruitment of inviters for the RCT. Uptake of HIV testing among invitees will be assessed across all HCT facilities in the study area.

Study sample

The RCT will include gender-balanced samples of 600 inviters, including 400 adult HCT clients and 200 adult PWH in care at participating CTCs.

Inclusion and exclusion criteria

Eligible participants will be ages 18 or older and live, work, or regularly receive care in Moshi. Minors (persons under age 18 years) will be excluded, as it will not practically be possible to obtain assent to minors' participation in a research study from a legal guardian.

Recruitment

Clients presenting for HIV testing at participating HCT facilities and PWH receiving care at participating CTCs will be consecutively approached for eligibility determination and informed consent and offered enrollment into the RCT. Recruitment will continue until the target sample sizes have been reached.

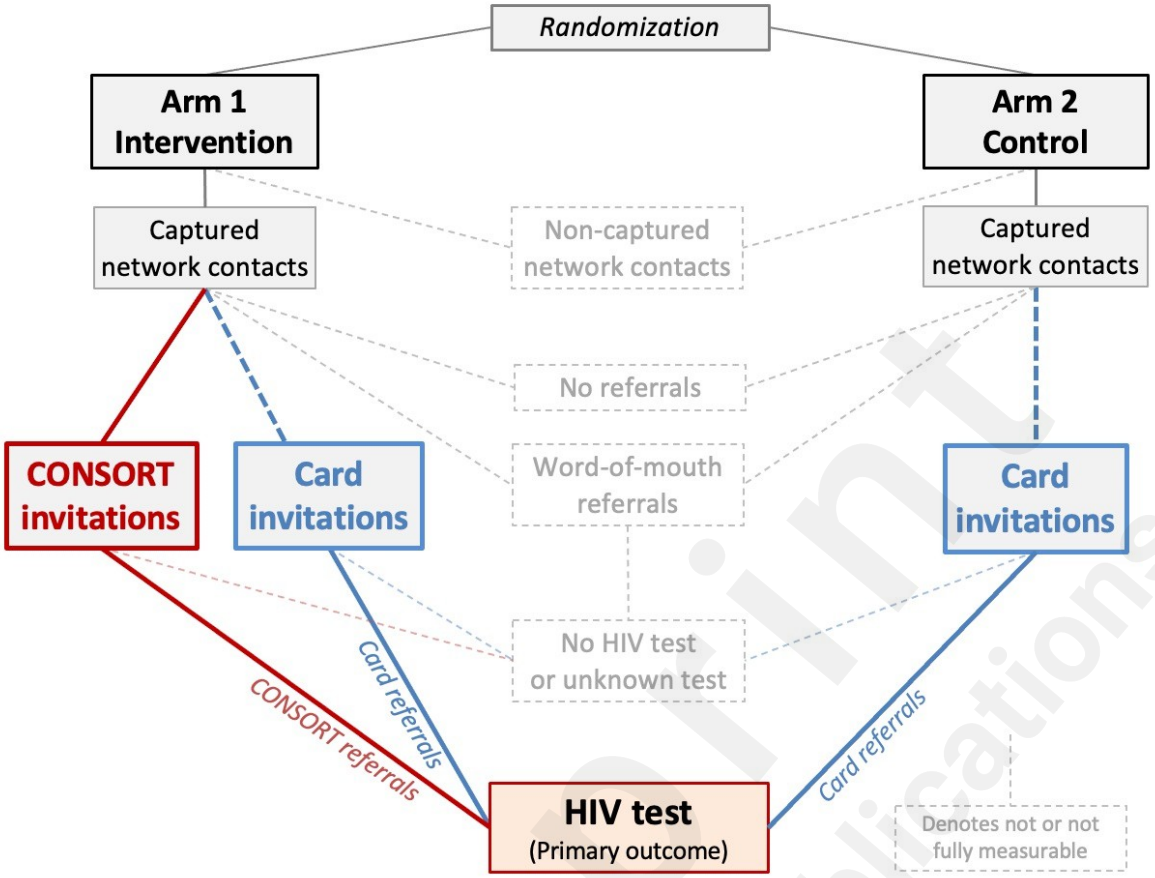
Study design

The study will evaluate the acceptability and efficacy of CONSORT. Because CONSORT may be a substitute for other referral options (e.g., word-of-mouth referrals) a full attribution of testing uptake among invitees would likely overstate the system's effectiveness. To derive valid estimates of the effect of CONSORT, we will evaluate CONSORT in the context of a traceable substitute referral option: physical invitation cards.

Design of the RCT

The design of the two-arm RCT is shown in **Figure 2**. Arm 1 participants will be offered to extend CONSORT invitations or physical invitation cards to any of their network contacts. Arm 2 participants will be offered physical invitation cards alone. Arm 1 represents the intervention arm; Arm 2 represents an active control arm.

Figure 2. Design of the two-arm randomized controlled trial



Notes: The 2-arm randomized controlled trial with 600 adult inviters will be conducted in Moshi, Tanzania. The primary outcome of interest is uptake of HIV testing among invitees, defined as the number of invitees testing for HIV within 30 days, per 100 inviters. While not all process elements can be observed, the trial results yield an unbiased estimate of the efficacy of CONSORT for the primary outcome: getting additional persons to test for HIV, relative to physical invitation cards alone.

Assignment to study arms

Assignment to study arms will be implemented by randomizing sequentially assigned participant IDs to either Arm 1 or Arm 2. Participant IDs will be assigned to study arms using a random number generator. The random assignment is expected to result in approximately equal numbers of participants in each study arm.

Blinding

Neither participants nor research staff will be blinded with respect to inviters' study arm assignment.

Primary outcome

The *primary outcome* is counselor-documented uptake of HIV testing among invitees within 30 days of the enrollment of the inviter. For invitees who then present for HIV testing ("invitee testers") after a CONSORT invitation, referral codes will be documented by counselors in electronic logbooks; for invitees presenting with physical invitation cards, counselors will collect the invitation cards.

Secondary outcomes

Secondary outcomes include the acceptability of *CONSORT* among inviters, the number of new HIV diagnoses, and the HIV risk among invitee testers. Secondary outcomes are detailed further below.

Study activities

Enrollment survey

Participants will complete an interviewer-administered enrollment survey to characterize their social networks and assess their HIV serostatus, HIV-related behaviors (e.g., HIV prevention behaviors, HIV testing history, number of partners, concurrency)[20] and stigma,[21-23] as well as key demographic, socioeconomic, household, and HIV risk characteristics that may correlate with the acceptability and efficacy of CONSORT.[24, 25] Surveys will be conducted in Kiswahili. Data will be captured electronically using tablet devices.

Social network-based HIV testing invitations

The enrollment survey will include a survey of inviters' preferences for extending HIV testing invitations within their social networks. Participants will be asked to think of social network contacts (their "alters") across multiple network dimensions, including partner(s), family, friends, co-workers, and other people who are 18 years of age or older and who would benefit from HIV testing. Participants will be asked to whom they would prefer to extend an HIV testing invitation via a physical invitation card; Arm 1 participants will also be able to select *CONSORT* invitations. At the end of the survey, inviters will be given the respective number of coded invitation cards and Arm 1 inviters will be able to send CONSORT invitations to their network contacts (**Figure 1**).

Phone-based follow-up survey

Distribution of physical invitation cards will be ascertained via self-reports from inviters during a phone-based follow-up survey after 1 month.

Assessment of outcomes

Primary outcome

The primary outcome measure is counselor-documented uptake of HIV testing by invitees within 30 days of the enrollment of the inviter. All clients presenting for HIV testing will be asked whether

they received an HIV testing invitation by SMS or a physical invitation card. Counselors will document referral codes from SMS messages and collect invitation cards. Referral codes will be validated against a database of referral codes issued. A match is interpreted as an invitee presenting for HIV testing.

Secondary outcomes

Acceptability among inviters. The acceptability of CONSORT among inviters will be described by the percentage of inviters extending at least one CONSORT invitation and the average number of CONSORT invitees per inviter. This outcome is assessed only for Arm 1 participants.
New HIV diagnoses. For invitees presenting for testing ("invitee testers"), the result of their HIV test will be abstracted from administrative data collected for reports to the National AIDS Control Programme (NACP). Clients testing positive for HIV will be linked to care at a local CTC, following Tanzania's NACP guidelines.[16]
HIV risk among invitees. For invitee testers, basic sociodemographic and risk characteristics (age, gender, marital status, prior testing) will be abstracted from administrative data collected for reports to the NACP. Invitee testers consenting to become inviters will complete the same enrollment survey as their inviters, which includes a comprehensive HIV risk assessment (see above).

Participant retention

Inviters who choose to extend physical invitation cards to their network contacts will be re-contacted by phone after 1 month and asked about the distribution of these cards. For all other inviters study activities will end after the initial visit.

Study timeline

Details of the intervention will be finalized after formative, qualitative work, including focus group discussions (FGDs) and in-depth interviews (IDIs) with HCT clients, CTC patients, and providers. FGDs and IDIs will elucidate key client-side characteristics of CONSORT, including refining appropriate message content for invitees, defining parameters for the timing of invitation messages, and exploring the feasibility of incentives for inviters and invitees. Prior to the implementation of the RCT, the intervention will be pilot tested with 50 adult HCT clients and 50 adult CTC patients. Formative work and pilot testing are expected to last 2 years.
Following formative work and a successful pilot test, the RCT is planned to commence in year 3 of this study. Enrollment into the trial will continue until the target numbers of N=400 HCT inviters and N=200 CTC inviters has been reached. Assessments of invitation card distribution and HIV testing uptake will continue until 1 month after the last CONSORT invitation was sent via mParis and the last invitation card was issued.

Statistical analysis

Analysis of the primary outcome

Efficacy will be analyzed descriptively by comparing, between the two study arms, the number of invitees testing for HIV within 1 month, per 100 inviters (**Figure 3**). Analytically, efficacy will be modeled at the level of the inviter, using a zero-inflated negative binomial model, with the number of invitees returning for testing as the dependent variable. The primary explanatory variable will be a binary indicator variable for the study arm. Covariates will characterize variation in invitees' testing uptake with inviters' sociodemographic and network characteristics, HIV risk, and stigma.

Analyses of secondary outcomes

Acceptability among inviters. Logistic regression will be used to model inviters' decisions to send at least one CONSORT invitation. Zero-inflated negative binomial models will model the number of invitations sent as a function of the covariates described above.
New HIV diagnoses. Differences between study arms in the number of new HIV diagnoses among invitees, per 100 inviters, will be analyzed descriptively using a Fisher's exact test.
HIV risk among invitees. Differences in invitees' sociodemographic and risk characteristics between study arms will be assessed descriptively using Student's t-tests and Chi-squared statistics.

Analytic considerations

The analysis of the primary outcome will be stratified by cohort (400 HCT inviters; 200 CTC inviters); generalized Hausman tests will evaluate whether the data can be pooled.

Sensitivity analyses

Sensitivity analyses will assess the potential impact of missing data on estimates and describe variation in the acceptability and efficacy of CONSORT by cohort (HCT vs. CTC inviters) and gender (male vs. female inviters).

Statistical power

The primary outcome analysis is a comparison between study arms of *rates* of invitees testing for HIV per 100 inviters (**Figure 3**). As *a priori* estimates of invitees' testing rates in the control arm are not known, power calculations for differences in rates between study arms would be speculative. Instead, the power calculations refer to changes in the *number* of invitees returning for testing, N_T, which can be assumed to follow a Poisson distribution with a standard error of sqrt(N_T). Assuming that 20 (alternatively 40 / 60 / 80 / 100) invitees of Arm 2 inviters present for testing, the study has 90% power to detect CONSORT-related differences of 7 (10 / 13 / 15 / 16) testers between study arms, and 80% power to detect differences of 6 (8 / 10 / 11 / 13) testers between study arms. These calculations apply to cohort- or gender-specific as well as aggregate analyses.

Reporting

This manuscript was prepared in accordance with the *Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)* checklist for clinical trial protocols. The completed checklist and figure are included in the **Supplemental Files**.

Monitoring and quality assurance

Adherence to intervention protocols and the completeness and quality of study data will be monitored by the principal investigators or a study monitor. Electronic data capture on tablet devices and daily uploads to secure servers allow for the continuous monitoring of study activities in near real time. All paper documents will be scanned. Rigorous quality assurance and quality control procedures will be established, including interviewer observation, validation and range checks during data entry, verification of entered data, and the monitoring of time stamps for electronic surveys.

Patient and public involvement

Formative, qualitative work with HCT clients, CTC patients, and providers will elucidate key characteristics of CONSORT, including the selection of relevant social network contacts, appropriate message content for invitees, and defining parameters for the timing of invitation SMSs. Discussions will also focus on ethical considerations and the potential role of economic incentives as means of motivating inviters to invite additional network contacts and/or at-risk invitees to test for HIV.

Findings will be used to identify features of the CONSORT system that will maximize its acceptability among inviters and invitees.

Ethical considerations

Human subjects research ethics review

The protocol was registered in ClinicalTrials.gov (NCT05967208) on July 25, 2023. The protocol was approved by the University of South Carolina IRB (Pro00120208) in the United States; the Ethics Review Committee at Kilimanjaro Christian Medical University College (Protocol #1404); and the National Institute for Medical Research (NIMR/HQ/R.8a/Vol.IX/4373). The project will consistently apply relevant ethical principles when working with individuals at risk for or affected by HIV. Protocol amendments will be submitted to these entities as required.

Informed consent

Informed consent documents will be developed in English and translated into Kiswahili. Trained research assistants will inform eligible individuals about the study's purpose, procedures, risks, and benefits before obtaining informed consent for participation. The potential risks and benefits of research participation will be carefully explained in culturally appropriate and understandable language during the consent process. Consenting individuals will be enrolled into the study, with the study ID dictating their assignment to one of the two RCT study arms.

Data security, privacy, and confidentiality

Data will be kept in compliance with relevant privacy regulations in Tanzania and the United States. Access to identifying information will be strictly limited. Study personnel will be instructed to keep the identity of all research subjects confidential and will sign confidentiality agreements. The CONSORT system will be designed with a focus on confidentiality. Only encrypted versions of the invitee phone numbers will be stored in mParis, and information about the invitee will be stored separately from information about the inviter. Encrypted invitee phone numbers will only ever be decrypted temporarily in order to schedule the sending of the SMS and 'in flight' to the SMS message center.

Compensation

Inviters and their invitee testers who agree to participate in the research will receive between TSH 5,000-10,000 (~ $2.20-$4.40) as compensation for their time.

Results

After qualitative formative work and pilot testing, enrollment into the randomized controlled trial is expected to start in September 2024.

Research results from the CONSORT study will be disseminated via peer-reviewed publications, at national and international conferences, and via media outlets. To comply with the publication policies of the National Institute for Medical Research (NIMR) in Tanzania, approval for publications will be obtained from NIMR.

As many stakeholders and policy makers interested in this research are residing in Tanzania, efforts will be made to translate the research abstracts into Kiswahili, to make them more widely accessible. All system components and expertise needed to sustain and scale up CONSORT will be in place locally at the end of this project.

Discussion

This study will evaluate the acceptability and efficacy of automated, confidential, SMS-based HIV

testing invitations as a means of ‘nudging’ individuals to test for HIV. If testing rates differ between the two study arms in the RCT, the results will support our hypothesis that an automated, confidential referral system is acceptable to both index participants (inviters) and referrals (invitees) and is effective for increasing uptake of HIV testing. If CONSORT is shown to be acceptable and effective, then confidential, digital, chain-referral methods could be used to improve the reach and cost-effectiveness of HIV testing efforts.

CONSORT’s potential is based on three key premises.

The first premise is that testing network contacts of PWH and those testing for HIV is an effective means for HIV case-finding. Identifying, tracing, and testing sexual contacts of persons with a sexually transmitted infection (STI) has been an essential component of public health STI management for decades. Assisted HIV partner notification, by which health care workers elicit information about an index case's sexual partners and contact partners to request HIV testing, has been shown to be effective for increasing testing uptake and identifying new HIV infections.[26-36] A meta-analysis of three individually randomized trials[33-35] found that assisted partner notification, compared with passive referral, resulted in a 1.5-fold increase in HIV testing uptake. Moreover, the proportion of HIV-positive partners identified was 1.5 times higher with this approach.[37] Prior research also suggests that persons presenting for HIV testing have higher rates of HIV infection and higher rates of HIV risk behaviors than the general population.[38, 39] Owing to similarities between members of social networks, a property known as homophily, referrals of HCT clients are, thus, also more likely to be infected with HIV than the general population. CONSORT, therefore, is well positioned to reach populations with above-average risk of HIV infection and to ‘nudge’ them to test for HIV.

The second premise is that an assurance of confidentiality promotes referrals for HIV testing within social networks. CONSORT is conceptually related to confidential partner notification strategies,[40, 41] which are known to be highly acceptable to participants.[42, 43] The evidence for technology based notification systems, mainly derived from internet-based applications in high-income setting, is mixed: some show success[44-51] while others do not.[52-54] The efficacy of an impersonal, confidential approach of accessing network contacts in LMICs has yet to be evaluated. On the one hand, this approach may reduce the cost of contacting partners[55] and circumvent barriers such as non-reciprocal relationships,[56] stigma,[57], disclosure, and legal risks.[58] On the other hand, a confidential SMS message is likely to be less motivating than personal communication. This study will compare the acceptability and efficacy of CONSORT vs. other means of inviting social network contacts to test for HIV.

The third premise is that SMS-based ‘nudges’ are inexpensive, effective tools for influencing health behaviors. Apart from incentives, reminders are among the simplest available nudging tools.[59] SMS-based ‘nudges’ in the context of HIV testing remain rare, despite their low cost and nearly universal reach. While there is evidence that SMS-based interventions are feasible and acceptable in LMICs,[60-64] and that ‘nudging’ can influence health related behaviors,[65-67] relatively few studies have evaluated the use of SMS messaging to encourage HIV testing.[9, 68-76] We identified only five protocols that evaluated SMS messaging for increasing uptake of facility-based HIV testing among at-risk adults in sub-Saharan Africa.[9, 71-73, 76] Although these studies demonstrated strong potential of SMS-based messages to influence testing uptake, each has significant limitations, including using self-reports of HIV testing,[68, 71-73, 76] use of a combined intervention that included SMS messaging with phone calls and in-person reminders,[9] and limiting the intervention to young adults,[9, 73, 75] women,[73] or specific high-risk populations.[72, 76-83] The design of our study is more rigorous in that (a) we will isolate the effect of SMS messaging alone, and (b) *actual* testing uptake will be assessed in real time (rather than by self-report). Finally, results from CONSORT will be more broadly applicable, as the index (inviter) population will include participants from both sexes and across a greater range of ages, and it will extend beyond specific high-risk populations. With low costs of SMS in the study area and an open-source and largely

autonomous implementation, CONSORT may overcome limits to growth encountered in traditional chain referral approaches[57] and support continuous, sustainable growth.

The study is subject to several limitations and considerations.

First, feasibility considerations limit the study area to include only HCT facilities in Moshi municipality. While referral codes and coded invitation cards collected from participating HCT providers offer definitive evidence of a completed HIV test, participants may test without disclosing receipt of CONSORT messages or invitation cards and may test outside the study area.

Second, the estimated effect sizes are not generalizable to other index populations, other areas in Tanzania or other parts of Africa. While high mobile phone use rates and stable cellular network coverage suggest good technical feasibility of CONSORT, illiteracy, lack of trust in confidentiality assurances, and stigma remain potential challenges. In formative work and the pilot study we will explore options such as computer-assisted self-interviewing (CASI) for capturing referral information, incentives, and system-level adjustments to maximize acceptability and efficacy.

Third, SMS messages must be short and concise, can only contain text, are not encrypted in transit, and are largely limited to one-way communication. If successful, future work will explore the use of alternative communication options that allow for the secure transfer of audiovisual information and a more interactive experience (e.g., via chatbots).

Finally, we note that this study is subject to two important ethical considerations: (1) inviters provide the phone numbers of their network contacts without the contacts' consent; and (2) CONSORT invitees need to be informed that the SMS messages they receive are part of a research project. Regarding the first consideration, Tanzania's 2019 *National Comprehensive Guidelines on HIV Testing Services* sets a precedent in its section on Index Client Testing and Partner Notification.[84] The guidance outlines several assisted voluntary approaches to disclose HIV status to the partners of index clients. One of the suggested approaches allows an HIV testing provider to contact the index client's partners directly and confidentially for testing. Providers need the index client's consent, but not their partners' consent. While this approach is primarily focused on index clients who are diagnosed with HIV, the guidelines "emphasize enhanced use of this approach throughout the country as among the new innovations to rapidly increase the number of PLHIV diagnosed." Regarding the second consideration, SMS messages to invitee phone numbers will include a statement indicating that the message is part of a research study. Throughout the study, we will continue discussions with the ethicists on our team to ensure that all procedures minimize potential risk of harm to both inviters and invitees, preserve strict confidentiality, and avoid potential stigmatization.

Conclusion

In conclusion, the CONSORT approach, which combines the ubiquity of mobile phones with an assurance of confidentiality, holds promise for efficiently engaging higher risk populations by 'nudging' their network contacts to test.[85-87] If CONSORT is acceptable and effective for increasing uptake of HIV testing, it can be readily sustained and scaled, and has the potential to shift current practices in HIV testing programs in the study area. Given the minimal costs of SMS reminders and the potential for exponential, but targeted, growth using chain referrals, this system could prove to be a cost-effective tool for accelerating Tanzania's goal to reach HIV epidemic control by 2030. Leveraging social networks and technologies for nudging is readily extensible to other areas of public health, particularly where health concerns overlap and cluster within stigmatized and/or hard-to-reach social networks.

Declarations

Funding

This study is supported by a grant from the Fogarty International Center of the National Institutes of Health (R21TW011667). The funding body has no role in the design of the study, the collection, analysis, and interpretation of data, or writing of the manuscript.

Data availability

Findings from this study will be published in peer-reviewed journals. Data from the proposed study will be stored in a data repository; these data will be de-identified so that they cannot be linked back to individuals. Investigators wishing to use study data to answer new research questions may submit data analysis concept proposals for consideration by the Principal Investigators. The Principal Investigators will review the proposal and will provide those submitting scientifically rigorous and promising proposals access to the data repository to address their research questions.

Consent for publication

All authors of the manuscript have read and agreed to its content and are accountable for all aspects of the accuracy and integrity of the manuscript in accordance with ICMJE criteria.

Competing interests

The authors declare that they have no competing interests.

Author contributions

JO, NT, and BN conceptualized the study. AH, BN, JO, NT, and TY were involved in the development and submission of the funding application. All authors contributed to the development of the study protocol. JO, BN, and NT co-led the development of this manuscript, wrote the first draft of the manuscript, and led subsequent revisions. MVZ developed the *mParis* software. All authors read the manuscript, provided critical input, and approved the final manuscript.

Acknowledgements

The authors acknowledge administrative support from the staff of the Kilimanjaro Clinical Research Institute, the University of South Carolina’s Arnold School of Public Health; the Duke Global Health Institute; and Duke University’s Center for Health Policy and Inequalities Research. The authors also acknowledge Dr. Jairy Khanga (Regional Medical Officer, Kilimanjaro Region) for supporting this effort to increase uptake of HIV testing in the Kilimanjaro Region and Prof. Spencer Moore for guidance on the collection of preliminary data for this study.

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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	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	4
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	13
	2b	All items from the World Health Organization Trial Registration Data Set	Supplementary Table S2
Protocol version	3	Date and version identifier	4
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Cover page
	5b	Name and contact information for the trial sponsor	Supplementary Table S2
	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	16

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	4
	6b	Explanation for choice of comparators	7
Objectives	7	Specific objectives or hypotheses	5
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)	7

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	7
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)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,7,8
	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
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (e.g, 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	9,9
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)	SPIRIT Figure S1

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	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target size	7
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	8
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	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
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	9,9,12
	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	n/a
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	13,12

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	10,11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12,12
	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)	12
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	n/a
	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
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	Error: Reference source not found
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
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)	13
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Error: Reference source not found

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
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	16
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
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	Error: Reference source not found
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental materials
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

*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.

Supplemental Figure: SPIRIT figure depicting schedule of enrolment, interventions, and assessments.

	STUDY PERIOD		
	Enrolment	**Allocation**	**Post-allocation**
TIMEPOINTS	T_0	T_1	T_3
ENROLMENT:			
Eligibility screen	X		
Informed consent	X		
Allocation		X	
INTERVENTIONS:			
Control condition		X	
Intervention condition		X	
ASSESSMENTS:			
Enrolment survey: Socio-demographics, social networks, HIV risk		X	
Card referrals, uptake of HIV testing, HIV infection			X

Supplementary Files

FIG 1-3 and SPIRIT Figure.
URL: http://asset.jmir.pub/assets/bbcdd6ff45dac5cdb3b73fbc2a843781.docx

Multimedia Appendixes

NIH summary statement: ZRG1 HDM-J (56) Center for Scientific Review Special Emphasis Panel Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21/R33 - clinical trial optional).
URL: http://asset.jmir.pub/assets/35e09a682797914056d8ebd18ac3e318.pdf

Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

NIH Summary Statement: ZRG1 HDM-J (56) Center for Scientific Review Special Emphasis Panel Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21/R33 - Clinical Trial Optional).
URL: http://asset.jmir.pub/assets/11243fa7509807743d717fac59be26ab.pdf