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Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Abstract

Introduction: Research with urban refugee youth in Uganda has documented co-occurring social (e.g., poverty) and health (e.g., depression) disparities associated with HIV vulnerabilities. Benefits of HIV self-testing (HIVST) in increasing HIV testing uptake among youth are well established, yet limited interventions have examined if combining HIVST with mental health promotion, or with mental health promotion alongside poverty reduction, is associated with greater improvements in HIV prevention and testing outcomes.

Objective: The aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) mobile health (mHealth) and graphic medicine (comic) program for mental health alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mHealth mental health program, in advancing the primary outcome of HIV testing uptake and secondary outcomes (HIV status knowledge, linkage to confirmatory testing and HIV care, HIV knowledge, consistent condom use, condom use self-efficacy, transactional sex) with urban refugee youth in Kampala, Uganda.

Methods: A three-arm randomized controlled trial will be implemented from 08/04/2024- 31/10/2024 with youth across five informal settlements in Kampala, grouped into three sites based on proximity, and randomized in a 1:1:1 design. Approximately 330 participants (110 per arm) are enrolled and data collection will occur at three time points (baseline enrollment, 3-month follow-up, 6-month follow-up).

Results: The study will be conducted in accordance with CONSORT guidelines. The study received ethical approval from the University of Toronto (#37496), Mildmay Uganda Research Ethics Committee (#MUREC-2021-41), and Uganda National Council for Science & Technology (#SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160).

Conclusions: Study findings will produce new knowledge of the impacts of a mental health program, and a combined mental health and livelihoods program, on improving HIV prevention outcomes among urban refugee youth in Kampala. Findings will be shared in peer-reviewed publications, conference presentations, and in community dissemination.

Trial registration: ClinicalTrials.gov: NCT06270160 (Date of registration: 02/13/2024)
Trial Sponsor: Dr. Carmen Logie, carmen.logie@utoronto.ca

Strengths and limitations:

- This trial will compare offering a mHealth delivered mental health program on its own vs. combined with a livelihoods program on HIV testing outcomes among urban refugee youth in Kampala.
- Addressing poverty and mental health challenges alongside HIV self-testing with urban refugee youth is innovative and can advance syndemics-informed programming.
- Conducting gender- and age-stratified analyses will provide insight into gender and/or age differences in intervention effectiveness.
- Study limitations may include attrition and potential loss to follow-up.

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Introduction

By mid 2023, there were 110 million persons forcibly displaced globally, three-quarters hosted in low and middle-income countries (LMIC)(1). Displaced persons experience HIV vulnerabilities that span social-ecological levels. For instance, structural-level factors include underfunded health systems in humanitarian settings and poverty-related barriers to accessing healthcare; community-level factors include intersecting stigma (e.g., refugee stigma, HIV stigma), sexual violence, and inequitable gender norms; and individual-level factors include disruption of family structures, mental health challenges, and transactional sex for survival needs (2–8). Knowledge gaps persist regarding efficacious approaches to increase HIV prevention and care cascades with forcibly displaced persons in LMIC, reflecting that "displaced populations are being neglected in efforts to end the AIDS epidemic" (p. 5) (8).

Uganda is relevant context to address these knowledge gaps and identify targeted needs for HIV prevention, testing and care. Uganda hosts over 1.5 million refugees, over 100,000 of whom live in the urban centre of Kampala (9), often in slums or informal settlements (9–13). While HIV prevalence and testing engagement among Uganda's refugees is uncertain due to the lack of standardized surveillance of refugees (14), a 2017 study (15) in Nakivale refugee settlement in western Uganda reported an HIV prevalence of 4% among refugee adults, of whom only 54% were linked to HIV care and 6% initiated antiretroviral treatment (ART). These rates fall far below the UNAIDS goals of 95% of PLHIV receiving ART by 2030, respectively (16), signaling the need for further attention to HIV care engagement among refugees.

HIV self-testing is a promising youth-friendly strategy for increasing HIV testing uptake with youth in diverse African countries, including Zimbabwe (17), South Africa (18), and Uganda (19). Innovative HIVST delivery strategies offer promise in linking persons with positive HIVST results to confirmatory testing and HIV care (20). As such, identifying strategies to promote linkage to HIV care is essential to realize the public health impact of HIVST (21). An HIVST study in 14 communities (n=14,004) in Malawi reported that HIVST uptake among adolescent girls aged 16-19 was 100%, yet only 56%(27) of people testing positive were linked to HIV care, which is far below the UNAIDS goal of 90% and 95% of PLHIV receiving ART (16,22,23). A 2014 systematic review reported a dearth of evidence-based strategies for linkage to HIV care with adolescents, highlighting the need for research focused in this age group (24). An HIVST trial with refugee youth in Kampala found increased uptake of HIV-testing and HIV status knowledge among participants in the HIVST arm (vs. standard of care), and in the study arm where HIVST was combined with mHealth support, there were further benefits in reduced adolescent sexual and reproductive health stigma (25).

Refugee youth in Kampala's urban informal settlements are at the nexus of health and social vulnerabilities experienced by youth in Uganda and youth living in Kampala's informal settlements. For instance, as of March 2021, the HIV prevalence among Ugandan youth aged 15-24 years was estimated at ~2% (26). The HIV prevalence among youth living in Kampala's slums and informal settlements may higher than the national prevalence, with estimates of 13.9-37.2% (27–29). This high prevalence may be driven by food insecurity, poverty, stigma, and inequitable gender norms, which may affect many residents in slum settings (30,31). These interlinked factors can increase HIV vulnerabilities through complex pathways, including limiting safer sex negotiation, increasing transactional sex, and constraining youth engagement with HIV prevention services (27,32). For instance, research with urban refugee youth in Kampala identified associations between mental health challenges (frequent alcohol use, depression), violence (intimate partner violence, violence in young adulthood), and HIV vulnerabilities (multiple sex partners, transactional sex) that reflect a syndemic

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(33). Syndemics refer to interactions between social inequities (e.g., poverty, violence) and health inequities (34,35). The poverty rate among refugees in Uganda worsened during COVID-19 from 44% to 50%, and employment dropped from 43% to 32%, and it is projected that recovery from the economic impacts of COVID-19 may be slower for refugees compared with Ugandan nationals (36). Other studies among urban refugee youth in Kampala have noted associations between poverty indicators and poorer health outcomes, including: food insecurity and poorer mental health (37); unemployment and reduced HIV testing uptake (38); and resource insecurity (food/water insecurity) and reduced sexual and reproductive health access (including HIV and STI testing) (39) and transactional sex (39,40). Multi-level approaches that jointly address this convergence of poverty, mental health and HIV vulnerabilities thus offer promise to address co-occurring social and health challenges yet are understudied with urban refugee youth in low-and middle-income income settings such as Uganda.

There are persistent knowledge gaps regarding integrating mental health and poverty reduction in HIV testing and prevention with urban refugee youth in LMIC such as Uganda. The study aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) an evidence-based mental health program delivered using mobile health (mHealth) and graphic medicine (comic) alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mental health program, in advancing HIV prevention outcomes, including increasing routine HIV testing, HIV status knowledge, and linkage to confirmatory testing and HIV care.

Methods and Analysis

Study Design

We will conduct a three-arm randomized controlled trial (RCT) to evaluate the effectiveness of HIVST delivery methods alone and combined with a mental health program, and mental health and livelihoods programs, among refugee youth living in Kampala (41) (**Figure 1**). Five informal settlements in Kampala where most urban refugees reside will be randomized in a 1:1:1 approach to one of the three study arms: 1) HIV self-testing; 2) HIV self-testing alongside a mental health program; and 3) HIV self-testing, a mental health program, and a livelihoods program (interventions described in-depth below). Refugee youth (aged 18-24 years) living in the same informal settlements who are trained in research methods and ethics will act as peer navigators and enroll other youth in the study after obtaining written informed consent. Participants will be randomly allocated to a study arm based on their informal settlement of residence. Youth living in slums and informal settlements have shared socio-physical environments (41). As such, except for individual-level outcome data, we will use a cluster approach to analyses and program delivery to limit challenges posed by experimental contamination and threats to internal validity. Data collection will be performed at baseline, and 3- and 6-months post-intervention implementation. The clusters will be numbered 1, 2 and 3. We will use a computer-generated randomization list created by a trained research assistant to allocate the cluster to intervention. The number of the clusters and the randomization list will be kept separate until it is time to implement the interventions. The trained study coordinators (FA, BK) will generate the allocation sequence, enroll participants, and assign participants to interventions.

Insert Figure 1

Study Setting

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We are conducting this RCT in five informal settlements in Kampala, Uganda. Settlements will be grouped into three arms based on close geographic proximity (1: Kabalagala and Kansanga, 2: Katwe and Nsambya, and 3: Rubaga), a strategy successfully used in prior interventions with this study population (25). We used the following criteria to select informal settlements: 1) settlements that host a large number of refugees or displaced persons (11–13,42), 2) communities with similar measures of socioeconomic status, healthcare access, languages, and living conditions; and 3) evidence of a high prevalence of depressive symptoms among urban refugee youth (37,43). We have previously published details on trial site location, population, and geography (44).

Study Population and Eligibility Criteria

We will use an existing cohort of approximately 330 (110 participants/cluster) youth aged 16-25. Cohort eligibility includes those: 1) currently living in one of the five selected Kampala informal settlements (Kabalagala, Kansanga, Katwe, Nsambya, or Rubaga); 2) who identify as a displaced person, refugee, or as having a refugee or displaced parent(s); 3) aged 16-25 years; 4) who own or have daily access to a mobile phone; 5) who speak French, English, Kirundi, Kinyarwanda, or Swahili. Participants were screened for eligibility (via phone, in person, or WhatsApp) by trained peer navigators.

Participant Recruitment and Retention

The project team includes academics, practitioners, Ugandan Ministry of Health stakeholders, and a nongovernmental organization with expertise in refugee youth community engagement. Participant recruitment, study design, and pilot testing will be facilitated by peer navigators, study coordinators, and implementing partners. Peer navigators (12: 6 young women, 6 young men) are all experienced health/peer educators within study communities and were identified and recruited by community-based collaborators for being respected and involved within their communities.

We employed purposive methods to recruit participants, such as word-of-mouth and venue-based sampling at community events and refugee agencies, beginning with participants who belonged to the Tushirkiane cohort and participated in previous trials on HIVST (44), COVID-19 prevention (45), and mental health interventions (41). We will refresh the cohort with additional purposive recruitment of 16- and 17-year-old participants.

Patient and Public Involvement in Research

This community-based study is a collaboration with Young African Refugees for Integral Development (YARID), a nongovernmental youth refugee organization in Kampala, who have been involved since the initial research question and focus development stage. We developed the study protocol after a formative qualitative research phase (Phase 1), which included semi-structured interviews with peer navigators and other key informants (e.g., refugee health professionals, migrant workers, teen mothers). We completed four focus group discussions stratified by age and gender to explore refugee youth perspectives on livelihood and mental health to identify key themes and prioritize the health needs of urban refugee youth.

Intervention Description

We designed a RCT consisting of three-arms: 1) HIVST, 2) HIVST + mHealth (bidirectional SMS), 3) HIVST + mHealth + creating futures. Data will be collected at baseline, and 3- and 6-months post-

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intervention implementation. All study arms will receive HIVST kits at each data collection timepoint. All participants will meet with trained research assistants at the three time points. Unique study identification (ID) numbers on coupons will be used to track HIV testing access and linkage to HIV and sexual and reproductive health services care. If a participant requests, they can discontinue the allocated intervention.

Arm 1: HIV self-testing (HIVST): Participants will be provided with HIVST instructions and education from peer navigators, who will also emphasize the importance of receiving a confirmatory test irrespective of HIV positive result. At each timepoint, participants will receive an HIVST package (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) with written and pictorial instructions and a referral sheet for confirmatory testing. Peer navigators will demonstrate how to use the HIVST kit, including how to 1) open the kit, 2) collect the oral fluid samples, and 3) read the results. In addition to HIVST education, participants will be offered optional pre-test counselling and SMS contact information to connect with their peer navigator. If participants do not want post-test counselling, the PN will follow up within two weeks. If the participants report testing HIV positive, then they will be immediately scheduled for confirmatory testing and enrolled in the support programs at the Uganda Ministry of Health Most at Risk Population Initiative (MARPI) Clinic for young people living with HIV led by study co-applicant and co-author (PK).

Arm 2: HIVST and mental health program: Participants in this arm will be enrolled into the HIVST intervention (as described above in Arm 1) as well as a mental health program delivered using mobile health (mHealth) and participatory comics. We will adapt and implement, using mHealth and participatory comic approaches detailed below, the World Health Organization (WHO) Program Management Plus (PM+) scalable, low-intensity brief psychological intervention that is transdiagnostic and developed for delivery by lay persons to address a range of common mental health challenges and adversities (46–49). PM+ has been adapted for delivery across settings (50), and during formative work for this specific intervention the study team adapted PM+ materials into all languages for delivery, and worked with the Peer Navigators to produce key messages from PM+ for delivery by mHealth and participatory comics (below). The four key strategies shared during PM+ are: stress management, problem solving, behavioural activation, and strengthening social support, and an additional relapse prevention (staying well) (48) (**Figure 2**). PM+ has also been adapted for group delivery (Group PM+) and digital delivery (Step-by-Step [SbS]), to increase access and help with cost saving (48). PM+, including Group PM+, participation was associated with reduced psychological distress, anxiety, depression, problems, and post-traumatic stress with adults in Kenya (46) and Nepal (51) and Syrian refugees in the Netherlands (52). A systematic review and meta-analyses of 23 studies implementing PM+ and SbS reported effects on reducing distress and promoting positive mental health, and called for additional evidence (53).

Insert Figure 2

In Uganda, over 13 million persons have access to mobile phones, and data suggest that HIV prevention messages through mobile phones are beneficial to supplement traditional modalities such as schools for adolescents (54,55). This reflects calls to integrate technology into health interventions with refugees/displaced persons (3,56). SbS was an online self-help intervention with minimal guidance that aimed to adapt PM+ for digital delivery, yet focused on the behavioural activation strategy as the problem management strategy required more facilitator support (57). To overcome this challenge and address all PM+ strategies, we are using (in addition to the participatory comics described below) a multi-step mHealth delivery strategy that includes: 1) weekly SMS check-ins moderated by the peer navigator; 2) weekly themed informational SMS to share PMP messages for each weekly strategy, and

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accompanying questions to enhance engagement; and 3) WhatsApp group multi-media sharing and discussions of participatory comic responses with peer navigators. The peer navigator and coordinator will review group discussions weekly to incentivize engagement; 4) participatory comic books: an adapted PM+ comic book, outlining problem management strategies and solutions across each of the four strategies and the relapse prevention strategy. We are collaborating with the WelTel non-profit agency for the implementation of the supportive SMS intervention (58–61). The WelTel system will manage the SMS intervention on their structured mobile phone platform (all SMS interactions are logged). Weekly 2-way supportive messages will automatically be sent on the same weekday with WelTel software to mental health program participants (Arm 2, Arm 3). The peer navigator will ask mental health program participants to respond to the SMS within 48 hours to confirm their wellbeing and will follow-up with non-responders. The peer navigators and Research Coordinator will access the server every 24-48 hours to triage and respond to participants who express a problem or need, including referral to the project social worker based at the collaborating agency.

The participatory comic delivery includes providing a combination of PMP written and pictorial content, and including one page of educational information and the second page with blank spaces for participants to write their answers in, as our team has done in prior research (62–65). Educational comics offer a youth-friendly, low-cost, scalable approach for providing education and health promotion on health topics such as HIV, sexually transmitted infections, vaccines, and dementia (66–68). Comics have been used to educate both the general population and healthcare providers to improve care and patient experiences, as they are accessible, do not require high levels of literacy, and can encourage participants to envision and share solutions to sexual violence through facilitating dialogue around emotionally difficult and often stigmatized issues (69–74).

Arm 3: HIVST and mental health and livelihoods program: In addition to HIVST and the mental health program, participants in Arm 3 will also be in enrolled in an 8-week Creating Futures program. Creating Futures is a group intervention that aims to help young people build their livelihoods, and was designed for use with youth (18-24) in urban informal settlements in South Africa (75). A key intervention aim is to address livelihood insecurity and gender inequality with the end goal of reducing HIV-related risks. Previous researchers have implemented the Creating Futures intervention in South Africa and found that after the intervention, men's earnings increased, women's experiences of intimate partner violence decreased, men and women scored better on gender attitudes, and depression and suicidal thoughts decreased amongst men (76). This manualized program was developed with youth in South Africa and adapted for the Kenyan context (77,78). Topics within the Creating Futures program include: 1) introduction and situating self; 2) sustainable and social resources; 3) peer group meeting; 4) education and learning; 5) getting and keeping jobs; 6) income generating activities; 7) saving and coping with shocks; 8) reflection and looking ahead (**Figure 3**). This intervention aims to help participants think about, and plan for, their futures to assist them in making a living in the long term. Each workshop will be conducted in-person, for approximately 3 hours, and will be facilitated by pairs of peer navigators. Our team met with the peer navigators on this planned study to adapt some aspects to fit the Kampala context, and found that the structure, and most materials, were relevant for participants in this study.

Insert Figure 3

Outcomes

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Primary Outcome: The primary outcome measured in this trial is routine (every 3 months) HIV testing uptake as a measure of HIV prevention. Participants will be asked to self-report when their last HIV test occurred and where it was received (i.e., HIVST, clinic, point-of-care).

Secondary Outcomes: The secondary outcomes of this trial include a) HIV status knowledge, b) confirmatory testing, c) HIV care linkage, d) HIV knowledge, and e) sexual risk. We will document antiretroviral therapy (ART) adherence for those who seroconvert during the study using a 3-item self-report scale (79).

Knowledge of HIV status: Since HIV status is self-reported, we will use multiple steps to overcome challenges of social desirability bias. First, interviewers will ask participants to report their current HIV status at 3- and 6-month follow-up surveys. Second, the trained interviewer will offer participants a voluntary rapid HIV test at the final survey (6-month follow-up). Knowledge of HIV status will be assessed as correct for participants who agree to take the rapid test and correctly report their HIV status. We will also record if participants were willing to take the interviewer administered rapid test. *Linkage to confirmatory HIV testing:* Participants will be asked if they used their HIVST kit at 3- and 6-month follow-up surveys. For those who affirm use of HIVST kits with a positive test result, we will ask if and where they received a confirmatory test. Participants can receive confirmatory testing without reporting to the interviewer and can submit coupons at MARPI or to local clinics. *Linkage to HIV care:* We will ask participants who seroconvert during the study to report the frequency of HIV care services. In addition, participants can present coupons when accessing MARPI or local clinic services. *HIV knowledge:* We will use an 18-item Brief HIV Knowledge Questionnaire to assess HIV knowledge (80). *Sexual practices that elevate HIV exposure*: We will assess sexual risk through self-reported measures of consistent condom use (anal, vaginal sex) with regular, causal, and paid sex partners in the past month, as well as the number of sex partners in the past month, condom use self-efficacy (81), and selling sex in the past 3 months.

Sample Size and Power Analysis

A parallel, 3-group cluster-randomized design will be used to test the difference among the 3 proportions that is defined by the contrast coefficients -2, 1, 1. The comparison will be made using a generalized estimating equation (GEE) logistic model Z-test with a Type I error rate (α) of 0.05. The autocorrelation matrix of the responses within a cluster is assumed to be compound symmetric with an intraclass correlation coefficient (ICC) of 0.013. Missing values are assumed to occur completely at random (MCAR), and the anticipated proportion missing is 0.05. To detect the group proportions 0.5, 0.75, 0.75, with contrast coefficients -2, 1, 1, with a total of 3 clusters (allocated to the 3 groups as 1, 1, 1), with an average cluster size of 110 subjects per cluster (for a total sample size of 330 subjects), the power is 0.80. The power was computed using PASS 2024, version 24.0.2.

Data Collection and Management

Data collection will be conducted by research assistants trained by the Ministry of Health in pre- and post-test counselling. We will collect data using a structured survey accessed via mobile phones or tablets in all study languages via the SurveyCTO app (Dobility). This app houses a secure platform and automatically encrypts data, which are then uploaded with a Secure Sockets Layer (SSL) certificate to a password-protected server. The use of SurveyCTO allows for multilingual and offline data collection with branching logic and consistency checks. All participants are assigned a unique ID number without any personal identifying information to enhance confidentiality. All datasets will be saved on a

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password-protected server that can only be accessed by study staff on a need-to-know basis for data management and outcome reporting.

Data Analysis Plan

The analysis and reporting of this study will be conducted following the CONSORT (Consolidated Standards of Reporting Trials) guidelines (84). The study analyst will be blinded to group allocation. Participant flow (screening, randomization, allocation, follow-up) will be illustrated using a CONSORT flow diagram. We will report baseline data for all groups summarized using mean (standard deviation) or median (first and third quartiles) for continuous variables and counts and frequencies (percent) for categorical variables. For this study, we will use an intention-to-treat approach with a complete data set whereby participants will be analyzed according to their initial group allocation irrespective of whether they received said intervention.

We will use a between-group comparison with multilevel mixed effect logistic or linear models (depending on the nature of the outcome), where the intervention group will be entered as fixed with a set significance of alpha=0.05, adjusted using the Bonferroni method for secondary outcomes (85,86). Results will thus be presented as odds ratios or mean differences as appropriate, with corresponding 95% confidence intervals and p-values. For the primary outcome (HIV testing), we will conduct an adjusted analysis to investigate the role of covariates in the relative effect. We will build mixed effect multilevel logistic regression models with intervention groups as the independent variable and HIV testing uptake in the past three months (yes/no) as the dependent variable, adjusting for covariates (e.g., age) entered as a block. We will then perform an economic evaluation using the intention-to-treat approach to assess how much the average costs and primary outcome differ between each intervention group and the control through estimation of the incremental cost-effectiveness ratio given as [(Cost of intervention)-(Cost of control)] /[(Success of intervention)-(Success of control)]. The economic analyses, conducted from the health system perspective, will include outcomes and costs in the trial's time horizon. We will use a graphical plane to present the cost-effectiveness ratio for each outcome, and bootstrapping techniques will be used to estimate cost-effectiveness ratio confidence intervals.

Ethical Considerations

The Tushirikiane Phase 2: HIV self-testing study protocol has been approved by the Research Ethics Boards University of Toronto (July 22, 2022, #37496), Mildmay Uganda Research Ethics Committee (March 13, 2023; #MUREC-2021-41), and Uganda National Council for Science & Technology (February 29, 2024; # SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160), who we will inform should there be modifications from the protocol. We will audit trial conduct through conducting data queries at 1 month post-intervention starting, 3 months, and 6 months; the process will be conducted by a trained data analysis and independent from investigators and the sponsor.

We developed the protocol for the study under the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement (87). Our study population consists of young adults aged 16 years and older who can provide informed consent for HIV testing in Uganda without parental involvement (at the age of 12 and above), and we received research ethics approval to allow youth aged 16-17 to participate in the trial without parental consent to reduce barriers to participation in sexual health research (88,89).

All participants will receive information about the study prior to enrollment and will be informed of their rights to refuse or withdraw from the study, as well as understand study processes and

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expectations. Participants will be given sufficient time to provide their voluntary written consent and all informed written consent processes will occur in a private room at a location provided by YARID. Participants or peer navigators will read consent forms themselves in a language comfortable to them (French, English, Luganda, Kirundi, Kinyarwanda, or Swahili). Consent forms (signed via signature or thumbprint) will not be connected to data collection and will be destroyed 5 years after study completion. Participants can withdraw from the study at any time during study data collection before interview completion, and will be informed that there are no adverse consequences to their care or health service delivery if they choose to withdraw. Data will be stored on password-protected and secure servers and all participants will be given a unique ID to maintain confidentiality. Only study investigators will have access to the final trial dataset per research ethics board approval for working with vulnerable populations (refugees).

Peer navigators and counsellors trained in psychological first aid (90) will be on-site throughout the intervention and participants will be provided with a list of community resources, although interventions are not expected to cause psychological distress. Peer navigators will report any adverse events to research assistants, who will then fill out an Adverse Event Reporting Form and Adverse Event Narrative Form if appropriate; participants can leave the study at any time, including if having experienced adverse events. Participants can also directly report adverse events to YARID or the study team. All adverse events require a narrative form to be sent to the principal investigators within 24 hours. There will be no Data Safety and Monitoring Board (DSMB) as this is a low risk intervention largely involving methods the team has already implemented with this population (HIV self-testing, group problem management plus), and YARID (RH, BK) has a long history of livelihoods interventions with this population, thus there is no need for a DSMB or interim analysis.

Data Sharing and Dissemination

The final data set will be shared between the Uganda- and Toronto-based research teams using a secured, encrypted, and password-protected system. Users entered under a data-sharing agreement and secure research ethics approval via a research ethics board amendment with the University of Toronto will be able to access the final de-identified data set. Findings will be shared in peer-reviewed publications, conference presentations, and with community dissemination.

Author's contributions: Study design: CHL, MO, RH, LM. Data management: LST, FM, ZA, RH, DKM, BK, AN. Manuscript writing: CHL, LST, FM, LM. Manuscript editing: MO, ZA, RH, DKM, BK, AN, PK.

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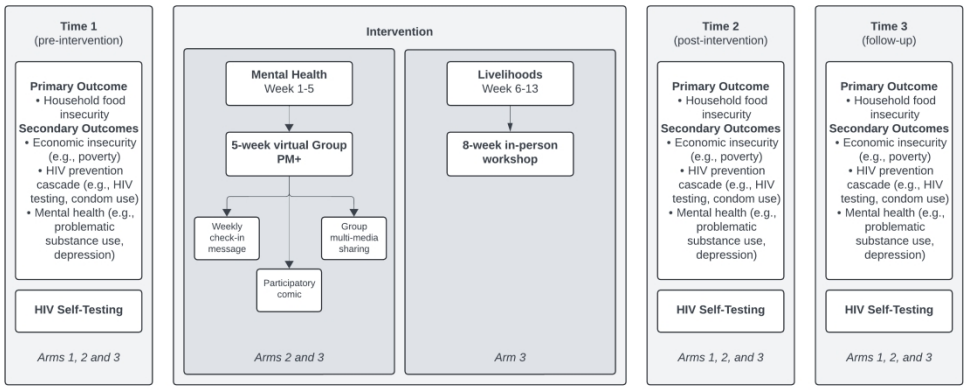

Figure 1. Flow chart of study phases and participant involvement

766x322mm (118 x 118 DPI)

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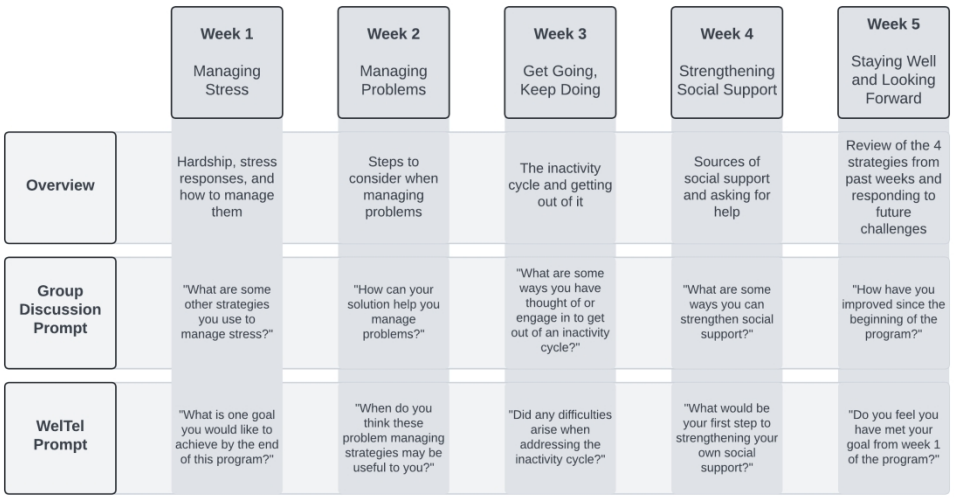

Figure 2. Overview of Problem Management Plus Sessions

581x314mm (118 x 118 DPI)

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Figure 3. Overview of Creating Futures Sessions

871x315mm (118 x 118 DPI)

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Appendix 1a – ***Arm 1*—HIVST Information & Consent**

UNIVERSITY OF TORONTO

FACTOR-INWENTASH FACULTY OF SOCIAL WORK

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including InterAid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), and Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing: where participants go to clinics/hospitals to receive HIV counseling and testing. Self-testing for HIV is when people use an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status. Information from this study will provide important information for national policies about HIV self-testing for refugee young people and youth in general in Uganda.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will also be connected with a peer navigator, who is a young refugee living in Kampala's slum communities. These young people will support you during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities. They will let you know the best times and ways to connect with them.

At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from

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today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricants, booklets with information on HIV, and a verbal and written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with your unique participant identification number, as well as clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Kinyarwanda, Kirundi and English. After each time you receive a kit, the research assistant will ask you to complete a survey about experiences with the kit and sexual practices. The first survey will be completed today in a private room or a place of your choice. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution.

Who can participate?
Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we won't be able to remove your data from the final analysis. You can skip questions you do not want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
Risks that may happen when you participate in the study is that you could feel emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for more tests. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks.

What will I get for participating in this study?
The findings from this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the

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surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and unique identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up.

Where will the survey be administered take place?
The surveys will be conducted in a private room at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com. If you have questions about your rights as a participant, you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto Health Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB)will be upheld to the same level of confidentiality that has been stated by the research team

Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

A. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months. I understand I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

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Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant	Signature	Date

B. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place where the surveys are being completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with additional information on clinics or organizations that can provide you with more support. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey will be conducted or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for additional tests. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Peer Navigator	Signature	Date

C. Consent for HIV self-testing kit at follow up survey at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you use them. You can do the test at home or in a private room at YARID. We will also offer a locked disposal container that is open during business hours at these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator or research assistant. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

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I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Peer Navigator Signature Date

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Appendix 1b – ***Arm 2*—HIVST and M-health Information & Consent**

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing where participants go to clinics/hospitals to receive HIV counseling and testing clinics. Self-testing for HIV is the use of an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will be also connected with a peer navigator, who is a young person who is also a refugee living in Kampala's communities. They will be there to provide you with support during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities, and are really there to support you in the study. They will let you know the best times and ways to connect with them.

At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricant, booklets with information on HIV, and a verbal and

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written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with a unique participant identification number, clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Kinyarwanda, Kirundi and English. Each time you receive a kit you will also be asked to complete a survey. You will be asked about your experience using the self-testing kit and experiencing receiving SMS support and participating in WhatsApp group. The first survey will be completed today. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

The peer navigator will also invite you to participate in a mobile health intervention. It has 2 components. The first is a weekly text that asks you how you are. The peer navigator will discuss with you the best day and time to send the text. They will ask you to reply ' I am ok' if you are ok, or 'I need help' or 'please call me' if you need support with testing or any other issue around the study or around HIV prevention, care or support. The peer navigator will respond to you and then ask you to respond back within 2 days. If the peer navigator does not hear from you, they will send another text asking how you are. You will also be invited to participate in WhatsApp discussion groups moderated by a peer navigator and the Research Coordinator. The purpose of this discussion group is to talk about issues related to managing problems.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution.

Who can participate?

Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we will not be in position to remove your data from the final analysis. You can skip questions you don't want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
There are unforeseen risks associated with your participation in the study including emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for confirmatory testing. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks. Given that the WhatsApp groups have other participants, we cannot guarantee confidentiality of the information shared in the groups. We will advise group members not to share information from the groups, but to only share what you feel comfortable being shared in public.

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What will I get for participating in this study?
The findings in this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is found to be effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people. We will also understand in mobile phone support results in better support with young refugees for HIV testing.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) at each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up.

Where will the survey be administered?
The study and completion of the surveys will be completed in a private room at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com.If you have questions about your rights as a participant you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto Health Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB) will be upheld to the same level of confidentiality that has been stated by the research team

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Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

A. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months, with the understanding I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

B. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place the where the surveys will be completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with a reference to a clinic that can provide you with more support. If the test is positive, you will also receive support for going for additional testing with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

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Name of Peer Navigator	Signature	Date

C. Consent for HIV self-testing kit at follow up surveys at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you do them. You can do the test at home or in a private room at YARID. We will also offer a locked disposal container that is open during business hours at both of these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator. If the test is positive, you will also receive support for going for confirmatory testing with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant	Signature	Date

D. Consent for weekly Text messages

I have had the opportunity to talk about the weekly texts and what day and time is best for me. I understand that I can text back "I am ok", or I can text a question or ask the peer navigator to follow up with me if I am not ok, if I have any study questions, or if I need support around HIV testing, prevention, or care. I voluntarily consent to take part in the weekly texting.

Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant	Signature	Date

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E. Consent for WhatsApp group participation

I have had the opportunity to talk about the biweekly WhatsApp groups and what day and time is best for me. I understand that I can participate, I can share what I want to share and ask any questions. I also know that there are other people in the group and that my confidentiality cannot be guaranteed as the other people might share what is discussed outside of the group. I voluntarily consent to take part in the WhatsApp groups.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

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Appendix 1c – *Arm 3*— HIV self-testing and Livelihoods Programming with Creating Futures

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including InterAid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), and Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing: where participants go to clinics/hospitals to receive HIV counseling and testing. Self-testing for HIV is when people use an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status. Information from this study will provide important information for national policies about HIV self-testing for refugee young people and youth in general in Uganda. We are also interested in seeing if livelihoods programs tested elsewhere in Africa with non-refugees may help with economic empowerment of urban refugee youth in Kampala.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will also be connected with a peer navigator, who is a young refugee living in Kampala's slum communities. These young people will support you during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities. They will let you know the best times and ways to connect with them.

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At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricants, booklets with information on HIV, and a verbal and written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with your unique participant identification number, as well as clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Luganda and English. After each time you receive a kit, the research assistant will ask you to complete a survey about experiences with the kit and sexual practices. The first survey will be completed today in a private room or a place of your choice. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

The peer navigator will also invite you to participate in a mobile health intervention. It has 2 components. The first is a weekly text that asks you how you are. The peer navigator will discuss with you the best day and time to send the text. They will ask you to reply ' I am ok' if you are ok, or 'I need help' or 'please call me' if you need support with testing or any other issue around the study or around HIV prevention, care or support. The peer navigator will respond to you and then ask you to respond back within 2 days. If the peer navigator does not hear from you, they will send another text asking how you are. You will also be invited to participate in WhatsApp discussion groups moderated by a peer navigator and the Research Coordinator. The purpose of this discussion group is to talk about issues related to managing problems.

You will also be invited to participate in Creating Futures, an economic livelihood program created for youth in South Africa and also tested with youth in Kenya. This will involve coming to YARID for 8 sessions, each approximately 2 hours, with a group of other young refugees. These session will cover topics such as your goals, income generating activities, social resources, saving and coping with shocks.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution;

Who can participate?
Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we won't be able to remove your data from the final analysis. You can skip questions you do not want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
Risks that may happen when you participate in the study is that you could feel emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of

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emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for more tests. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks.

What will I get for participating in this study?
The findings from this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people. These findings will also give us information about the possibilities of Creating Futures for economic empowerment among young refugees like yourself living in Kampala.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and unique identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up. You will also receive $5 CAD honorarium for each of the 10 sessions you attend on Creating Futures.

Where will the survey be administered take place?
The surveys will be conducted in a private room at YARID. The Creating Futures sessions will also be taking place at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com. If you have

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questions about your rights as a participant, you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto HIV Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB)will be upheld to the same level of confidentiality that has been stated by the research team

Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

D. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months. I understand I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

E. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place where the surveys are being completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with additional information on clinics or organizations that can provide you with more support. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey will be conducted or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for additional tests.

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If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

_____ _____
Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____
Name of Peer Navigator Signature Date

F. Consent for HIV self-testing kit at follow up survey at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you use them. You can do the test at home or in a private room at YARID or OGERA or InterAid. We will also offer a locked disposal container that is open during business hours at these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator or research assistant. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or OGERA or InterAid or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

_____ _____
Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____
Name of Peer Navigator Signature Date

G. Consent for Creating Futures Program

You will be invited to attend 8 sessions for the Creating Futures program held at YARID at a time and day that will be organized between you and the peer navigator. Each group will have about 15 other refugee youth like you. The session will last about 2 hours.

I understand that it is my choice to participate in the Creating Futures session at YARID. I voluntarily consent to attending the sessions and understand there will be a peer navigator as well as YARID research coordinator there to answer any questions that I may have.

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Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Peer Navigator	Signature	Date

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BMJ Open

Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Conflict of interest: None to declare.

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Abstract

Introduction: Research with urban refugee youth in Uganda has documented co-occurring social (e.g., poverty) and health (e.g., depression) disparities associated with HIV vulnerabilities. Benefits of HIV self-testing (HIVST) in increasing HIV testing uptake among youth are well established, yet limited interventions have examined if combining HIVST with mental health promotion, or with mental health promotion alongside poverty reduction, is associated with greater improvements in HIV prevention and testing outcomes.

Objective: The aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) mobile health (mHealth) and graphic medicine (comic) program for mental health alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mHealth mental health program, in advancing the primary outcome of HIV testing uptake and secondary outcomes (HIV status knowledge, linkage to confirmatory testing and HIV care, HIV knowledge, consistent condom use, condom use self-efficacy, transactional sex) with urban refugee youth in Kampala, Uganda.

Methods: A three-arm randomized controlled trial will be implemented from 08/04/2024- 31/10/2024 with youth across five informal settlements in Kampala, grouped into three sites based on proximity, and randomized in a 1:1:1 design. Approximately 330 participants (110 per arm) are enrolled and data collection will occur at three time points (baseline enrollment, 3-month follow-up, 6-month follow-up).

Results: The study will be conducted in accordance with CONSORT guidelines. The study received ethical approval from the University of Toronto (#37496), Mildmay Uganda Research Ethics Committee (#MUREC-2021-41), and Uganda National Council for Science & Technology (#SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160).

Conclusions: Study findings will produce new knowledge of the impacts of a mental health program, and a combined mental health and livelihoods program, on improving HIV prevention outcomes among urban refugee youth in Kampala. Findings will be shared in peer-reviewed publications, conference presentations, and in community dissemination.

Trial registration: ClinicalTrials.gov: NCT06270160 (Date of registration: 02/13/2024)
Trial Sponsor: Dr. Carmen Logie, carmen.logie@utoronto.ca

Strengths and limitations:

- This trial will compare offering a mHealth delivered mental health program on its own vs. combined with a livelihoods program on HIV testing outcomes among urban refugee youth in Kampala.
- Addressing poverty and mental health challenges alongside HIV self-testing with urban refugee youth is innovative and can advance syndemics-informed programming.
- Conducting gender- and age-stratified analyses will provide insight into gender and/or age differences in intervention effectiveness.
- Study limitations may include attrition and potential loss to follow-up.

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Introduction

By mid 2023, there were 110 million persons forcibly displaced globally, three-quarters hosted in low and middle-income countries (LMIC)(1). Displaced persons experience HIV vulnerabilities that span social-ecological levels. For instance, structural-level factors include underfunded health systems in humanitarian settings and poverty-related barriers to accessing healthcare; community-level factors include intersecting stigma (e.g., refugee stigma, HIV stigma), sexual violence, and inequitable gender norms; and individual-level factors include disruption of family structures, mental health challenges, and transactional sex for survival needs (2–8). Knowledge gaps persist regarding efficacious approaches to increase HIV prevention and care cascades with forcibly displaced persons in LMIC, reflecting that "displaced populations are being neglected in efforts to end the AIDS epidemic" (p. 5) (8).

Uganda is relevant context to address these knowledge gaps and identify targeted needs for HIV prevention, testing and care. Uganda hosts over 1.5 million refugees, over 100,000 of whom live in the urban centre of Kampala (9), often in slums or informal settlements (9–13). While HIV prevalence and testing engagement among Uganda's refugees is uncertain due to the lack of standardized surveillance of refugees (14), a 2017 study (15) in Nakivale refugee settlement in western Uganda reported an HIV prevalence of 4% among refugee adults, of whom only 54% were linked to HIV care and 6% initiated antiretroviral treatment (ART). These rates fall far below the UNAIDS goals of 95% of PLHIV receiving ART by 2030, respectively (16), signaling the need for further attention to HIV care engagement among refugees.

HIV self-testing is a promising youth-friendly strategy for increasing HIV testing uptake with youth in diverse African countries, including Zimbabwe (17), South Africa (18), and Uganda (19). Innovative HIVST delivery strategies offer promise in linking persons with positive HIVST results to confirmatory testing and HIV care (20). As such, identifying strategies to promote linkage to HIV care is essential to realize the public health impact of HIVST (21). An HIVST study in 14 communities (n=14,004) in Malawi reported that HIVST uptake among adolescent girls aged 16-19 was 100%, yet only 56%(27) of people testing positive were linked to HIV care, which is far below the UNAIDS goal of 90% and 95% of PLHIV receiving ART (16,22,23). A 2014 systematic review reported a dearth of evidence-based strategies for linkage to HIV care with adolescents, highlighting the need for research focused in this age group (24). An HIVST trial with refugee youth in Kampala found increased uptake of HIV-testing and HIV status knowledge among participants in the HIVST arm (vs. standard of care), and in the study arm where HIVST was combined with mHealth support, there were further benefits in reduced adolescent sexual and reproductive health stigma (25).

Refugee youth in Kampala's urban informal settlements are at the nexus of health and social vulnerabilities experienced by youth in Uganda and youth living in Kampala's informal settlements. For instance, as of March 2021, the HIV prevalence among Ugandan youth aged 15-24 years was estimated at ~2% (26). The HIV prevalence among youth living in Kampala's slums and informal settlements may higher than the national prevalence, with estimates of 13.9-37.2% (27–29). This high prevalence may be driven by food insecurity, poverty, stigma, and inequitable gender norms, which may affect many residents in slum settings (30,31). These interlinked factors can increase HIV vulnerabilities through complex pathways, including limiting safer sex negotiation, increasing transactional sex, and constraining youth engagement with HIV prevention services (27,32). For instance, research with urban refugee youth in Kampala identified associations between mental health challenges (frequent alcohol use, depression), violence (intimate partner violence, violence in young adulthood), and HIV vulnerabilities (multiple sex partners, transactional sex) that reflect a syndemic

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(33). Syndemics refer to interactions between social inequities (e.g., poverty, violence) and health inequities (34,35). The poverty rate among refugees in Uganda worsened during COVID-19 from 44% to 50%, and employment dropped from 43% to 32%, and it is projected that recovery from the economic impacts of COVID-19 may be slower for refugees compared with Ugandan nationals (36). Other studies among urban refugee youth in Kampala have noted associations between poverty indicators and poorer health outcomes, including: food insecurity and poorer mental health (37); unemployment and reduced HIV testing uptake (38); and resource insecurity (food/water insecurity) and reduced sexual and reproductive health access (including HIV and STI testing) (39) and transactional sex (39,40). Multi-level approaches that jointly address this convergence of poverty, mental health and HIV vulnerabilities thus offer promise to address co-occurring social and health challenges yet are understudied with urban refugee youth in low-and middle-income income settings such as Uganda.

There are persistent knowledge gaps regarding integrating mental health and poverty reduction in HIV testing and prevention with urban refugee youth in LMIC such as Uganda. The study aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) an evidence-based mental health program delivered using mobile health (mHealth) and graphic medicine (comic) alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mental health program, in advancing HIV prevention outcomes, including increasing routine HIV testing, HIV status knowledge, and linkage to confirmatory testing and HIV care.

Methods and Analysis

Study Design

We will conduct a three-arm randomized controlled trial (RCT) to evaluate the effectiveness of HIVST delivery methods alone and combined with a mental health program, and mental health and livelihoods programs, among refugee youth living in Kampala (41) (**Figure 1**). Five informal settlements in Kampala where most urban refugees reside will be randomized in a 1:1:1 approach to one of the three study arms: 1) HIV self-testing; 2) HIV self-testing alongside a mental health program; and 3) HIV self-testing, a mental health program, and a livelihoods program (interventions described in-depth below). Refugee youth (aged 18-24 years) living in the same informal settlements who are trained in research methods and ethics will act as peer navigators and enroll other youth in the study after obtaining written informed consent. Participants will be randomly allocated to a study arm based on their informal settlement of residence. Youth living in slums and informal settlements have shared socio-physical environments (41). As such, except for individual-level outcome data, we will use a cluster approach to analyses and program delivery to limit challenges posed by experimental contamination and threats to internal validity. Data collection will be performed at baseline, and 3- and 6-months post-intervention implementation. The clusters will be numbered 1, 2 and 3. We will use a computer-generated randomization list created by a trained research assistant to allocate the cluster to intervention. The number of the clusters and the randomization list will be kept separate until it is time to implement the interventions. The trained study coordinators (FA, BK) will generate the allocation sequence, enroll participants, and assign participants to interventions.

Insert Figure 1

Study Setting

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We are conducting this RCT in five informal settlements in Kampala, Uganda. Settlements will be grouped into three arms based on close geographic proximity (1: Kabalagala and Kansanga, 2: Katwe and Nsambya, and 3: Rubaga), a strategy successfully used in prior interventions with this study population (25). We used the following criteria to select informal settlements: 1) settlements that host a large number of refugees or displaced persons (11–13,42), 2) communities with similar measures of socioeconomic status, healthcare access, languages, and living conditions; and 3) evidence of a high prevalence of depressive symptoms among urban refugee youth (37,43). We have previously published details on trial site location, population, and geography (44).

Study Population and Eligibility Criteria

We will use an existing cohort of approximately 330 (110 participants/cluster) youth aged 16-25. Cohort eligibility includes those: 1) currently living in one of the five selected Kampala informal settlements (Kabalagala, Kansanga, Katwe, Nsambya, or Rubaga); 2) who identify as a displaced person, refugee, or as having a refugee or displaced parent(s); 3) aged 16-25 years; 4) who own or have daily access to a mobile phone; 5) who speak French, English, Kirundi, Kinyarwanda, or Swahili. Participants were screened for eligibility (via phone, in person, or WhatsApp) by trained peer navigators. Self-reported HIV serostatus is not an inclusion criterion for participation; we anticipate based on our prior work with this cohort and population (25) that most participants will be HIV negative, and we will collect self-reported HIV serostatus at each data collection timepoint (see Outcome section below for more detail).

Participant Recruitment and Retention

The project team includes academics, practitioners, Ugandan Ministry of Health stakeholders, and a nongovernmental organization with expertise in refugee youth community engagement. Participant recruitment, study design, and pilot testing will be facilitated by peer navigators, study coordinators, and implementing partners. Peer navigators (12: 6 young women, 6 young men) are all experienced health/peer educators within study communities and were identified and recruited by community-based collaborators for being respected and involved within their communities.

We employed purposive methods to recruit participants, such as word-of-mouth and venue-based sampling at community events and refugee agencies, beginning with participants who belonged to the Tushirkiane cohort and participated in previous trials on HIVST (44), COVID-19 prevention (45), and mental health interventions (41). We will refresh the cohort with additional purposive recruitment of 16- and 17-year-old participants.

Patient and Public Involvement in Research

This community-based study is a collaboration with Young African Refugees for Integral Development (YARID), a nongovernmental youth refugee organization in Kampala, who have been involved since the initial research question and focus development stage. We developed the study protocol after a formative qualitative research phase (Phase 1), which included semi-structured interviews with peer navigators and other key informants (e.g., refugee health professionals, migrant workers, teen mothers). We completed four focus group discussions stratified by age and gender to explore refugee youth perspectives on livelihood and mental health to identify key themes and prioritize the health needs of urban refugee youth.

Intervention Description

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We designed a RCT consisting of three-arms: 1) HIVST, 2) HIVST + mHealth (bidirectional SMS), 3) HIVST + mHealth + creating futures. Data will be collected at baseline, and 3- and 6-months post-intervention implementation. All study arms will receive HIVST kits at each data collection timepoint. All participants will meet with trained research assistants at the three time points. Unique study identification (ID) numbers on coupons will be used to track HIV testing access and linkage to HIV and sexual and reproductive health services care. If a participant requests, they can discontinue the allocated intervention.

Arm 1: HIV self-testing (HIVST): Participants will be provided with HIVST instructions and education from peer navigators, who will also emphasize the importance of receiving a confirmatory test irrespective of HIV positive result. At each timepoint, participants will receive an HIVST package (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) with written and pictorial instructions and a referral sheet for confirmatory testing. Peer navigators will demonstrate how to use the HIVST kit, including how to 1) open the kit, 2) collect the oral fluid samples, and 3) read the results. In addition to HIVST education, participants will be offered optional pre-test counselling and SMS contact information to connect with their peer navigator. If participants do not want post-test counselling, the PN will follow up within two weeks. If the participants report testing HIV positive, then they will be immediately scheduled for confirmatory testing and enrolled in the support programs at the Uganda Ministry of Health Most at Risk Population Initiative (MARPI) Clinic for young people living with HIV led by study co-applicant and co-author (PK). If participants report being HIV positive after enrollment (prior to the intervention) we will similarly refer them to the MARPI clinic resources.

Arm 2: HIVST and mental health program: Participants in this arm will be enrolled into the HIVST intervention (as described above in Arm 1) as well as a mental health program delivered using mobile health (mHealth) and participatory comics. We will adapt and implement, using mHealth and participatory comic approaches detailed below, the World Health Organization (WHO) Program Management Plus (PM+) scalable, low-intensity brief psychological intervention that is transdiagnostic and developed for delivery by lay persons to address a range of common mental health challenges and adversities (46–49). PM+ has been adapted for delivery across settings (50), and during formative work for this specific intervention the study team adapted PM+ materials into all languages for delivery, and worked with the Peer Navigators to produce key messages from PM+ for delivery by mHealth and participatory comics (below). The four key strategies shared during PM+ are: stress management, problem solving, behavioural activation, and strengthening social support, and an additional relapse prevention (staying well) (48) (**Figure 2**). PM+ has also been adapted for group delivery (Group PM+) and digital delivery (Step-by-Step [SbS]), to increase access and help with cost saving (48). PM+, including Group PM+, participation was associated with reduced psychological distress, anxiety, depression, problems, and post-traumatic stress with adults in Kenya (46) and Nepal (51) and Syrian refugees in the Netherlands (52). A systematic review and meta-analyses of 23 studies implementing PM+ and SbS reported effects on reducing distress and promoting positive mental health, and called for additional evidence (53).

Insert Figure 2

In Uganda, over 13 million persons have access to mobile phones, and data suggest that HIV prevention messages through mobile phones are beneficial to supplement traditional modalities such as schools for adolescents (54,55). This reflects calls to integrate technology into health interventions with refugees/displaced persons (3,56). SbS was an online self-help intervention with minimal guidance that aimed to adapt PM+ for digital delivery, yet focused on the behavioural activation strategy as the

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problem management strategy required more facilitator support (57). To overcome this challenge and address all PM+ strategies, we are using (in addition to the participatory comics described below) a multi-step mHealth delivery strategy that includes: 1) weekly SMS check-ins moderated by the peer navigator; 2) weekly themed informational SMS to share PMP messages for each weekly strategy, and accompanying questions to enhance engagement; and 3) WhatsApp group multi-media sharing and discussions of participatory comic responses with peer navigators. The peer navigator and coordinator will review group discussions weekly to incentivize engagement; 4) participatory comic books: an adapted PM+ comic book, outlining problem management strategies and solutions across each of the four strategies and the relapse prevention strategy. We are collaborating with the WelTel non-profit agency for the implementation of the supportive SMS intervention (58–61). The WelTel system will manage the SMS intervention on their structured mobile phone platform (all SMS interactions are logged). Weekly 2-way supportive messages will automatically be sent on the same weekday with WelTel software to mental health program participants (Arm 2, Arm 3). The peer navigator will ask mental health program participants to respond to the SMS within 48 hours to confirm their wellbeing and will follow-up with non-responders. The peer navigators and Research Coordinator will access the server every 24-48 hours to triage and respond to participants who express a problem or need, including referral to the project social worker based at the collaborating agency.

The participatory comic delivery includes providing a combination of PMP written and pictorial content, and including one page of educational information and the second page with blank spaces for participants to write their answers in, as our team has done in prior research (62–65). Educational comics offer a youth-friendly, low-cost, scalable approach for providing education and health promotion on health topics such as HIV, sexually transmitted infections, vaccines, and dementia (66–68). Comics have been used to educate both the general population and healthcare providers to improve care and patient experiences, as they are accessible, do not require high levels of literacy, and can encourage participants to envision and share solutions to sexual violence through facilitating dialogue around emotionally difficult and often stigmatized issues (69–74).

Arm 3: HIVST and mental health and livelihoods program: In addition to HIVST and the mental health program, participants in Arm 3 will also be in enrolled in an 8-week Creating Futures program. Creating Futures is a group intervention that aims to help young people build their livelihoods, and was designed for use with youth (18-24) in urban informal settlements in South Africa (75). A key intervention aim is to address livelihood insecurity and gender inequality with the end goal of reducing HIV-related risks. Previous researchers have implemented the Creating Futures intervention in South Africa and found that after the intervention, men's earnings increased, women's experiences of intimate partner violence decreased, men and women scored better on gender attitudes, and depression and suicidal thoughts decreased amongst men (76). This manualized program was developed with youth in South Africa and adapted for the Kenyan context (77,78). Topics within the Creating Futures program include: 1) introduction and situating self; 2) sustainable and social resources; 3) peer group meeting; 4) education and learning; 5) getting and keeping jobs; 6) income generating activities; 7) saving and coping with shocks; 8) reflection and looking ahead (**Figure 3**). This intervention aims to help participants think about, and plan for, their futures to assist them in making a living in the long term. Each workshop will be conducted in-person, for approximately 3 hours, and will be facilitated by pairs of peer navigators. Our team met with the peer navigators on this planned study to adapt some aspects to fit the Kampala context, and found that the structure, and most materials, were relevant for participants in this study.

Insert Figure 3

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Outcomes

Primary Outcome: The primary outcome measured in this trial is routine (every 3 months) HIV testing uptake as a measure of HIV prevention. Participants will be asked to self-report when their last HIV test occurred and where it was received (i.e., HIVST, clinic, point-of-care).

Secondary Outcomes: The secondary outcomes of this trial include a) HIV status knowledge, b) confirmatory testing, c) HIV care linkage, d) HIV knowledge, and e) sexual risk. We will document antiretroviral therapy (ART) adherence for those who seroconvert during the study using a 3-item self-report scale (79).

Knowledge of HIV status: Since HIV status is self-reported, we will use multiple steps to overcome challenges of social desirability bias. First, interviewers will ask participants to report their current HIV status at 3- and 6-month follow-up surveys. Second, the trained interviewer will offer participants a voluntary rapid HIV test at the final survey (6-month follow-up). Knowledge of HIV status will be assessed as correct for participants who agree to take the rapid test and correctly report their HIV status. We will also record if participants were willing to take the interviewer administered rapid test. *Linkage to confirmatory HIV testing:* Participants will be asked if they used their HIVST kit at 3- and 6-month follow-up surveys. For those who affirm use of HIVST kits with a positive test result, we will ask if and where they received a confirmatory test. Participants can receive confirmatory testing without reporting to the interviewer and can submit coupons at MARPI or to local clinics. *Linkage to HIV care:* We will ask participants who seroconvert during the study to report the frequency of HIV care services. In addition, participants can present coupons when accessing MARPI or local clinic services. *HIV knowledge:* We will use an 18-item Brief HIV Knowledge Questionnaire to assess HIV knowledge (80). *Sexual practices that elevate HIV exposure*: We will assess sexual risk through self-reported measures of consistent condom use (anal, vaginal sex) with regular, causal, and paid sex partners in the past month, as well as the number of sex partners in the past month, condom use self-efficacy (81), and selling sex in the past 3 months.

Sample Size and Power Analysis

A parallel, 3-group cluster-randomized design will be used to test the difference among the 3 proportions that is defined by the contrast coefficients -2, 1, 1. The comparison will be made using a generalized estimating equation (GEE) logistic model Z-test with a Type I error rate (α) of 0.05. The autocorrelation matrix of the responses within a cluster is assumed to be compound symmetric with an intraclass correlation coefficient (ICC) of 0.013. Missing values are assumed to occur completely at random (MCAR), and the anticipated proportion missing is 0.05. To detect the group proportions 0.5, 0.75, 0.75, with contrast coefficients -2, 1, 1, with a total of 3 clusters (allocated to the 3 groups as 1, 1, 1), with an average cluster size of 110 subjects per cluster (for a total sample size of 330 subjects), the power is 0.80. The power was computed using PASS 2024, version 24.0.2.

Data Collection and Management

Data collection will be conducted by research assistants trained by the Ministry of Health in pre- and post-test counselling. We will collect data using a structured survey accessed via mobile phones or tablets in all study languages via the SurveyCTO app (Dobility). This app houses a secure platform and automatically encrypts data, which are then uploaded with a Secure Sockets Layer (SSL) certificate to a password-protected server. The use of SurveyCTO allows for multilingual and offline data collection with branching logic and consistency checks. All participants are assigned a unique ID number without

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any personal identifying information to enhance confidentiality. All datasets will be saved on a password-protected server that can only be accessed by study staff on a need-to-know basis for data management and outcome reporting.

Data Analysis Plan

The analysis and reporting of this study will be conducted following the CONSORT (Consolidated Standards of Reporting Trials) guidelines (82). The study analyst will be blinded to group allocation. Participant flow (screening, randomization, allocation, follow-up) will be illustrated using a CONSORT flow diagram. We will report baseline data for all groups summarized using mean (standard deviation) or median (first and third quartiles) for continuous variables and counts and frequencies (percent) for categorical variables. For this study, we will use an intention-to-treat approach with a complete data set whereby participants will be analyzed according to their initial group allocation irrespective of whether they received said intervention.

We will conduct a between-group comparison using generalized estimating equation (GEE) models, treating the intervention group as a fixed effect. To specify a GEE model for our binary categorical outcomes, we will employ a binomial distribution with a logit link function and select an appropriate working correlation structure (exchangeable) to address the within-cluster correlation of observations (83).

Model fit will be evaluated using the quasi-likelihood under the independence model criterion (QIC). This approach enables us to analyze the relationship between the predictors and the binary outcome while providing robust estimates that account for clustering in our data (84). The significance level will be set at alpha =0.05 for the primary outcome to ensure sufficient power for our analysis and to test a pre-specified hypothesis. For the secondary outcomes and subgroup analyses (by gender), we will employ a Bonferroni adjustment to mitigate the increased risk of Type I error associated with multiple comparisons 86,87).

Results will be presented as odds ratios or mean differences as appropriate, with corresponding 95% confidence intervals and p-values. For the primary outcome (HIV testing), we will conduct an adjusted analysis using GEE to investigate the influence of covariates on the relative effect. We will then perform an economic evaluation using the intention-to-treat approach to assess how much the average costs and primary outcome differ between each intervention group and the control group through estimation of the incremental cost-effectiveness ratio given as [(Cost of intervention)-(Cost of control)] /[(Success of intervention)-(Success of control)].

We will perform an economic evaluation using the intention-to-treat approach to assess the differences in average costs and primary outcomes between each intervention groups. This will involve estimating the incremental cost-effectiveness ratio (ICER), calculated as [(Cost of intervention) - (Cost of control)] / [(Effectiveness of intervention) - (Effectiveness of control)]. The economic analyses, conducted from the health system perspective, will include outcomes and costs in the trial's time horizon. We will use a graphical plane to present the cost-effectiveness ratio for each outcome, and bootstrapping techniques will be used to estimate cost-effectiveness ratio confidence intervals.

Ethical Considerations

The Tushirikiane Phase 2: HIV self-testing study protocol has been approved by the Research Ethics Boards University of Toronto (July 22, 2022, #37496), Mildmay Uganda Research Ethics Committee

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(March 13, 2023; #MUREC-2021-41), and Uganda National Council for Science & Technology (February 29, 2024; # SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160), who we will inform should there be modifications from the protocol. We will audit trial conduct through conducting data queries at 1 month post-intervention starting, 3 months, and 6 months; the process will be conducted by a trained data analysis and independent from investigators and the sponsor.

We developed the protocol for the study under the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement (88). Our study population consists of young adults aged 16 years and older who can provide informed consent for HIV testing in Uganda without parental involvement (at the age of 12 and above), and we received research ethics approval to allow youth aged 16-17 to participate in the trial without parental consent to reduce barriers to participation in sexual health research (89,90).

All participants will receive information about the study prior to enrollment and will be informed of their rights to refuse or withdraw from the study, as well as understand study processes and expectations. Participants will be given sufficient time to provide their voluntary written consent and all informed written consent processes will occur in a private room at a location provided by YARID. Participants or peer navigators will read consent forms themselves in a language comfortable to them (French, English, Luganda, Kirundi, Kinyarwanda, or Swahili). Consent forms (signed via signature or thumbprint) will not be connected to data collection and will be destroyed 5 years after study completion. Participants can withdraw from the study at any time during study data collection before interview completion, and will be informed that there are no adverse consequences to their care or health service delivery if they choose to withdraw. Data will be stored on password-protected and secure servers and all participants will be given a unique ID to maintain confidentiality. Only study investigators will have access to the final trial dataset per research ethics board approval for working with vulnerable populations (refugees).

Peer navigators and counsellors trained in psychological first aid (91) will be on-site throughout the intervention and participants will be provided with a list of community resources, although interventions are not expected to cause psychological distress. Peer navigators will report any adverse events to research assistants, who will then fill out an Adverse Event Reporting Form and Adverse Event Narrative Form if appropriate; participants can leave the study at any time, including if having experienced adverse events. Participants can also directly report adverse events to YARID or the study team. All adverse events require a narrative form to be sent to the principal investigators within 24 hours. There will be no Data Safety and Monitoring Board (DSMB) as this is a low risk intervention largely involving methods the team has already implemented with this population (HIV self-testing, group problem management plus), and YARID (RH, BK) has a long history of livelihoods interventions with this population, thus there is no need for a DSMB or interim analysis.

Data Sharing and Dissemination

The final data set will be shared between the Uganda- and Toronto-based research teams using a secured, encrypted, and password-protected system. Users entered under a data-sharing agreement and secure research ethics approval via a research ethics board amendment with the University of Toronto will be able to access the final de-identified data set. Findings will be shared in peer-reviewed publications, conference presentations, and with community dissemination.

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Author's contributions: CHL is the guarantor. Study design: CHL, MO, RH, LM. Data management: LST, FM, ZA, RH, DKM, BK, AN. Manuscript writing: CHL, LST, FM, LM. Manuscript editing: MO, ZA, RH, DKM, BK, AN, PK.

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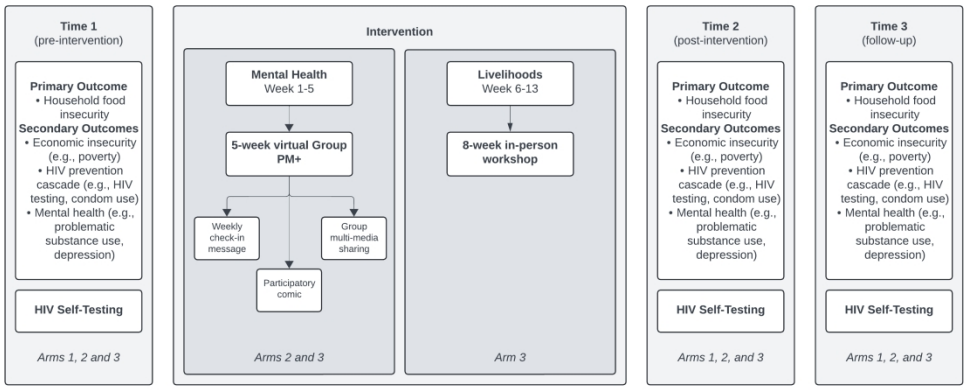

Figure 1. Flow chart of study phases and participant involvement

766x322mm (118 x 118 DPI)

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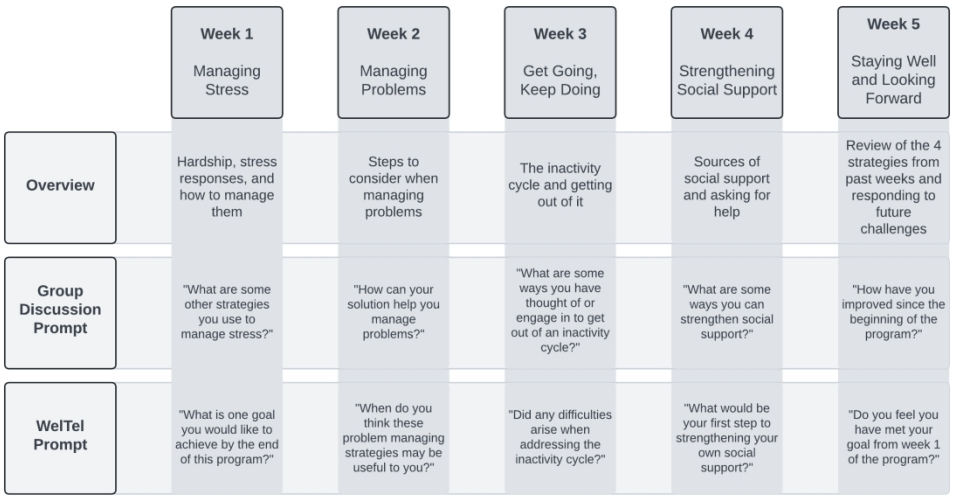

Figure 2. Overview of Problem Management Plus Sessions

581x314mm (118 x 118 DPI)

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Figure 3. Overview of Creating Futures Sessions

871x315mm (118 x 118 DPI)

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Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Tushirikiane-4-Uthabiti (Supporting Each Other For Resilience): study protocol of a mental health, HIV self-testing, and livelihoods randomized controlled trial for advancing HIV prevention outcomes among urban refugee youth in Kampala, Uganda

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Abstract

Introduction: Research with urban refugee youth in Uganda has documented co-occurring social (e.g., poverty) and health (e.g., depression) disparities associated with HIV vulnerabilities. Benefits of HIV self-testing (HIVST) in increasing HIV testing uptake among youth are well established, yet limited interventions have examined if combining HIVST with mental health promotion, or with mental health promotion alongside poverty reduction, is associated with greater improvements in HIV prevention and testing outcomes.

Methods and analysis: The aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) mobile health (mHealth) and graphic medicine (comic) program for mental health alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mHealth mental health program, in advancing the primary outcome of HIV testing uptake and secondary outcomes (HIV status knowledge, linkage to confirmatory testing and HIV care, HIV knowledge, consistent condom use, condom use self-efficacy, transactional sex) with urban refugee youth in Kampala, Uganda. A three-arm randomized controlled trial will be implemented from 08/04/2024- 31/10/2024 with youth across five informal settlements in Kampala, grouped into three sites based on proximity, and randomized in a 1:1:1 design. Approximately 330 participants (110 per arm) are enrolled and data collection will occur at three time points (baseline enrollment, 3-month follow-up, 6-month follow-up).

Ethics and dissemination: The study received ethical approval from the University of Toronto (#37496), Mildmay Uganda Research Ethics Committee (#MUREC-2021-41), and Uganda National Council for Science & Technology (#SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160). Study findings will produce new knowledge of the impacts of a mental health program, and a combined mental health and livelihoods program, on improving HIV prevention outcomes among urban refugee youth in Kampala. Findings will be shared in peer-reviewed publications, conference presentations, and in community dissemination.

Trial registration: ClinicalTrials.gov: NCT06270160 (Date of registration: 02/13/2024)
Trial Sponsor: Dr. Carmen Logie, carmen.logie@utoronto.ca

Strengths and limitations:

- This trial will compare offering a mHealth delivered mental health program on its own vs. combined with a livelihoods program on HIV testing outcomes among urban refugee youth in Kampala.
- Addressing poverty and mental health challenges alongside HIV self-testing with urban refugee youth is innovative and can advance syndemics-informed programming.
- Conducting gender- and age-stratified analyses will provide insight into gender and/or age differences in intervention effectiveness.
- Study limitations may include attrition and potential loss to follow-up.

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Introduction

By mid 2023, there were 110 million persons forcibly displaced globally, three-quarters hosted in low and middle-income countries (LMIC)[1]. Displaced persons experience HIV vulnerabilities that span social-ecological levels. For instance, structural-level factors include underfunded health systems in humanitarian settings and poverty-related barriers to accessing healthcare; community-level factors include intersecting stigma (e.g., refugee stigma, HIV stigma), sexual violence, and inequitable gender norms; and individual-level factors include disruption of family structures, mental health challenges, and transactional sex for survival needs [2–8]. Knowledge gaps persist regarding efficacious approaches to increase HIV prevention and care cascades with forcibly displaced persons in LMIC, reflecting that "displaced populations are being neglected in efforts to end the AIDS epidemic" (p. 5) [8].

Uganda is relevant context to address these knowledge gaps and identify targeted needs for HIV prevention, testing and care. Uganda hosts over 1.5 million refugees, over 100,000 of whom live in the urban centre of Kampala [9], often in slums or informal settlements [9–13]. While HIV prevalence and testing engagement among Uganda's refugees is uncertain due to the lack of standardized surveillance of refugees [14], a 2017 study [15] in Nakivale refugee settlement in western Uganda reported an HIV prevalence of 4% among refugee adults, of whom only 54% were linked to HIV care and 6% initiated antiretroviral treatment (ART). These rates fall far below the UNAIDS goals of 95% of PLHIV receiving ART by 2030, respectively [16], signaling the need for further attention to HIV care engagement among refugees.

HIV self-testing is a promising youth-friendly strategy for increasing HIV testing uptake with youth in diverse African countries, including Zimbabwe [17], South Africa [18], and Uganda [19]. Innovative HIVST delivery strategies offer promise in linking persons with positive HIVST results to confirmatory testing and HIV care [20]. As such, identifying strategies to promote linkage to HIV care is essential to realize the public health impact of HIVST [21]. An HIVST study in 14 communities (n=14,004) in Malawi reported that HIVST uptake among adolescent girls aged 16-19 was 100%, yet only 56%(27) of people testing positive were linked to HIV care, which is far below the UNAIDS goal of 90% and 95% of PLHIV receiving ART [16,22,23]. A 2014 systematic review reported a dearth of evidence-based strategies for linkage to HIV care with adolescents, highlighting the need for research focused in this age group [24]. An HIVST trial with refugee youth in Kampala found increased uptake of HIV-testing and HIV status knowledge among participants in the HIVST arm (vs. standard of care), and in the study arm where HIVST was combined with mHealth support, there were further benefits in reduced adolescent sexual and reproductive health stigma [25].

Refugee youth in Kampala's urban informal settlements are at the nexus of health and social vulnerabilities experienced by youth in Uganda and youth living in Kampala's informal settlements. For instance, as of March 2021, the HIV prevalence among Ugandan youth aged 15-24 years was estimated at ~2% [26]. The HIV prevalence among youth living in Kampala's slums and informal settlements may higher than the national prevalence, with estimates of 13.9-37.2% [27–29]. This high prevalence may be driven by food insecurity, poverty, stigma, and inequitable gender norms, which may affect many residents in slum settings [30,31]. These interlinked factors can increase HIV vulnerabilities through complex pathways, including limiting safer sex negotiation, increasing transactional sex, and constraining youth engagement with HIV prevention services [27,32]. For instance, research with urban refugee youth in Kampala identified associations between mental health challenges (frequent alcohol use, depression), violence (intimate partner violence, violence in young adulthood), and HIV vulnerabilities (multiple sex partners, transactional sex) that reflect a syndemic

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[33]. Syndemics refer to interactions between social inequities (e.g., poverty, violence) and health inequities [34,35]. The poverty rate among refugees in Uganda worsened during COVID-19 from 44% to 50%, and employment dropped from 43% to 32%, and it is projected that recovery from the economic impacts of COVID-19 may be slower for refugees compared with Ugandan nationals [36]. Other studies among urban refugee youth in Kampala have noted associations between poverty indicators and poorer health outcomes, including: food insecurity and poorer mental health [37]; unemployment and reduced HIV testing uptake [38]; and resource insecurity (food/water insecurity) and reduced sexual and reproductive health access (including HIV and STI testing) [39] and transactional sex [39,40]. Multi-level approaches that jointly address this convergence of poverty, mental health and HIV vulnerabilities thus offer promise to address co-occurring social and health challenges yet are understudied with urban refugee youth in low-and middle-income income settings such as Uganda.

There are persistent knowledge gaps regarding integrating mental health and poverty reduction in HIV testing and prevention with urban refugee youth in LMIC such as Uganda. The study aim is to evaluate the effectiveness of: 1) HIV self-testing (HIVST) alone (standard of care); 2) an evidence-based mental health program delivered using mobile health (mHealth) and graphic medicine (comic) alongside HIVST; and 3) the combination of HIVST, a livelihoods program, and mental health program, in advancing HIV prevention outcomes, including increasing routine HIV testing, HIV status knowledge, and linkage to confirmatory testing and HIV care.

Methods and Analysis

Study Design

We will conduct a three-arm randomized controlled trial (RCT) to evaluate the effectiveness of HIVST delivery methods alone and combined with a mental health program, and mental health and livelihoods programs, among refugee youth living in Kampala [41] (**Figure 1**). Five informal settlements in Kampala where most urban refugees reside will be randomized in a 1:1:1 approach to one of the three study arms: 1) HIV self-testing; 2) HIV self-testing alongside a mental health program; and 3) HIV self-testing, a mental health program, and a livelihoods program (interventions described in-depth below). Refugee youth (aged 18-24 years) living in the same informal settlements who are trained in research methods and ethics will act as peer navigators and enroll other youth in the study after obtaining written informed consent. Participants will be randomly allocated to a study arm based on their informal settlement of residence. Youth living in slums and informal settlements have shared socio-physical environments [41]. As such, except for individual-level outcome data, we will use a cluster approach to analyses and program delivery to limit challenges posed by experimental contamination and threats to internal validity. Data collection will be performed at baseline, and 3- and 6-months post-intervention implementation. The clusters will be numbered 1, 2 and 3. We will use a computer-generated randomization list created by a trained research assistant to allocate the cluster to intervention. The number of the clusters and the randomization list will be kept separate until it is time to implement the interventions. The trained study coordinators (FA, BK) will generate the allocation sequence, enroll participants, and assign participants to interventions.

Insert Figure 1

Study Setting

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We are conducting this RCT in five informal settlements in Kampala, Uganda. Settlements will be grouped into three arms based on close geographic proximity (1: Kabalagala and Kansanga, 2: Katwe and Nsambya, and 3: Rubaga), a strategy successfully used in prior interventions with this study population [25]. We used the following criteria to select informal settlements: 1) settlements that host a large number of refugees or displaced persons [11–13,42], 2) communities with similar measures of socioeconomic status, healthcare access, languages, and living conditions; and 3) evidence of a high prevalence of depressive symptoms among urban refugee youth [37,43]. We have previously published details on trial site location, population, and geography [44].

Study Population and Eligibility Criteria

We will use an existing cohort of approximately 330 (110 participants/cluster) youth aged 16-25. Cohort eligibility includes those: 1) currently living in one of the five selected Kampala informal settlements (Kabalagala, Kansanga, Katwe, Nsambya, or Rubaga); 2) who identify as a displaced person, refugee, or as having a refugee or displaced parent(s); 3) aged 16-25 years; 4) who own or have daily access to a mobile phone; 5) who speak French, English, Kirundi, Kinyarwanda, or Swahili. Participants were screened for eligibility (via phone, in person, or WhatsApp) by trained peer navigators. Self-reported HIV serostatus is not an inclusion criterion for participation; we anticipate based on our prior work with this cohort and population [25] that most participants will be HIV negative, and we will collect self-reported HIV serostatus at each data collection timepoint (see Outcome section below for more detail). Youth living with HIV will not be excluded from this study.

Participant Recruitment and Retention

The project team includes academics, practitioners, Ugandan Ministry of Health stakeholders, and a nongovernmental organization with expertise in refugee youth community engagement. Participant recruitment, study design, and pilot testing will be facilitated by peer navigators, study coordinators, and implementing partners. Peer navigators (12: 6 young women, 6 young men) are all experienced health/peer educators within study communities and were identified and recruited by community-based collaborators for being respected and involved within their communities.

We employed purposive methods to recruit participants, such as word-of-mouth and venue-based sampling at community events and refugee agencies, beginning with participants who belonged to the Tushirkiane cohort and participated in previous trials on HIVST [44], COVID-19 prevention [45], and mental health interventions [41]. We will refresh the cohort with additional purposive recruitment of 16- and 17-year-old participants.

Patient and Public Involvement in Research

This community-based study is a collaboration with Young African Refugees for Integral Development (YARID), a nongovernmental youth refugee organization in Kampala, who have been involved since the initial research question and focus development stage. We developed the study protocol after a formative qualitative research phase (Phase 1), which included semi-structured interviews with peer navigators and other key informants (e.g., refugee health professionals, migrant workers, teen mothers). We completed four focus group discussions stratified by age and gender to explore refugee youth perspectives on livelihood and mental health to identify key themes and prioritize the health needs of urban refugee youth.

Intervention Description

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We designed a RCT consisting of three-arms: 1) HIVST, 2) HIVST + mHealth (bidirectional SMS), 3) HIVST + mHealth + creating futures. Data will be collected at baseline, and 3- and 6-months post-intervention implementation. All study arms will receive HIVST kits at each data collection timepoint. All participants will meet with trained research assistants at the three time points. Unique study identification (ID) numbers on coupons will be used to track HIV testing access and linkage to HIV and sexual and reproductive health services care. If a participant requests, they can discontinue the allocated intervention.

Arm 1: HIV self-testing (HIVST): Participants will be provided with HIVST instructions and education from peer navigators, who will also emphasize the importance of receiving a confirmatory test irrespective of HIV positive result. At each timepoint, participants will receive an HIVST package (OraQuick Rapid HIV-1/2 Antibody Test, OraSure Technologies) with written and pictorial instructions and a referral sheet for confirmatory testing. Peer navigators will demonstrate how to use the HIVST kit, including how to 1) open the kit, 2) collect the oral fluid samples, and 3) read the results. In addition to HIVST education, participants will be offered optional pre-test counselling and SMS contact information to connect with their peer navigator. If participants do not want post-test counselling, the PN will follow up within two weeks. If the participants report testing HIV positive, then they will be immediately scheduled for confirmatory testing and enrolled in the support programs at the Uganda Ministry of Health Most at Risk Population Initiative (MARPI) Clinic for young people living with HIV led by study co-applicant and co-author (PK). If participants report being HIV positive after enrollment (prior to the intervention) we will similarly refer them to the MARPI clinic resources.

Arm 2: HIVST and mental health program: Participants in this arm will be enrolled into the HIVST intervention (as described above in Arm 1) as well as a mental health program delivered using mobile health (mHealth) and participatory comics. We will adapt and implement, using mHealth and participatory comic approaches detailed below, the World Health Organization (WHO) Program Management Plus (PM+) scalable, low-intensity brief psychological intervention that is transdiagnostic and developed for delivery by lay persons to address a range of common mental health challenges and adversities [46–49]. PM+ has been adapted for delivery across settings [50], and during formative work for this specific intervention the study team adapted PM+ materials into all languages for delivery, and worked with the Peer Navigators to produce key messages from PM+ for delivery by mHealth and participatory comics (below). The four key strategies shared during PM+ are: stress management, problem solving, behavioural activation, and strengthening social support, and an additional relapse prevention (staying well) [48] (**Figure 2**). PM+ has also been adapted for group delivery (Group PM+) and digital delivery (Step-by-Step [SbS]), to increase access and help with cost saving [48]. PM+, including Group PM+, participation was associated with reduced psychological distress, anxiety, depression, problems, and post-traumatic stress with adults in Kenya [46] and Nepal [51] and Syrian refugees in the Netherlands [52]. A systematic review and meta-analyses of 23 studies implementing PM+ and SbS reported effects on reducing distress and promoting positive mental health, and called for additional evidence [53].

Insert Figure 2

In Uganda, over 13 million persons have access to mobile phones, and data suggest that HIV prevention messages through mobile phones are beneficial to supplement traditional modalities such as schools for adolescents [54,55]. This reflects calls to integrate technology into health interventions with refugees/displaced persons [3,56]. SbS was an online self-help intervention with minimal guidance that aimed to adapt PM+ for digital delivery, yet focused on the behavioural activation strategy as the

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problem management strategy required more facilitator support [57]. To overcome this challenge and address all PM+ strategies, we are using (in addition to the participatory comics described below) a multi-step mHealth delivery strategy that includes: 1) weekly SMS check-ins moderated by the peer navigator; 2) weekly themed informational SMS to share PMP messages for each weekly strategy, and accompanying questions to enhance engagement; and 3) WhatsApp group multi-media sharing and discussions of participatory comic responses with peer navigators. The peer navigator and coordinator will review group discussions weekly to incentivize engagement; 4) participatory comic books: an adapted PM+ comic book, outlining problem management strategies and solutions across each of the four strategies and the relapse prevention strategy. We are collaborating with the WelTel non-profit agency for the implementation of the supportive SMS intervention [58–61]. The WelTel system will manage the SMS intervention on their structured mobile phone platform (all SMS interactions are logged). Weekly 2-way supportive messages will automatically be sent on the same weekday with WelTel software to mental health program participants (Arm 2, Arm 3). The peer navigator will ask mental health program participants to respond to the SMS within 48 hours to confirm their wellbeing and will follow-up with non-responders. The peer navigators and Research Coordinator will access the server every 24-48 hours to triage and respond to participants who express a problem or need, including referral to the project social worker based at the collaborating agency.

The participatory comic delivery includes providing a combination of PMP written and pictorial content, and including one page of educational information and the second page with blank spaces for participants to write their answers in, as our team has done in prior research [62–65]. Educational comics offer a youth-friendly, low-cost, scalable approach for providing education and health promotion on health topics such as HIV, sexually transmitted infections, vaccines, and dementia [66–68]. Comics have been used to educate both the general population and healthcare providers to improve care and patient experiences, as they are accessible, do not require high levels of literacy, and can encourage participants to envision and share solutions to sexual violence through facilitating dialogue around emotionally difficult and often stigmatized issues [69–74].

Arm 3: HIVST and mental health and livelihoods program: In addition to HIVST and the mental health program, participants in Arm 3 will also be in enrolled in an 8-week Creating Futures program. Creating Futures is a group intervention that aims to help young people build their livelihoods, and was designed for use with youth (18-24) in urban informal settlements in South Africa [75]. A key intervention aim is to address livelihood insecurity and gender inequality with the end goal of reducing HIV-related risks. Previous researchers have implemented the Creating Futures intervention in South Africa and found that after the intervention, men's earnings increased, women's experiences of intimate partner violence decreased, men and women scored better on gender attitudes, and depression and suicidal thoughts decreased amongst men [76]. This manualized program was developed with youth in South Africa and adapted for the Kenyan context [77,78]. Topics within the Creating Futures program include: 1) introduction and situating self; 2) sustainable and social resources; 3) peer group meeting; 4) education and learning; 5) getting and keeping jobs; 6) income generating activities; 7) saving and coping with shocks; 8) reflection and looking ahead (**Figure 3**). This intervention aims to help participants think about, and plan for, their futures to assist them in making a living in the long term. Each workshop will be conducted in-person, for approximately 3 hours, and will be facilitated by pairs of peer navigators. Our team met with the peer navigators on this planned study to adapt some aspects to fit the Kampala context, and found that the structure, and most materials, were relevant for participants in this study.

Insert Figure 3

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Outcomes

Primary Outcome: The primary outcome measured in this trial is routine (every 3 months) HIV testing uptake as a measure of HIV prevention. Participants will be asked to self-report when their last HIV test occurred and where it was received (i.e., HIVST, clinic, point-of-care).

Secondary Outcomes: The secondary outcomes of this trial include a) HIV status knowledge, b) confirmatory testing, c) HIV care linkage, d) HIV knowledge, and e) sexual risk. We will document antiretroviral therapy (ART) adherence for those who seroconvert during the study using a 3-item self-report scale [79].

Knowledge of HIV status: Since HIV status is self-reported, we will use multiple steps to overcome challenges of social desirability bias. First, interviewers will ask participants to report their current HIV status at 3- and 6-month follow-up surveys. Second, the trained interviewer will offer participants a voluntary rapid HIV test at the final survey (6-month follow-up). Knowledge of HIV status will be assessed as correct for participants who agree to take the rapid test and correctly report their HIV status. We will also record if participants were willing to take the interviewer administered rapid test. *Linkage to confirmatory HIV testing:* Participants will be asked if they used their HIVST kit at 3- and 6-month follow-up surveys. For those who affirm use of HIVST kits with a positive test result, we will ask if and where they received a confirmatory test. Participants can receive confirmatory testing without reporting to the interviewer and can submit coupons at MARPI or to local clinics. *Linkage to HIV care:* We will ask participants who seroconvert during the study to report the frequency of HIV care services. In addition, participants can present coupons when accessing MARPI or local clinic services. *HIV knowledge:* We will use an 18-item Brief HIV Knowledge Questionnaire to assess HIV knowledge [80]. *Sexual practices that elevate HIV exposure*: We will assess sexual risk through self-reported measures of consistent condom use (anal, vaginal sex) with regular, causal, and paid sex partners in the past month, as well as the number of sex partners in the past month, condom use self-efficacy [81], and selling sex in the past 3 months.

Sample Size and Power Analysis

A parallel, 3-group cluster-randomized design will be used to test the difference among the 3 proportions that is defined by the contrast coefficients -2, 1, 1. The comparison will be made using a generalized estimating equation (GEE) logistic model Z-test with a Type I error rate (α) of 0.05. The autocorrelation matrix of the responses within a cluster is assumed to be compound symmetric with an intraclass correlation coefficient (ICC) of 0.013. Missing values are assumed to occur completely at random (MCAR), and the anticipated proportion missing is 0.05. To detect the group proportions 0.5, 0.75, 0.75, with contrast coefficients -2, 1, 1, with a total of 3 clusters (allocated to the 3 groups as 1, 1, 1), with an average cluster size of 110 subjects per cluster (for a total sample size of 330 subjects), the power is 0.80. The power was computed using PASS 2024, version 24.0.2.

Data Collection and Management

Data collection will be conducted by research assistants trained by the Ministry of Health in pre- and post-test counselling. We will collect data using a structured survey accessed via mobile phones or tablets in all study languages via the SurveyCTO app (Dobility). This app houses a secure platform and automatically encrypts data, which are then uploaded with a Secure Sockets Layer (SSL) certificate to a password-protected server. The use of SurveyCTO allows for multilingual and offline data collection with branching logic and consistency checks. All participants are assigned a unique ID number without

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any personal identifying information to enhance confidentiality. All datasets will be saved on a password-protected server that can only be accessed by study staff on a need-to-know basis for data management and outcome reporting.

Data Analysis Plan

The analysis and reporting of this study will be conducted following the CONSORT (Consolidated Standards of Reporting Trials) guidelines [82]. The study analyst will be blinded to group allocation. Participant flow (screening, randomization, allocation, follow-up) will be illustrated using a CONSORT flow diagram. We will report baseline data for all groups summarized using mean (standard deviation) or median (first and third quartiles) for continuous variables and counts and frequencies (percent) for categorical variables. For this study, we will use an intention-to-treat approach with a complete data set whereby participants will be analyzed according to their initial group allocation irrespective of whether they received said intervention.

We will conduct a between-group comparison using generalized estimating equation (GEE) models, treating the intervention group as a fixed effect. To specify a GEE model for our binary categorical outcomes, we will employ a binomial distribution with a logit link function and select an appropriate working correlation structure (exchangeable) to address the within-cluster correlation of observations [83].

Model fit will be evaluated using the quasi-likelihood under the independence model criterion (QIC). This approach enables us to analyze the relationship between the predictors and the binary outcome while providing robust estimates that account for clustering in our data [84]. The significance level will be set at alpha =0.05 for the primary outcome to ensure sufficient power for our analysis and to test a pre-specified hypothesis. For the secondary outcomes and subgroup analyses (by gender), we will employ a Bonferroni adjustment to mitigate the increased risk of Type I error associated with multiple comparisons 86,87).

Results will be presented as odds ratios or mean differences as appropriate, with corresponding 95% confidence intervals and p-values. For the primary outcome (HIV testing), we will conduct an adjusted analysis using GEE to investigate the influence of covariates on the relative effect. We will then perform an economic evaluation using the intention-to-treat approach to assess how much the average costs and primary outcome differ between each intervention group and the control group through estimation of the incremental cost-effectiveness ratio given as [(Cost of intervention)-(Cost of control)] /[(Success of intervention)-(Success of control)].

We will perform an economic evaluation using the intention-to-treat approach to assess the differences in average costs and primary outcomes between each intervention groups. This will involve estimating the incremental cost-effectiveness ratio (ICER), calculated as [(Cost of intervention) - (Cost of control)] / [(Effectiveness of intervention) - (Effectiveness of control)]. The economic analyses, conducted from the health system perspective, will include outcomes and costs in the trial's time horizon. We will use a graphical plane to present the cost-effectiveness ratio for each outcome, and bootstrapping techniques will be used to estimate cost-effectiveness ratio confidence intervals.

Ethics and Dissemination

Ethical Considerations

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The Tushirikiane Phase 2: HIV self-testing study protocol has been approved by the Research Ethics Boards University of Toronto (July 22, 2022, #37496), Mildmay Uganda Research Ethics Committee (March 13, 2023; #MUREC-2021-41), and Uganda National Council for Science & Technology (February 29, 2024; # SS1021ES). The trial is registered at ClinicalTrials.gov (NCT06270160), who we will inform should there be modifications from the protocol. We will audit trial conduct through conducting data queries at 1month post-intervention starting, 3 months, and 6 months; the process will be conducted by a trained data analysis and independent from investigators and the sponsor.

We developed the protocol for the study under the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement [88]. Our study population consists of young adults aged 16 years and older who can provide informed consent for HIV testing in Uganda without parental involvement (at the age of 12 and above), and we received research ethics approval to allow youth aged 16-17 to participate in the trial without parental consent to reduce barriers to participation in sexual health research [89,90].

All participants will receive information about the study prior to enrollment and will be informed of their rights to refuse or withdraw from the study, as well as understand study processes and expectations. Participants will be given sufficient time to provide their voluntary written consent and all informed written consent processes will occur in a private room at a location provided by YARID. Participants or peer navigators will read consent forms (**supplemental file 1**) themselves in a language comfortable to them (French, English, Luganda, Kirundi, Kinyarwanda, or Swahili). Consent forms (signed via signature or thumbprint) will not be connected to data collection and will be destroyed 5 years after study completion. Participants can withdraw from the study at any time during study data collection before interview completion, and will be informed that there are no adverse consequences to their care or health service delivery if they choose to withdraw. Data will be stored on password-protected and secure servers and all participants will be given a unique ID to maintain confidentiality. Only study investigators will have access to the final trial dataset per research ethics board approval for working with vulnerable populations (refugees).

Peer navigators and counsellors trained in psychological first aid [91] will be on-site throughout the intervention and participants will be provided with a list of community resources, although interventions are not expected to cause psychological distress. Peer navigators will report any adverse events to research assistants, who will then fill out an Adverse Event Reporting Form and Adverse Event Narrative Form if appropriate; participants can leave the study at any time, including if having experienced adverse events. Participants can also directly report adverse events to YARID or the study team. All adverse events require a narrative form to be sent to the principal investigators within 24 hours. There will be no Data Safety and Monitoring Board (DSMB) as this is a low risk intervention largely involving methods the team has already implemented with this population (HIV self-testing, group problem management plus), and YARID (RH, BK) has a long history of livelihoods interventions with this population, thus there is no need for a DSMB or interim analysis.

Data Sharing and Dissemination

The final data set will be shared between the Uganda- and Toronto-based research teams using a secured, encrypted, and password-protected system. Users entered under a data-sharing agreement and secure research ethics approval via a research ethics board amendment with the University of Toronto will be able to access the final de-identified data set. Findings will be shared in peer-reviewed publications, conference presentations, and with community dissemination.

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Author's contributions: CHL is the guarantor. Study design: CHL, MO, RH, LM. Data management: LST, FM, ZA, RH, DKM, BK, AN. Manuscript writing: CHL, LST, FM, LM. Manuscript editing: MO, ZA, RH, DKM, BK, AN, PK.

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Figure Legend

Figure 1. Study design for Tushirikiane-4-Uthabiti, a three-arm randomized controlled trial (RCT) to evaluate the effectiveness of HIVST delivery methods alone and combined with a mental health program, and mental health and livelihoods programs, among urban refugee youth living in Kampala, Uganda.

Figure 2. Overview of the 4-key strategies in the adapted GPM+ mental health program and the themes delivered using mobile health (mHealth), including WhatsApp group discussion and WelTel, and participatory comics. GPM+: Group Problem Management Plus

Figure 3. Overview and key themes of the 8-week adapted creating futures livelihoods program, that aims to help young people build their livelihoods.

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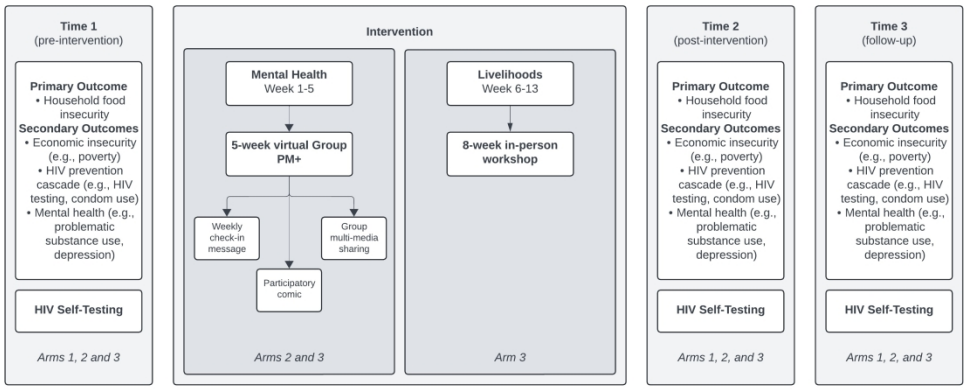

Figure 1. Flow chart of study phases and participant involvement

301x127mm (300 x 300 DPI)

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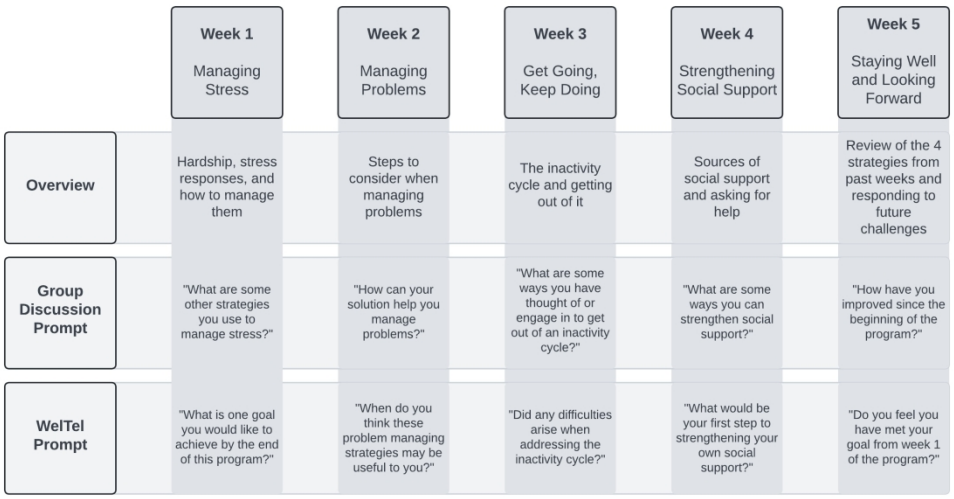

Figure 2. Overview of Problem Management Plus Sessions

228x123mm (300 x 300 DPI)

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Figure 3. Overview of Creating Futures Sessions

342x124mm (300 x 300 DPI)

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Appendix 1a – ***Arm 1*—HIVST Information & Consent**

UNIVERSITY OF TORONTO

FACTOR-INWENTASH FACULTY OF SOCIAL WORK

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including InterAid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), and Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing: where participants go to clinics/hospitals to receive HIV counseling and testing. Self-testing for HIV is when people use an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status. Information from this study will provide important information for national policies about HIV self-testing for refugee young people and youth in general in Uganda.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will also be connected with a peer navigator, who is a young refugee living in Kampala's slum communities. These young people will support you during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities. They will let you know the best times and ways to connect with them.

At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from

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today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricants, booklets with information on HIV, and a verbal and written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with your unique participant identification number, as well as clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Kinyarwanda, Kirundi and English. After each time you receive a kit, the research assistant will ask you to complete a survey about experiences with the kit and sexual practices. The first survey will be completed today in a private room or a place of your choice. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution.

Who can participate?
Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we won't be able to remove your data from the final analysis. You can skip questions you do not want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
Risks that may happen when you participate in the study is that you could feel emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for more tests. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks.

What will I get for participating in this study?
The findings from this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the

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surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and unique identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up.

Where will the survey be administered take place?
The surveys will be conducted in a private room at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com. If you have questions about your rights as a participant, you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto Health Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB)will be upheld to the same level of confidentiality that has been stated by the research team

Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

A. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months. I understand I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

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Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant Signature Date

B. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place where the surveys are being completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with additional information on clinics or organizations that can provide you with more support. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey will be conducted or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for additional tests. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Peer Navigator Signature Date

C. Consent for HIV self-testing kit at follow up survey at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you use them. You can do the test at home or in a private room at YARID. We will also offer a locked disposal container that is open during business hours at these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator or research assistant. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

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I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Peer Navigator Signature Date

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Appendix 1b – ***Arm 2*—HIVST and M-health Information & Consent**

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing where participants go to clinics/hospitals to receive HIV counseling and testing clinics. Self-testing for HIV is the use of an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will be also connected with a peer navigator, who is a young person who is also a refugee living in Kampala's communities. They will be there to provide you with support during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities, and are really there to support you in the study. They will let you know the best times and ways to connect with them.

At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricant, booklets with information on HIV, and a verbal and

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written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with a unique participant identification number, clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Kinyarwanda, Kirundi and English. Each time you receive a kit you will also be asked to complete a survey. You will be asked about your experience using the self-testing kit and experiencing receiving SMS support and participating in WhatsApp group. The first survey will be completed today. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

The peer navigator will also invite you to participate in a mobile health intervention. It has 2 components. The first is a weekly text that asks you how you are. The peer navigator will discuss with you the best day and time to send the text. They will ask you to reply ' I am ok' if you are ok, or 'I need help' or 'please call me' if you need support with testing or any other issue around the study or around HIV prevention, care or support. The peer navigator will respond to you and then ask you to respond back within 2 days. If the peer navigator does not hear from you, they will send another text asking how you are. You will also be invited to participate in WhatsApp discussion groups moderated by a peer navigator and the Research Coordinator. The purpose of this discussion group is to talk about issues related to managing problems.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution.

Who can participate?

Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we will not be in position to remove your data from the final analysis. You can skip questions you don't want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
There are unforeseen risks associated with your participation in the study including emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for confirmatory testing. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks. Given that the WhatsApp groups have other participants, we cannot guarantee confidentiality of the information shared in the groups. We will advise group members not to share information from the groups, but to only share what you feel comfortable being shared in public.

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What will I get for participating in this study?
The findings in this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is found to be effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people. We will also understand in mobile phone support results in better support with young refugees for HIV testing.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) at each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up.

Where will the survey be administered?
The study and completion of the surveys will be completed in a private room at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com.If you have questions about your rights as a participant you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto Health Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB) will be upheld to the same level of confidentiality that has been stated by the research team

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Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

A. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months, with the understanding I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

B. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place the where the surveys will be completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with a reference to a clinic that can provide you with more support. If the test is positive, you will also receive support for going for additional testing with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

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Name of Peer Navigator _____ Signature _____ Date _____

C. Consent for HIV self-testing kit at follow up surveys at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you do them. You can do the test at home or in a private room at YARID. We will also offer a locked disposal container that is open during business hours at both of these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator. If the test is positive, you will also receive support for going for confirmatory testing with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

Date _____ Sign an X _____

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant _____ Signature _____ Date _____

D. Consent for weekly Text messages

I have had the opportunity to talk about the weekly texts and what day and time is best for me. I understand that I can text back "I am ok", or I can text a question or ask the peer navigator to follow up with me if I am not ok, if I have any study questions, or if I need support around HIV testing, prevention, or care. I voluntarily consent to take part in the weekly texting.

Date _____ Sign an X _____

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Research Assistant _____ Signature _____ Date _____

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E. Consent for WhatsApp group participation

I have had the opportunity to talk about the biweekly WhatsApp groups and what day and time is best for me. I understand that I can participate, I can share what I want to share and ask any questions. I also know that there are other people in the group and that my confidentiality cannot be guaranteed as the other people might share what is discussed outside of the group. I voluntarily consent to take part in the WhatsApp groups.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

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Appendix 1c – *Arm 3*— HIV self-testing and Livelihoods Programming with Creating Futures

Research Project: *Tushirikiane-4-Uthabiti (Supporting Each Other for Resilience)*

Investigators:
Dr. Carmen Logie, Factor-Inwentash Faculty of Social Work, University of Toronto

Funding: *Canadian Institutes of Health Research (CIHR) Pandemic Response Operating Grant*

You are invited to participate in a research study being done by researchers from the University of Toronto (in Canada) in collaboration with the Ugandan Ministry of Health and community agencies in Uganda including InterAid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), and Tomorrow Vijana. You are being invited to participate because you are between ages 16-24 years, have a mobile phone, you either identify as a refugee or displaced person, or your parents identify as a refugee and speak Swahili, English, French, Kinyarwanda or Kirundi. You are also being invited as you already took part in other research projects as a Tushirikiane participant, including for HIV testing and COVID-19 prevention. We would like you to understand the study before agreeing to participate. You have the right to not participate or leave the study before it is finished. This is the informed consent process, where we describe the risks and benefits of the research, so you can decide if you would like to participate or not. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

What is this study about?
We are doing this 6-month study to understand how acceptable self-testing is for HIV, and to test technologies to support linking to care among refugee young people in Kampala. We will compare differences between HIV self-testing and standard of care testing: where participants go to clinics/hospitals to receive HIV counseling and testing. Self-testing for HIV is when people use an oral swab test (around your gums in your mouth) and tube solutions to understand your HIV status. Information from this study will provide important information for national policies about HIV self-testing for refugee young people and youth in general in Uganda. We are also interested in seeing if livelihoods programs tested elsewhere in Africa with non-refugees may help with economic empowerment of urban refugee youth in Kampala.

How will I participate?
Your participation in this study will only last 6 months. You will be asked to complete three surveys across 6 months starting with one today, another in 3 months from today and final one in six months from today. A research assistant will help you complete the surveys at each timepoint. You will also be connected with a peer navigator, who is a young refugee living in Kampala's slum communities. These young people will support you during the study, can answer any of your questions, will follow up with you to make sure you remember any study activities. They will let you know the best times and ways to connect with them.

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At three different time points, the peer navigator will provide you with a self-testing HIV kit that you will be asked to use. The first kit will be given to you today. You can do the self-testing for HIV today in a private room, or later at home. It is your choice. You can also choose not to complete the test and return the kit to the peer navigator today or at a later date. The second kit will be given to you three months from today, and the third kit will be given to you six months from today. Each time you get a kit, the peer navigator will also give you condoms and lubricants, booklets with information on HIV, and a verbal and written step-by-step description of how to use the kit. This written description will include text and pictures. The peer navigator will also give you a referral card with your unique participant identification number, as well as clinic addresses and phone numbers, and also their phone number so you can send them an SMS if you need more information on how to use the kits, or if you need support to go for more tests at a clinic. The kits are available in French, Swahili, Luganda and English. After each time you receive a kit, the research assistant will ask you to complete a survey about experiences with the kit and sexual practices. The first survey will be completed today in a private room or a place of your choice. Three months from today, and 6 months from today, a research assistant will contact you to complete a survey.

The peer navigator will also invite you to participate in a mobile health intervention. It has 2 components. The first is a weekly text that asks you how you are. The peer navigator will discuss with you the best day and time to send the text. They will ask you to reply ' I am ok' if you are ok, or 'I need help' or 'please call me' if you need support with testing or any other issue around the study or around HIV prevention, care or support. The peer navigator will respond to you and then ask you to respond back within 2 days. If the peer navigator does not hear from you, they will send another text asking how you are. You will also be invited to participate in WhatsApp discussion groups moderated by a peer navigator and the Research Coordinator. The purpose of this discussion group is to talk about issues related to managing problems.

You will also be invited to participate in Creating Futures, an economic livelihood program created for youth in South Africa and also tested with youth in Kenya. This will involve coming to YARID for 8 sessions, each approximately 2 hours, with a group of other young refugees. These session will cover topics such as your goals, income generating activities, social resources, saving and coping with shocks.

What kind of questions will be asked in the study?
We will ask questions about:

- Your HIV testing history;
- HIV risks;
- HIV self-testing use, acceptability and distribution;

Who can participate?
Your participation is voluntary. Doing this study will in no way affect the services you receive from Interaid Uganda, Young African Refugees for Integral Development (YARID), Organization for Gender Empowerment and Rights Advocacy (OGERA), Tomorrow Vijana, government facilities or other organizations. You can leave the study at any time, and we will remove your data from our analysis. After the end of data collection, we won't be able to remove your data from the final analysis. You can skip questions you do not want to answer. There are no right or wrong answers to the questions.

What are the risks in participating in the study?
Risks that may happen when you participate in the study is that you could feel emotional distress as a result of learning about an HIV-positive status and false reading of the HIV test. The peer navigators will ensure that HIV self-test kits are kept confidential and will provide you with support during times of

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emotional distress. They will also refer you to resources that can give you more support you. The peer navigators will be available to provide you with a second opinion on the results when and if you are in doubt and can accompany you to the clinic if you would like that, for more tests. We need to let you know that if you are HIV-positive, or test HIV positive during the study, Uganda's HIV and AIDS Prevention and Control ACT of 2014 requires HIV positive persons to disclose their status to sex partners. If you become HIV positive during the study, we will allow you to complete the survey responses on your own and we will not be collecting your full name anywhere to reduce any legal risks.

What will I get for participating in this study?
The findings from this study may help broaden our understanding of the effectiveness and acceptability of HIV self-testing and delivery strategies aimed at increasing HIV testing and support for young people like yourself. If HIV self-testing is effective and acceptable as an alternative HIV testing strategy, this research may pave the way for national scale-up of HIV self-testing interventions among refugees and other young people. These findings will also give us information about the possibilities of Creating Futures for economic empowerment among young refugees like yourself living in Kampala.

What will happen to my answers?
All data will be de-identified meaning that your name, birthdate, address, and any other kind of identifying information will not be included with your data. You will be assigned a unique participant identification number that will appear on the kits and surveys you receive. It will not be possible to link answers to a specific person and researchers are the only people who will see your answers on the surveys. The identification number will allow the researchers doing analysis of the data to understand if there have been any changes throughout the 6 months. Individual data will not be reported on. Only group level data will be reported on. You will be asked to give your phone number so that we can contact you at the 3 month and 6 month time points. A document will be created with your phone number and unique identification number, and this document will be stored on a password protected device (tablet/computer). Survey answers will be stored on a different password protected device than where this document will be stored. Once the study is done, we will destroy the document that includes your phone number and identification number. Data will be retained for a maximum of 5 years and after it will be destroyed.

Will I be compensated for participating in this study?
Yes, for your time and participation in completing each survey, you receive a mobile data top up (~$8 CAD) each time you receive a kit and survey. If you start the survey and withdraw during the survey you will still receive $8 CAD. If you don't do the survey at all, you won't receive any data top up. You will also receive $5 CAD honorarium for each of the 10 sessions you attend on Creating Futures.

Where will the survey be administered take place?
The surveys will be conducted in a private room at YARID. The Creating Futures sessions will also be taking place at YARID.

What if I have concerns?
If you need to talk to someone about anything that bothers you during and/or after completing the survey you can contact the Research Coordinator (**Dr. Daniel Kibuuka- 0772-58-70-94**) or the counsellors at Interaid Uganda, YARID or OGERA during working hours: Monday to Friday from 8:00 AM – 5:30 PM. You can also contact the National Health Hotline: 1) toll free number 0- 800-200-600 (you will not be charged) and 2) non-toll-free number 0-312-500-600 (you will be charged) during working hours: Monday to Friday from 8:00 AM – 4:00 PM.

If you have concerns or questions about this study please contact the Mildmay Uganda Research Ethics Committee Chairperson: Ms. Harriet Chemusto- 0392-174-236. You can also contact Simon Mwima at Uganda's Ministry of Health, +256779222111 or by email at simonmwima@yahoo.com. If you have

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questions about your rights as a participant, you can contact the University of Toronto Research Oversight and Compliance Office - Human Research Ethics Program at ethics.review@utoronto.ca or 416-946-3273.

Note: The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Mildmay Uganda Research Ethics Committee and the University of Toronto HIV Research Ethics Board (REB) may access study-related data and/or consent materials as part of the review. All information accessed by the Mildmay Uganda Research Ethics Committee and University of Toronto HIV Research Ethics Board (REB)will be upheld to the same level of confidentiality that has been stated by the research team

Copy of Informed Consent: You will receive a copy of the consent form immediately after the consenting process.

Note: Please take your time to re-read the consent form or ask questions before consenting to participate in the study.

D. Consent for the study

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study that involves a survey now, a survey in 3 months, and a survey in 6 months. I understand I may withdraw at any time without affecting any care or services I receive. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

_____ _____

Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____

Name of Research Assistant Signature Date

E. Consent for HIV self-testing kit at baseline visit

After learning about the HIV self-testing process from the peer navigator at the first visit, you will be informed that you have the choice to conduct your own HIV self-test. You can do this in a private room at the place where the surveys are being completed, or you can take it home with you. It is totally up to you to share the results with the research assistant and/or the peer navigator. If you would like to do the test here, you will have the option to receive counselling before and/or after you do the test. You can choose to get counseling from either the research assistant or peer navigator. The research assistant or peer navigator can also provide you with additional information on clinics or organizations that can provide you with more support. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room here at the survey will be conducted or take it home with me. I understand I don't need to tell the research assistant or peer navigator about the result. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for additional tests.

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If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive the HIV self-testing kit at this baseline visit.

_____ _____
Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____
Name of Peer Navigator Signature Date

F. Consent for HIV self-testing kit at follow up survey at 3-months and 6-months

You will be offered 2 HIV self-testing kits at the end of each survey to take home with you, one is for you and you can share the other with a friend if you like. You have the choice to take the HIV self-test kits, and if you take them, it is your choice whether or not you use them. You can do the test at home or in a private room at YARID or OGERA or InterAid. We will also offer a locked disposal container that is open during business hours at these locations in case you want to throw your kit away before you go home. If you would like to receive counselling before and/or after doing the HIV self-testing, you can contact the peer navigator or research assistant. If the test is positive, you will also receive support for going for additional tests with the peer navigator if you like.

I have had the opportunity to discuss HIV-self testing and understand it is my choice to take the HIV self-test, and I can do it at a private room at YARID or OGERA or InterAid or take it home with me and do it later. I understand I don't need to tell the result to the research assistant and/or peer navigator. I also understand if I need counselling support before or after I do the test I can ask the research assistant and/or peer navigator. If my test is positive, I can also ask the peer navigator to support me to go for confirmatory testing. If I test positive and want my results to be part of this study, it is my choice to bring the referral card to the study clinic. I voluntarily consent to receive HIV self-testing kits at follow-up visits.

_____ _____
Date Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____ _____ _____
Name of Peer Navigator Signature Date

G. Consent for Creating Futures Program

You will be invited to attend 8 sessions for the Creating Futures program held at YARID at a time and day that will be organized between you and the peer navigator. Each group will have about 15 other refugee youth like you. The session will last about 2 hours.

I understand that it is my choice to participate in the Creating Futures session at YARID. I voluntarily consent to attending the sessions and understand there will be a peer navigator as well as YARID research coordinator there to answer any questions that I may have.

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Date	Sign an X

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

Name of Peer Navigator	Signature	Date

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