


BMJ Open Todurujo na Kadurok (empowering youth): study protocol of an HIV self-testing and edutainment comic cluster randomised trial among refugee youth in a humanitarian setting in Uganda

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ABSTRACT

Introduction Refugees experience HIV vulnerabilities due to the confluence of displacement, violence and poverty. HIV self-testing, understudied with refugees, is a promising method to increase testing uptake, yet challenges remain with linkages to confirmatory testing following a positive HIV self-test. This study aims to evaluate the effectiveness of HIV self-testing kits and ‘edutainment’ comics in increasing HIV testing and HIV status knowledge among refugee youth aged 16–24 years in Bidi Bidi Refugee Settlement, Uganda.

Methods and analysis This study will be conducted in Bidi Bidi. We conducted a qualitative formative phase with focus groups (n=40) to generate knowledge of barriers and facilitators of HIV prevention, testing and care among refugee youth (aged 16–24) in Bidi Bidi. These findings were used to create comic scenarios aligning with edutainment approaches to health promotion and inform a four-arm cluster randomised controlled trial in Bidi Bidi using a 2×2 factorial design: (1) HIV self-testing alongside edutainment comics, (2) HIV self-testing alone, (3) edutainment comic alone and (4) standard of care. The target sample size will be 120 youth (30 per arm), who will be enrolled in the trial and followed for 3 months. Data will be collected at baseline and 3 months after enrolment. The primary outcomes (HIV testing frequency, HIV status knowledge) and secondary outcomes (linkage to confirmatory HIV testing, HIV care linkage, HIV self-test kit use, HIV-related stigma, HIV knowledge, safer sex efficacy, condom use, adolescent sexual and reproductive health (SRH) stigma, sexual relationship power, access to SRH services) will be evaluated using descriptive statistics and regression analyses.

Ethics and dissemination This study was approved by the University of Toronto Research Ethics Board, Mildmay Uganda Research Ethics Committee and the Uganda National Council for Science and Technology. Results will be shared in peer-reviewed publications and community knowledge sharing.

Trial registration number NCT05213689.

BACKGROUND

HIV vulnerabilities among displaced and refugee adolescents are shaped by a complex

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The formative qualitative phase informed intervention design (edutainment comics, HIV self-testing) to ensure the study is tailored to youth in a humanitarian context.
- ⇒ Applying community-based research approaches in study design can improve the implementation and sustainability of HIV testing, prevention and care.
- ⇒ The study setting will allow for multiple interventions to be tested with sufficient sample size among youth living in a humanitarian context.
- ⇒ The primary study limitations are potential lost to follow-up.
- ⇒ Knowledge translation will be an important aspect of this study protocol, with implications for scaling-up HIV self-testing in humanitarian contexts.

interplay of factors including poverty, violence, host community HIV prevalence, HIV urbanisation, HIV testing and care access, and living conditions.^{1–3} There is a dearth of data on HIV rates among displaced persons and refugees, but globally in 2006 5.4% of people and 7.2% of children living with HIV were affected by conflict, humanitarian crises and/or displacement.¹ Displaced and refugee populations often do not have the same access to HIV testing and treatment as host populations, and therefore, the United Nations has prioritised refugees as a key population for HIV policy and programming in their 2022 report.² A systematic review of studies conducted among refugee, migrant and displaced girls and young women across the African continent reported limited knowledge regarding HIV and other sexually transmitted infections (STIs) among this population and that access and availability of

sexual health services is constrained by distance, costs and stigma.³

Uganda is the largest refugee hosting nation in Africa with over 1.4 million refugees in 2020, with more than 240 000 living in Bidi Bidi settlement near the South Sudan border.⁴ Youth represent 44.4% of all new HIV infections in Uganda, with most infections sexually transmitted.⁵ HIV prevalence among adolescents and young people in Uganda is 10.8% and is markedly higher among women (15.4%) compared with men (4.8%).⁶ Less is known of HIV prevalence, testing and prevention engagement among youth living in refugee settlements in Uganda, including in Bidi Bidi.⁷

There is limited inclusion of refugee adolescents and youth in sexual and reproductive health (SRH) research and programming^{8–10} that may result in a lack of age, gender, and culturally tailored programmes, which in turn may contribute to low engagement with HIV testing and prevention services in humanitarian contexts.¹¹ Studies conducted among urban refugee youth in Kampala, Uganda have found that inequitable gender norms and intersecting forms of stigma, including HIV-related stigma and refugee stigma, may also limit HIV testing and prevention engagement among refugee youth.^{12–15} Social network breakdown, poverty and travel distance to clinics, confidentiality concerns, language barriers and other logistic hurdles may also present obstacles to HIV testing.^{16 17}

HIV self-testing (HIVST) is a promising approach documented across systematic reviews to increase HIV testing access and uptake.^{18–20} This approach may mitigate confidentiality concerns, increase convenience and reduce the risk of stigmatisation, particularly important considerations for HIV testing with adolescents and youth.^{21–24} HIVST involves an individual collecting their own oral specimen, conducting the test and interpreting the results independently with support from pictorial and written instructions. There is also a dearth of information regarding advances in HIV testing, such as HIVST, among youth in humanitarian contexts,²⁵ including countries with a high HIV prevalence and large number of refugees such as Uganda.

There remain gaps in linkage to care following a positive HIV self-test when compared with standard HIV testing services, and addressing these gaps requires innovative approaches.²⁶ Innovative approaches will often be population-specific and community-driven, repurposing tools that are used in other fields of work. Comics—a form of graphic medicine—integrate text and visual images and are a promising health promotion tool used to address a variety of health conditions such as HIV, STIs, vaccines and dementia.^{27–32} Edutainment comics have been used to educate both the general population and healthcare providers.^{33 34} Comics align with the entertainment-education (‘edutainment’) approach to improve health knowledge, attitudes and practices applied in HIV prevention research.^{35 36} In the field of HIV, comics have been used in an HIV adherence intervention in the USA, PrEP

research, as well as in HIV education in schools in Kenya that improved students’ knowledge about HIV, reduced stigma towards people living with HIV, and increased likelihood and intention of testing.^{37–39} Among refugees, comics have been used in mental health research in Greece and Lebanon.^{40 41} We did not locate research using comics focused on HIV testing interventions at large, or with refugees on HIV research.

This cluster randomised trial, *Todurujo na Kadurok* (loosely translated to ‘Empowering Youth’ in Bari), aims to conduct an HIVST and edutainment comic intervention and evaluate its effectiveness in increasing HIV testing and HIV status knowledge among refugee youth in Bidi Bidi refugee settlement, Uganda. The comic intervention will be theoretically informed by the HIV prevention cascade^{42–44} to address gaps in motivation, access and effective use identified in formative research. Study findings can inform local and global responses to increase HIV testing engagement with youth in humanitarian contexts.

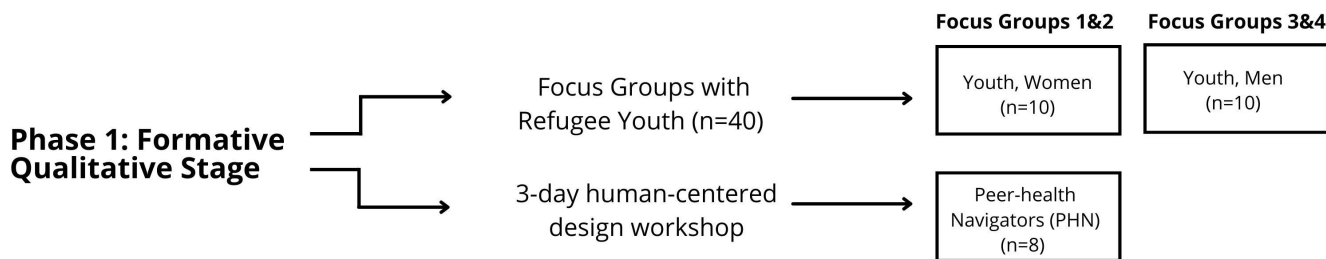
METHODS

Study aims and objectives

The overarching study goal is to evaluate the effectiveness of HIVST, edutainment comic or a combination of both interventions on increasing HIV testing, HIV status knowledge and linkage to confirmatory testing and care among refugee youth aged 16–24 years living in Bidi Bidi refugee settlement, Uganda. The primary objectives are to evaluate the effectiveness of the interventions on participants (1) HIV status knowledge and (2) HIV testing frequency. Secondary objectives include examining the impact of the intervention on: (1) HIVST kit use, (2) linkage to confirmatory HIV testing for those testing positive on the HIVST and (3) linkage to HIV care for those testing positive, (4) HIV-related stigma, (5) adolescent sexual and reproductive health stigma, (6) HIV knowledge, (7) safer sex efficacy, (8) condom use, (9) sexual relationship power (SRP) and (10) access to other SRH services (eg, contraception, postexposure prophylaxis).

Study design

We are conducting a cluster randomised trial using a 2×2 factorial design (see [figure 1](#)).⁴⁵ This approach will specifically test the effectiveness of offering: (1) HIVST alongside the edutainment comic, (2) HIVST alone, (3) edutainment comic alone and (4) standard of care, on defined primary and secondary outcomes. Factorial designs are an appropriate and efficient approach to understand synergies between interventions. As HIVST is an established testing approach that is feasible and acceptable,^{26 45–47} we are particularly interested to see if the benefits of HIVST with youth in a humanitarian context are increased with accompanying edutainment comics that are theoretically designed to address barriers to testing and care across the HIV cascade. This design can help with identifying effective strategies to reach study aims and in turn can



Comic Book Development Using HIV Prevention Cascade*

Motivation

Knowledge

- Awareness of HIV
- Misinformation that can be corrected

Example: Youth acknowledges that HIV no longer means a death sentence, despite popular beliefs.

Risk Perception

- Who is at risk for HIV

Example: Youth discussing that anyone can be at risk for HIV.

Consequences of Use

- Negatives associated with testing
- Positives associated with testing

Example: Youth notes that self-testing can lead to early access to care and confidential results.

Social Norms

- Fear of Social Rejection
- Fear of Violence upon Results

Example: Youth acknowledge stigma associated with HIV testing

Access

Availability

- Where can individuals get HIV testing

Example: Outreach explains to youth that self-testing increases availability.

Acceptable Provision

- What do individuals think of HIV self-testing

Example: Youth notes barriers for existing HIV testing

Affordability

- How can individuals travel to clinics
- Are services free?

Example: Depicting perceived barriers to receiving health care.

Effective Use

Skills

- How does self-testing work and next steps.

Example: Health care provider providing a step-by-step guide for self-testing.

Self-Efficacy

- Do individuals know how to use testing kits

Example: Youth feeling empowered in their ability to take their health into their own hands.

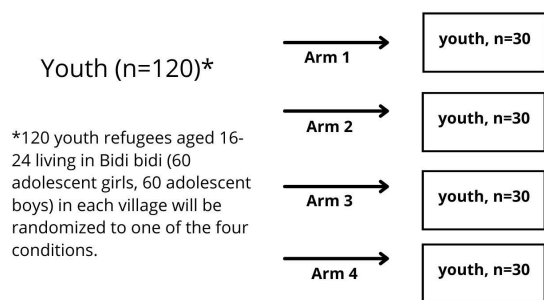
Partner

- Decision-making around partner HIV testing

Example: A woman discusses the potential of self-testing in an abusive relationship

*HIV Prevention Cascade based on Moorehouse L, Schaefer R, Thomas R, et al. Application of the HIV prevention cascade to identify, develop and evaluate interventions to improve use of prevention methods: examples from a study in East Zimbabwe, 2019.

Phase 2: Cluster-randomized Study



*120 youth refugees aged 16-24 living in Bidi bidi (60 adolescent girls, 60 adolescent boys) in each village will be randomized to one of the four conditions.

		HIV SELF-TESTING APPROACH	
		YES	NO
EDUTAINMENT COMIC	YES	Arm 1: HIV self-testing + edutainment comic	Arm 3: Edutainment comic alone
	NO	Arm 2: HIV self-testing alone	Arm 4: Standard of care

All arms will have linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

Figure 1 Flow chart of study phases and participant involvement. URDMC, Uganda Refugee and Disaster Management Council.

inform intervention design to include the most effective components.⁴⁸ Study design and research implementation was in collaboration between the University of Toronto and Uganda Refugee and Disaster Management

Council (URDMC), a refugee agency based in Bidi Bidi. Data will be collected from all participants directly before providing the intervention (baseline: time 1), and again at 3-month follow-up (time 2).

Study setting

This trial will be conducted in four villages located in two zones in Bidi Bidi Refugee Settlement within the Yumbe district in Northwestern Uganda. With over 245 000 refugees largely (99.9%) from South Sudan, Bidi Bidi is the world's second-largest refugee settlement with one-quarter of the population (25%; n=61 036) youth aged 15–24 years.⁴⁹ In Bidi Bidi, health centres offer free regular testing for HIV and comprehensive HIV care services including adult and paediatric antiretroviral therapy (ART) and cotrimoxazole prophylaxis. However, only a few facilities in the settlement offer comprehensive HIV care such as Prevention of Mother to Child Transmission services. Moreover, there are reported challenges including lack of facility accreditation to offer HIV care, drug and test kits stock out and poor adherence to ART by the refugees.^{50 51}

The clinical trial study setting includes two villages in zone 3, with more than 58 000 residents, and two villages in zone 4 annex, with more than 52 000 residents.⁴⁹ To ensure anonymity of participants, the village numbers are not included in this protocol. The zones and villages were selected due to large geographical separation to avoid contamination of intervention arms, eagerness of youth in these areas to learn more about HIV testing, and to fill a void of HIV research in these particular areas. In zone 3, there are the following participating health centres: Jomorogo Health Centre 3, Kongbe Health Centre 3, Yoyo Health Centre 3, Luzira Health Centre 3. In zone 4 annex the following health centres will participate: Igamara Health Centre 3, Bolomoni Health Centre 3, Bangatuti Health Centre and Kulikulunga Government Centre. All participants will be able to access these health centres throughout the study for HIV testing and treatment.

Participants and recruitment

We will use convenience sampling methods, including peer driven recruitment supported by collaborators at URDMC and eight peer navigators. Peer navigators are self-identified young refugees aged 20–24 years living in Bidi Bidi, specifically zone 3 and zone 4 annex, who received training from the study team in research methods and confidentiality and are supervised by URDMC. Inclusion criteria for participants in the Todurujo na Kadurok study include: (1) living in one of the four selected villages in zone 3 and zone 4 annex in Bidi Bidi; (2) identifying as a refugee or displaced person; (3) aged 16–24 years; and (4) speaking and reading one of the study languages (English, Bari, Juba Arabic).

For the cluster randomised controlled trial, participants will be randomised by the village they live in. URDMC and peer navigators will recruit a total of 120 participants, with 30 participants in each of the four arms. The arms will be geographically separated into four different villages from two zones to avoid contamination of the intervention effects. The villages will be randomly assigned to a study arm. Youth will be approached by peer navigators and study staff at URDMC to be recruited to

the study. At the baseline visit (time 1) the youth will be provided a written consent form, which will be available in English, Bari and Juba Arabic. Once the youth have provided informed written consent they will be enrolled into the study, assigned to a study arm based on the village that they live in, and baseline data will be collected by a URDMC research assistant. Peer navigators will use multiple study reminder strategies (eg, texts, private messages over social media) to maintain engagement until the follow-up visit at 3 months after enrolment. These efforts will be supplemented with existing outreach services to youth by URDMC.

Patient and public involvement

This study protocol was developed after a formative qualitative research phase. As depicted in [figure 1](#), this formative research in phase I included four focus groups conducted by two URDMC research assistants (two with young women, two with young men) with refugee youth in Bidi Bidi (n=10 in each focus group; n=40 in total) aged 16–24 years to collect information on knowledge of current HIV testing opportunities and experiences in Bidi Bidi and perspectives on HIVST. HIV prevention cascade conceptual frameworks were used by analysts at the University of Toronto in the analysis of the qualitative data to inform the study to address gaps in linkage to care following HIVST.^{42 43} Three key domains of the HIV prevention cascade include motivation, access and effective use, and these dimensions can be tailored to identify population specific needs.^{43 44} For instance, Moorhouse *et al*⁴² applied the HIV prevention cascade framework to develop community-based HIV prevention interventions and noted dimensions of motivation (knowledge, risk perception, consequence of use, social norms), access (availability, acceptable provision, affordability) and effective use (skills, self-efficacy, partner). The qualitative findings were used to identify key themes for the development of the edutainment comics (see [table 1](#)), in this way the study responds to the health needs and priorities of refugee youth in this humanitarian context.

These focus groups were followed by a 3-day human-centred design workshop led by URDMC research managers who engaged eight peer navigators to adapt and develop HIVST edutainment materials to enhance cultural, gender, age and contextual relevance (see [figure 1](#)). The study was designed and will be conducted as a collaboration with local physicians, clinics and the implementing partner is a refugee agency based in Bidi Bidi. These study collaborators have been involved since the study inception and will lead implementation. Peer navigators (n=8) who share the participants' refugee lived experiences, and include youth living with HIV, have meaningfully contributed to the study design through the human centred design workshops, feedback into edutainment comic development, pilot testing of study tools and will support implementation of the cluster randomised controlled trial through actively contributing to participant recruitment, engagement and retention.

Table 1 Scenarios on the HIV prevention cascade included in the edutainment comic

Domain of prevention cascade	Stage of the prevention cascade	Description
Motivation	Risk perception	Discussion explores perceived risk for HIV and (A) misinformation (eg, sharing body lotion is not as an HIV risk factor) and (B) provides information about condom breakage and postexposure prophylaxis.
	Consequence of use	Discussion between healthcare provider and youth of how to manage a positive HIV test result, including the ability to manage confidentiality and access support services.
	Social norms	Discussion of experiences of HIV stigma and discrimination, as well as an example of receiving support from a friend.
	Knowledge	Discussion of knowledge as power, including benefits of knowing one's HIV positive and HIV negative serostatus.
Access	Access and availability	Parallel conversations between youth around testing barriers, including travel costs and stockouts of HIV testing kits, with a discussion of locations for testing and support in Bidi Bidi.
	Acceptable provision	Discussions of (A) the possibility of receiving an HIV test while accessing other health services such as contraception and condoms; (B) accessing HIV testing from a healthcare provider of a different gender; (C) feeling empowered to find a doctor one feels comfortable talking with about sexual health
Effective use	Partner	Discussion of HIV testing with partner to assess partner perspectives on HIV testing and evaluate concerns (eg, negative partner reaction, violence, consequence of positive test result). Healthcare provider discussion of partner testing with a couple, including possible sero-discordant results. Decision-making considerations for engaging in partner testing, including motivations (empowerment, support, open communication, stronger relationship) and barriers (loss of trust, violence, conflict, break up).
	Skills	Discussion of disclosure process and decision making regarding who to disclose an HIV positive test result with.
	Self-efficacy	Discussion of how knowledge of HIV testing benefits, HIV positive serostatus and available resources increase empowerment to take care of oneself and support others.

Intervention description

Todurujo na Kadurok is a 2×2 factorial cluster randomised trial, with clusters randomised to one of the following four arms: (1) HIVST and edutainment comic, (2) HIVST only, (3) edutainment comic only and (4) standard of care.

Participants in the HIVST arms (arm 1; arm 2) will each receive two HIVST kits (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) at baseline along with verbal, written and visual instructions (in their choice of study language), as well as linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

Participants in the edutainment comic arms (arm 1; arm 3) will receive a hard copy of the edutainment comic at baseline. They will meet with the peer navigator to review and discuss the comic themes and will be provided with a blank version to complete on their own. This approach to edutainment comics provides a participatory component whereby participants can contextualise the comic themes within their own lives and experiences.⁵² In addition to the comic, the participants in arms 1 and 3 will also have linkages to peer navigators and URDMC for support accessing confirmatory testing and care.

Participants in the standard of care arm (arm 4) will receive verbal and written information and resources about HIV testing, care and support services in Bidi Bidi and Yumbe Hospital from their peer navigator as well as contact information for URDMC and an overview of

their programmes offered. The existing standard of HIV care in Bidi Bidi is offered through clinics located in Bidi Bidi settlement and the hospital in Yumbe and includes pretest and post-test counselling for HIV, follow-up visits for HIV care in the community, intensive treatment adherence counselling for immunosuppressed and non-immunosuppressed patients in the community and facility, and community drug refills for people living with HIV.

Outcomes

The primary outcomes measured in this trial will be:

1. Changes in HIV testing frequency: This is measured as participants' self-reported last HIV test. To capture changes, this measure is assessed at both study time points (baseline (time 1), 3 months (time 2)).
2. Changes in HIV status knowledge: At the final 3-month visit, a clinician supported by trained peer navigators will offer all participants a completely voluntary rapid point-of-care HIV test (Alere Determine HIV-1/2) to measure HIV status knowledge. HIV status knowledge will be assessed as correct for participants that agree to take the rapid test and correctly report their HIV status before receiving the result.

The secondary outcomes include:

1. Changes in linkage to confirmatory HIV testing: Participants in arm 1 and arm 2 (eg, those given an HIVST) will be asked at time 2 if they used their HIV self-test kit. All participants who report using the test

will be asked the result, and participants who self-report a positive result will be asked if they received confirmatory testing, and if so, where they received the test. Participants will also be provided study coupons (with only the name of the UDRMC and their study ID#) that they can provide when receiving HIV or other SRH services at collaborating health clinics; this clinic engagement will be linked to the participant study ID#.

2. Changes in linkage to HIV care: At time 2, participants who seroconvert in the study will be asked if they received HIV care, including ART and counselling, since receiving an HIV-positive diagnosis.
3. HIV self-test kit use: In order to understand the use of HIV self-test kits and to reduce social desirability bias, 1 month after time 2 the participants in arm 1 and arm 2 will be asked if they have unused test kits. They will be informed this information is just to guide future trials.
4. HIV-related stigma assessed with 12-item short HIV stigma assessment⁵³, including vicarious and felt-normative HIV stigma dimensions through an internalised AIDS-related stigma scale from Kalichman *et al.*^{54 55}
5. HIV knowledge assessed with the HIV knowledge questionnaire by Carey and Schroder.⁵⁶
6. Safer sex efficacy using the Condom Use Self-Efficacy Scale.^{57 58}
7. Condom use in past 3 months (condom use at last sex; condom use at sex every time in last 3 months (dichotomous: yes/no)).
8. Adolescent SRH stigma, assessed with the Ugandan Adolescent SRH Stigma scale (Logie *et al.*) adapted from Hall *et al.*'s Adolescent SRH Stigma scale.⁵⁹
9. SRP using the Relationship Control Sub-Scale from the Sexual and Relationship Power Scale.⁶⁰
10. Access to other SRH services will be assessed by asking if the participants went to any health clinic/hospital or service provider in the past 3 months to access: condoms, lubricant, contraception, postexposure prophylaxis, pre-exposure prophylaxis, pregnancy test, sexual and gender-based violence information, STI testing or other services. Participants will be provided coupons with UDRMC logo and their study ID to bring to participating clinics when accessing services, so this variable will be assessed by self-report by the participant as well as by collecting study coupons that will be attached to a list of services accessed during the study time frame.

All participants, regardless of study arm, will receive an HIV self-test kit at the end of the study with accompanying instructions, information and resources to ensure the study arms without access to HIVST are made aware of this approach and can access its benefits.

Sample size and power

We will recruit 120 refugee youth aged 16–24 years living in Bidi Bidi (60 adolescent girls, 60 adolescent boys) in the

cluster randomised trial. The recruited youth will come from four villages in two zones (zone 3 and zone 4 annex) within Bidi Bidi, and each village will be randomised to a study arm such that all youth living in the village are clustered to receive the same intervention. Calculated using G*Power 3.1, a sample size of 105 is sufficient for multivariable regression analyses (effect size: 0.2, power: 0.95, number of tested predictors: 5, critical F: 2.306).⁶¹ To account for 15% attrition, we have selected a sample size of 120.

Data collection and management

For the cluster randomised trial, we will collect sociodemographic characteristics from participants at time 1, and exposures relevant to SRH and outcome data at both timepoints (time 1, time 2). Data will be collected using tablet-based structured surveys conducted by trained URDMC research assistants in all study languages. Data will be collected using SurveyCTO (Dobility, Cambridge, USA), which is a secure platform whereby data collected is automatically encrypted and uploaded to a password-protected server using a Secure Sockets Layer certificate. SurveyCTO allows for data to be collected offline and has branching logic, consistency checks, and facilitates multi-lingual data collection. No personal identifying information will be collected with the survey data, all participants will instead be given a unique participant ID to enhance confidentiality. Only study staff at URDMC and University of Toronto will have access to the dataset for the purpose of data management and outcome reporting, and all datasets will be saved on a password-protected server.

Data analysis

Analysis and reporting for the cluster randomised trial will be conducted in accordance with Consolidated Standards of Reporting Trials guidelines.⁶² The analyst at the University of Toronto will be blinded to group allocation. A flow diagram will be used to illustrate patient flow (consent/enrolment, randomisation, baseline and follow-up). Baseline data will be reported for all four arms and summarised as mean and SD or median and IQR for continuous variables and as number and percentage for categorical variables. The primary analysis will involve intention-to-treat analysis (data from participants will be analysed according to their allocation, irrespective of whether they received the intervention). Between-group comparisons will be performed using generalised estimating equations logistic or linear regression models—depending on which outcome is being evaluated—using unstructured correlation matrix and robust standard errors to account for clustering. For these models, the intervention effects across time (from baseline to 3-month follow-up) will be included as the main effects of intervention arm, time and an arm×time interaction. The level of significance will be set at alpha=0.05. The results will be expressed as ORs or mean differences as appropriate, accompanied by 95% CIs and p values. We will conduct an adjusted analysis for the primary outcome

(changes in HIV testing frequency, HIV self-test kit use, HIV status knowledge, changes to linkage to confirmatory HIV testing and to HIV care) to investigate the role of various covariates in the relative effect. Covariates, such as age and gender, will be entered as a block. We will explore gender differences in primary and secondary intervention outcomes. Given the outcomes of this study are related to behaviour change and the trial is of a short duration with minimal risks, a data monitoring committee was not deemed necessary.

DISCUSSION

This study approach has the potential to inform research, practice and policy surrounding measuring the efficacy of new programming and HIV testing. Study findings, therefore, have the potential to not only inform a larger, fully powered randomised controlled trial to test the effectiveness of an edutainment comic book HIVST intervention but can also inform policies on how strategies such as comic books can be integrated into school health curricula for HIV prevention. Our findings can also inform research, practice and policy on HIV among youth to better meet the needs of refugee adolescents and youth. An edutainment comic book intervention approach holds promise for meaningfully engaging youth and healthcare providers in humanitarian contexts in dialogue on HIV and STI prevention, care and support.

Strengths and limitations of this study

The Todurujo na Kadurok cluster randomised trial is unique in exploring HIVST feasibility and uptake among youth living in a large refugee settlement using innovative community-based health promotion activities. The study design will allow us to assess if HIVST alone, edutainment comics or HIVST alongside the edutainment comics increase HIV testing frequency and status knowledge compared with standard of care. By clustering the interventions to areas within Bidi Bidi Refugee Settlement we aim to mitigate threats to internal validity and contamination of the intervention effects.

The study is subject to limitations commonly incurred by prospective longitudinal studies—loss to follow-up and missing data. However, we will mitigate these limitations by using peer navigators to recruit and follow-up on participants in the community and also by using digital questionnaires on tablets that are programmed to flag missing data.

ETHICS AND DISSEMINATION

Ethical approval

Ethical approval for the study was provided through the Mildmay Uganda Research Ethics Committee (REC REF 0802-2021), UNCST (SS884ES) and the University of Toronto Research Ethics Board (37496). This trial is registered at ClinicalTrials.gov (#NCT05213689). The protocol for the study was developed in accordance with

the Standard Protocol Items: Recommendations for Interventional Trials Statement.^{63 64} To ensure the protection of human subjects, all participants in the formative phase and the cluster randomised controlled trial will be provided with enough time to provide written voluntary consent to participate in the study. All informed written consent processes will occur in a private room at a location provided by URDMC. The participant will read the consent form themselves or a peer navigator will read aloud the informed consent in a language comfortable to the participant (English, Bari or Juba Arabic) and will ask if the participant has any questions and will answer their questions. Participants will be asked to sign the consent form or provide a thumbprint to indicate their consent. The consent form will in no way be connected with focus group transcripts or data collected during the cluster randomised trial and will be destroyed 5 years after data collection is completed. As Uganda's HIV and AIDS Prevention and Control Act permits youth aged 12 years or above to independently access HIV testing and counselling without parental permission, we received ethics approval to allow youth aged 16–17 years to participate without parental consent; this is a common approach to reduce barriers to youth participation in SRH research.^{65–67}

Emotional risks include that participants may feel uncomfortable, anxious, or upset taking an HIV test, stigma due to accidental disclosure of HIV serostatus, psychosocial harm as a result of learning HIV status, discussing HIV, STI, sexual risk factors and social capital. The study has been designed to minimise psychological/emotional risks of feeling uncomfortable, anxious, or upset with study questions and topics of discussion through wellbeing-focussed training for data collectors. URDMC will also collaborate with a local psychological and mental health support organisation to support peer navigators and participants during any mental distress. Moreover, we will ensure the confidentiality of all participants by not collecting identifying information (ie, no full names, no date of birth).

Dissemination plan

We will employ participatory methods for knowledge dissemination, working with youth peer navigators to develop strategies such as youth community forums and arts-based methods (eg, comic books) and brief videos. We will make findings available in English, Bari and Juba Arabic. Findings will be disseminated through a variety of methods including the preparation of community reports (disseminated to the Ugandan National AIDS Programme, UNHCR, Ministry of Health and our collaborators (eg, URDMC)) and peer-reviewed publications (eg, *Journal of the International AIDS Society*). 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.

Box 1 Items from the US National Institutes of Health Trial Registry

Data category information

Primary registry and trial identifying number: ClinicalTrials.gov NCT05213689.

Date of registration: 28 January 2022.

Source(s) of monetary support: ViiV Healthcare (Grant#628520-1652450711)

Primary sponsor: University of Toronto.

Primary sponsor: University of Toronto.

Contact for public and scientific queries: Carmen Logie, PhD (carmen.logie@utoronto.ca).

Public and scientific title: HIV Self-Testing and Comic Intervention with Refugee Adolescents and Youth.

Countries of recruitment: Uganda.

Health condition(s) or problem(s) studied: HIV testing, status knowledge, linkage to confirmatory and care.

Intervention(s): HIV self-testing kits and edutainment comic books.

Key inclusion criteria: living in one of the four selected villages in zone 3 and zone 4 annex in Bidi Bidi; identifying as a refugee or displaced person; aged 16–24 years; and speaking and reading one of the study languages (English, Bari, Juba Arabic).

Study type: interventional (clinical trial); cluster randomised control trial with four study arms.

Date of first enrolment: June 2022 (estimate)

Target sample size: 120.

Primary outcome(s): HIV testing frequency, HIV status knowledge, linkage to confirmatory HIV testing, linkage to HIV care, HIV self-test kit use.

Key secondary outcomes: HIV-related stigma, HIV knowledge, safer sex efficacy, condom-use, sexual and reproductive health (SRH) stigma, sexual relationship power and access to SRH services.

Trial status

The formative qualitative phase of the Todurujo na Kadurok (Empowering Youth) study was launched in September 2021. The study team has been trained and ethics approval obtained. All qualitative activities from phase 1 and the development of the comic book have been completed. We anticipate for the intervention to begin in late Fall 2022 along with baseline data collection, and the final follow-up survey to be conducted 3 months later in early 2023. Any important protocol modifications will be included as amendments in REB and updated on the ClinicalTrials.gov registry, as and when needed. **Box 1** details the information on the ClinicalTrials.gov registry.

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REFERENCES

- 1 Spiegel PB, Bennedsen AR, Claass J. Prevalence of HIV infection in conflict-affected and displaced people in seven sub-Saharan African countries: a systematic review [Internet]. Vol. 369, 2007. Available: www.thelancet.com
- 2 Mafigiri R, Matovu JKB, Makumbi FE, *et al.* HIV prevalence and uptake of HIV/AIDS services among Youths (15–24 years) in fishing and neighboring communities of Kasensero, Rakai district, South Western Uganda. *BMC Public Health* 2017;17:251.
- 3 Logie C, Okumu M, Hakiza R, *et al.* 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). *JMIR Res Protoc* 2021;10:e26192.
- 4 Refugee Statistics February 2022 - Bidibidi [Internet]. [cited 2022 May 26], 2022. Available: <https://data2.unhcr.org/en/documents/details/91322>
- 5 Presidential Fast-Track Initiative On Ending HIV & AIDS In Uganda. Kampala 2017.
- 6 Nanyonjo G, Asiki G, Ssetaala A, *et al.* Prevalence and correlates of HIV infection among adolescents and young people living in fishing populations along lake Victoria fishing communities in Uganda. *Pan Afr Med J* 2020;37:1–12.
- 7 O'Laughlin KN, Rouhani SA, Faustin ZM. Testing experiences of HIV positive refugees in Nakivale refugee settlement in Uganda: informing interventions to encourage priority shifting. *Conflict and Health* 2013;7:1–9.
- 8 Jennings L, George AS, Jacobs T, *et al.* A forgotten group during humanitarian crises: a systematic review of sexual and reproductive health interventions for young people including adolescents in humanitarian settings. *Confl Health* 2019;13:57.
- 9 Singh NS, Smith J, Aryasinghe S, *et al.* Evaluating the effectiveness of sexual and reproductive health services during humanitarian crises: a systematic review. *PLoS One* 2018;13:e0199300.
- 10 Singh NS, Aryasinghe S, Smith J, *et al.* A long way to go: a systematic review to assess the utilisation of sexual and reproductive

- health services during humanitarian crises. *BMJ Glob Health* 2018;3:e000682.
- 11 Liebling H, Barrett H, Artz L. South Sudanese refugee survivors of sexual and gender-based violence and torture: health and justice service responses in northern Uganda. *Int J Environ Res Public Health* 2020;17. doi:10.3390/ijerph17051685. [Epub ahead of print: 05 03 2020].
 - 12 Warren E, Post N, Hossain M, et al. Systematic review of the evidence on the effectiveness of sexual and reproductive health interventions in humanitarian crises. *BMJ Open* 2015;5:e008226. doi:10.1136/bmjopen-2015-008226
 - 13 Logie CH, Okumu M, Kibuuka Musoke D, et al. Intersecting stigma and HIV testing practices among urban refugee adolescents and youth in Kampala, Uganda: qualitative findings. *J Int AIDS Soc* 2021;24:e25674.
 - 14 Logie CH, Okumu M, Berry I, et al. Social contextual factors associated with lifetime HIV testing among the Tushirikiane urban refugee youth cohort in Kampala, Uganda: cross-sectional findings. *Int J STD AIDS* 2022;33:374–84.
 - 15 Logie CH, Okumu M, Mwima SP, et al. Exploring associations between adolescent sexual and reproductive health stigma and HIV testing awareness and uptake among urban refugee and displaced youth in Kampala, Uganda. *Sex Reprod Health Matters* 2019;27:86–106.
 - 16 Hlongwa M, Mashamba-Thompson T, Makhunga S, et al. Barriers to HIV testing uptake among men in sub-Saharan Africa: a scoping review. *Afr J AIDS Res* 2020;19:13–23.
 - 17 Logie CH, Okumu M, Kibuuka Musoke D, et al. The role of context in shaping HIV testing and prevention engagement among urban refugee and displaced adolescents and youth in Kampala, Uganda: findings from a qualitative study. *Trop Med Int Health* 2021;26:572–81.
 - 18 Witzel TC, Eshun-Wilson I, Jamil MS, et al. Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis. *BMC Med* 2020;18:381.
 - 19 Qin Y, Han L, Babbitt A. Experiences using and organizing HIV Self-Testing: a global qualitative systematic review. *AIDS* 2018;32:371–81.
 - 20 Johnson CC, Kennedy C, Fonner V, et al. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. *J Int AIDS Soc* 2017;20:21594.
 - 21 Johnson C, Baggaley R, Forsythe S, et al. Realizing the potential for HIV self-testing. *AIDS Behav* 2014;18 Suppl 4:391–5.
 - 22 Choko AT, Nanfuka M, Birungi J, et al. A pilot trial of the peer-based distribution of HIV Self-Test kits among fishermen in Bulisa, Uganda. *PLoS One* 2018;13:e0208191.
 - 23 Smith P, Wallace M, Bekker L-G. Adolescents' experience of a rapid HIV self-testing device in youth-friendly clinic settings in Cape town South Africa: a cross-sectional community based usability study. *J Int AIDS Soc* 2016;19:21111.
 - 24 Hatzold K, Gudukeya S, Mutseta MN, et al. HIV self-testing: breaking the barriers to uptake of testing among men and adolescents in sub-Saharan Africa, experiences from STAR demonstration projects in Malawi, Zambia and Zimbabwe. *J Int AIDS Soc* 2019;22 Suppl 1:e25244–52.
 - 25 Logie CH, Khoshnood K, Okumu M, et al. Self care interventions could advance sexual and reproductive health in humanitarian settings. *BMJ* 2019;365:l1083.
 - 26 Johnson CC, Kennedy C, Fonner V, et al. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. *J Int AIDS Soc* 2017;20:21594.
 - 27 Greensides DR, Berkelman R, Lansky A, et al. Alternative HIV testing methods among populations at high risk for HIV infection. *Public Health Rep* 2003;118:531–9.
 - 28 Gillies PA, Stork A, Bretman M. Streetwise UK: a controlled trial of an AIDS education comic [Internet]. Vol. 5, Source: Health Education Research, 1990. Available: <https://about.jstor.org/terms>
 - 29 Gallagher-Thompson D, Tzuang M, Hinton L, et al. Effectiveness of a fotonovela for reducing depression and stress in Latino dementia family caregivers. *Alzheimer Dis Assoc Disord* 2015;29:146–53.
 - 30 Krasnoryadtseva A, Dalbeth N, Petrie KJ. The effect of different styles of medical illustration on information comprehension, the perception of educational material and illness beliefs. *Patient Educ Couns* 2020;103:556–62.
 - 31 Muzumdar JM, Pantaleo NL. Comics as a medium for providing information on adult immunizations. *J Health Commun* 2017;22:783–91.
 - 32 Celentano I, Winer RL, Jang SH, et al. Development of a theory-based HPV vaccine promotion comic book for East African adolescents in the US. *BMC Public Health* 2021;21:1137.
 - 33 Waite M. Writing medical comics. *J Vis Commun Med* 2019;42:144–50.
 - 34 Towe F. Comics and medicine. *Lancet Oncol* 2014;15:927–8.
 - 35 Orozco-Olvera V, Shen F, Cluver L. The effectiveness of using entertainment education narratives to promote safer sexual behaviors of youth: a meta-analysis, 1985–2017. *PLoS One* 2019;14:e0209969.
 - 36 Vaughan PW, Rogers EM, Singhal A, et al. Entertainment-education and HIV/AIDS prevention: a field experiment in Tanzania. *J Health Commun* 2000;5 Suppl:81–100.
 - 37 Ghose T, Shubert V, Poitevien V, et al. Effectiveness of a viral load suppression intervention for highly vulnerable people living with HIV. *AIDS Behav* 2019;23:2443–52.
 - 38 Kuhn A, Maatman T. Web Exclusive. Annals Graphic Medicine - Should I PrEP? Barriers to HIV-Related Preventive Care Faced by Black MSM. *Ann Intern Med* 2021;174:W37–44.
 - 39 Obare F, Birungi H, Deacon B, et al. Effectiveness of using comic books to communicate HIV and AIDS messages to in-school youth: insights from a pilot intervention study in Nairobi, Kenya. *African Population Studies* 2013;27:203.
 - 40 Moore T. Strengths-based narrative storytelling as therapeutic intervention for refugees in Greece. *World Federation of Occupational Therapists Bulletin* 2017;73:45–51.
 - 41 Bosqui T, Mayya A, Younes L, et al. Disseminating evidence-based research on mental health and coping to adolescents facing adversity in Lebanon: a pilot of a psychoeducational comic book 'Somoud'. *Confl Health* 2020;14:78.
 - 42 Moorhouse L, Schaefer R, Thomas R, et al. Application of the HIV prevention cascade to identify, develop and evaluate interventions to improve use of prevention methods: examples from a study in East Zimbabwe, 2019. Available: <http://onlinelibrary.wiley.com/doi/10.1002/jia2.25309/full>
 - 43 et alSchaefer R, Gregson S, Fearon E. HIV prevention cascades: a unifying framework to replicate the successes of treatment cascades [Internet]. Vol. 6, 2019. Available: www.thelancet.com/hiv
 - 44 HIV Prevention Cascades Stakeholder Consultation Meeting and Workshop Report on a consultation and workshop organised by the Manicaland Centre for Public Health Research* Biomedical Research and Training Institute Imperial College London * In association with UNAIDS, Zimbabwe Ministry of Health and Child Care, and Zimbabwe National AIDS Council; with funding from the Bill and Melinda Gates Foundation.
 - 45 Montgomery AA, Peters TJ, Little P. Design, analysis and presentation of factorial randomised controlled trials. *BMC Med Res Methodol* 2003;3:1–5.
 - 46 Witzel TC, Eshun-Wilson I, Jamil MS, et al. Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis. *BMC Med* 2020;18:1–13.
 - 47 Qin Y, Han L, Babbitt A, et al. Experiences using and organizing HIV self-testing. *AIDS* 2018;32:371–81.
 - 48 Watkins ER, Newbold A. Factorial designs help to understand how psychological therapy works. *Front Psychiatry* 2020;11:1–14.
 - 49 Uganda - Refugee Statistics January 2022. Bidi Bidi 2022.
 - 50 Nakanwagi M, Okethwangu D, Kwesiga B. Availability of HIV services in BidiBidi refugee settlement, October to March 2017. *UNIPH Bulletin Articles* 2021;2.
 - 51 Palattiyil G, Kisaakye P, Mwenyango H, et al. Access to HIV/AIDS or TB care among refugees in Kampala, Uganda: exploring the enablers and barriers during the COVID-19 pandemic. *J Migr Health* 2022;5:100098.
 - 52 Logie CH, Okumu M, Lukone SO, et al. Ngutulu Kagwero (agents of change): study design of a participatory comic pilot study on sexual violence prevention and post-rape clinical care with refugee youth in a humanitarian setting in Uganda. *Glob Health Action* 2021;14:1940763.
 - 53 Reinius M, Wettergren L, Wiklander M, et al. Development of a 12-Item short version of the HIV stigma scale. *Health Qual Life Outcomes* 2017;15:115.
 - 54 Kalichman SC, Simbayi LC, Cloete A, et al. Measuring AIDS stigmas in people living with HIV/AIDS: the internalized AIDS-related stigma scale. *AIDS Care* 2009;21:87–93.
 - 55 Pantelic M, Steinert JI, Park J, et al. 'Management of a spoiled identity': systematic review of interventions to address self-stigma among people living with and affected by HIV. *BMJ Glob Health* 2019;4:e001285.
 - 56 Carey MP, Schroder KEE. Development and psychometric evaluation of the brief HIV knowledge questionnaire. *AIDS Educ Prev* 2002;14:172–82.
 - 57 Shaweno D, Tekletsadiq E. Validation of the condom use self-efficacy scale in Ethiopia. *BMC Int Health Hum Rights* 2013;13:1–8.
 - 58 Brafford LJ, Beck KH. Development and validation of a condom self-efficacy scale for college students. *J Am Coll Health* 1991;39:219–25.



- 59 Hall KS, Manu A, Morhe E, *et al.* Development and validation of a scale to measure adolescent sexual and reproductive health stigma: results from young women in Ghana. *J Sex Res* 2018;55:60–72.
- 60 Pulerwitz J, Gortmaker SL, DeJong W. Measuring sexual relationship power in HIV/STD research. *Sex Roles* 2000;42:637–60.
- 61 Faul F, Erdfelder E, Lang A-G, *et al.* G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39:175–91.
- 62 Smith BA, Lee H-J, Lee JH, *et al.* Quality of reporting randomized controlled trials (RCTs) in the nursing literature: application of the consolidated standards of reporting trials (consort). *Nurs Outlook* 2008;56:31–7.
- 63 Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al.* Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.
- 64 Chan A-W, Tetzlaff JM, Altman DG, *et al.* Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
- 65 Flicker S, Guta A. Ethical approaches to adolescent participation in sexual health research. *J Adolesc Health* 2008;42:3–10.
- 66 Nakalega R, Akello C, Gati B, *et al.* Ethical considerations for involving adolescents in biomedical HIV prevention research. *BMC Med Ethics* 2021;22:127.
- 67 Day S, Kapogiannis BG, Shah SK, *et al.* Adolescent participation in HIV research: Consortium experience in low and middle-income countries and scoping review. *Lancet HIV* 2020;7:e844–52.