STUDY PROTOCOL

Study Title: Early Community Client-Led ART Delivery (CCLAD) to Optimize HIV Care Engagement in Nakivale Refugee Settlement

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1. **Background and rationale:**
Sub-Saharan Africa, home to 71% of all people living with HIV/AIDS worldwide, is the site of 3.4 million refugees and asylum seekers and many long-standing refugee settlements (1, 2). While often thought to be a short-term phenomenon, refugees remain displaced for an average of 17 years (3). Though HIV prevalence among refugees is largely unknown, refugees are an extremely vulnerable population due to violence and persecution, and are at risk of exposure to HIV infection (4). Refugees also face unique challenges accessing HIV care. Efforts to meet daily survival needs while living in a refugee settlement can be all-consuming (5). As such, barriers to HIV services that are commonly encountered in resource-limited settings have magnified impacts for refugees (5).

We have a research site at Nakivale Refugee Settlement in southwestern Uganda with a dedicated and skilled refugee-centered research team focused on investigating HIV-related interventions. Nakivale is 71 square miles and hosts over 100,000 refugees from 11 countries of origin. From prior research our team conducted in Nakivale, we found that only 54% of refugees and Ugandan nationals newly diagnosed with HIV subsequently linked to HIV clinical care in one of the four health centers in Nakivale Refugee Settlement (6). This finding motivates our current research to evaluate an intervention which may improve linkage to HIV care in this setting.

2. **Statement of the problem**
Refugees face unique barriers to accessing HIV care given the need to focus energy on meeting daily survival needs (5, 7). Refugees and Ugandan nationals newly diagnosed with HIV in Nakivale Refugee Settlement demonstrated difficulty overcoming barriers to linkage to HIV care, with only 54% of newly diagnosed individuals linking to one of the four clinics in Nakivale that provide free HIV services (6).

3. **Study justification**
In recent research conducted by Dr. Kelli O'Laughlin (PI) and her research team in Nakivale Refugee Settlement to assess barriers to linkage to care in this setting, refugees and Ugandan nationals were hesitant to disclose their HIV status given fear of perceived stigma, and many endorsed lacking social support (unpublished research). Further, physical barriers to care (e.g. distance to clinic and time required to attend HIV clinic and pick-up antiretroviral therapy [ART]) make it difficult to engage in HIV clinical care in this setting.

We aim to design and implement an HIV linkage intervention that is feasible, acceptable, and effective in Nakivale Refugee Settlement. We believe implementing community client-led ART

delivery (CCLAD) at the time of diagnosis will help people to link to HIV clinical care and remain engaged in care by providing psychosocial support, motivating engagement in HIV care, increasing ART accessibility, and decreasing the workload for HIV clinic staff. It is plausible that refugees will be more willing to engage in HIV care if they are immediately connected to peers in their community whom they can partner with to navigate living with HIV in the refugee settlement. This will help to provide needed social support and may decrease perceived stigma. Further, receiving ART as a group will help decrease the burden of frequent travel to clinic in terms of cost of travel, time required to attend clinic, and distraction from other daily activities needed to survive in this setting (e.g. getting water, collecting firewood, cooking, maintaining shelter, harvesting food/picking up food rations, ensuring security of self/family). It is likely that Early Community Client-Led ART Delivery, combined with support from a peer-navigator, will help to enhance linkage to care in this unique setting.

4. Aims/specific objectives

To pilot early community client-led ART delivery (CCLAD) in Nakivale Refugee Settlement and assess the feasibility and acceptability of this intervention in this setting.

5. Research question:

Is an early community client-led ART delivery (CCLAD) intervention feasible and acceptable in Nakivale Refugee Settlement and does it demonstrate a trend toward efficacy?

6. Literature review

There is global movement in HIV care to provide client-centered care that improves access to HIV services and meets the needs of individuals living with HIV to help them better engage in HIV care. A means to enhance client-centered HIV care is by providing "differentiated service delivery". According to the International AIDS Society (IAS), differentiated ART delivery can be divided into four categories: health care worker-managed group models, client-managed group models, facility-based individual models, and out-of-facility individual models (8). In all these models, clients continue to have clinical consultations in a variety of forms and intervals. To date, differentiated ART delivery has been evaluated in clients deemed to be stable in care (defined by >6months on ART, >3 months on same regimen, viral load < 1,000 copies/mL or no current evidence of immunological failure, and no clinical condition requiring more frequent follow-up). (8) For these models, ART refills have been stretched up to every 3 months and clinical consults occur as infrequent as every 6-12 months (8).

There have been numerous studies evaluating models of differentiated service delivery for HIV in sub-Saharan Africa. An intervention that was assessed recently in Eswatini that assisted with linkage to HIV care was peer-delivered linkage case management along with same-day ART initiation (9). Following community-based HIV testing, peers offered linkage case management which included counselling and psychosocial support, treatment navigation, phone calls, reminders and follow-up counselling sessions on HIV disclosure and testing of partners/family (9). Peer navigation has been demonstrated to enhance linkage to HIV care in other resource limited settings as well as extended counselling and peer support (10, 11).

An intervention that has been shown to improve retention in HIV care and viral suppression for adults stable in care in sub-Saharan Africa are health care worker-managed ART group models, sometimes called adherence clubs. Initially piloted by Medecins Sans Frontieres (MSF) in South Africa, adherence clubs were offered to adults with self-reported ART adherence, more than 12 months on ART and with viral suppression (<400 copies/mL) (12). These groups met in the

community and were facilitated by community health workers. The groups met every 8 weeks for group counselling, a brief symptom screen and distribution of pre-packed ART. The group also had an annual visit in the community that included blood collection and a clinical consultation. Findings revealed retention in care at 12 months was 95% and at 24 months was 89%, and that of the 88% of clients with a viral load, 97% were ≤ 400 copies/mL (12-14). These adherence clubs were also cost-effective and enhanced healthcare efficiency and patient accessibility to services (15).

Different than "adherence clubs" which are health care worker-managed, client-managed community ART groups have also been demonstrated to be an effective differentiated care model. In client-managed ART groups, group members take turns attending HIV clinic on behalf of the group, reporting on each members' health status and picking up ART for each group member. They then returned to the group and delivered the medications as well as any important information from the clinic. A study of community ART groups in Mozambique showed favorable long-term retention in care with retention 97% at 12 months, 96% at 24 months, 93% at 36 months, and 92% at 48 months (16). While this study was also conducted among those "stable" on ART, the authors wrote that there was a need to investigate the impact of enrolling clients earlier on ART into community ART groups (16). Community ART groups in Mozambique, were shown to be successful at providing peer support and decreasing barriers to ART helping to address low retention rates and health facilities absorptive capacity (17). In Lesotho, participants in community ART groups had 99% retention in care at one year compared to 90% for those in standard care (18). Further, community ART groups improved access to ART for participants and improved their life within the community (18). Medecins Sans Frontieres reported their experiences with community ART in four countries in sub-Saharan Africa (Malawi, South Africa, Democratic Republic of the Congo, and Mozambique), noting the intervention benefited patients by enhancing retention in care and benefited the health system by lightened the burden for clinical providers (19).

"Community Client-Led ART Delivery (CCLAD)" groups, are recognized by the Ugandan Ministry of Health as a differentiated service delivery model option for those stable in care (20). The Ugandan Ministry of Health outlines the "Community Client-Led ART Delivery (CCLAD) Model" in the 2017 "Implementation Guide for Differentiated Service Delivery Models of HIV Services in Uganda," (20). CCLAD groups are described as psychosocial community ART groups to improve access and to empower clients to rotate collection and delivery of ART to group members. Group members are asked to visit a health facility twice a year for a comprehensive clinical assessment. Team leaders work with health workers to coordinate communication between groups and the health facility. Clients go to the clinic at any point if any issues arise. The Ministry of Health recommends groups of 3-12 members. They outline steps for CCLAD implementation (13).

7. Methodology

Study area

Nakivale Refugee Settlement, established in 1960, is in southwestern Uganda and spans 71 mi^2. There are over 100,000 refugees from 11 countries living in Nakivale; the predominant countries of origin presently are the Democratic Republic of the Congo, Rwanda, Somalia, and Burundi. Free HIV services, including HIV testing and anti-retroviral therapy (ART), can be utilized by refugees and Ugandan nationals and are offered at Nakivale Health Center III and three smaller clinics in the settlement (Rubondo Health Center II, Kibengo Health Center II, and Juru Health Center II). HIV testing at these sites follows the Ugandan Ministry of Health approved serial testing algorithm (Ministry of Health, National HIV testing Services Policy and Implementation Guidelines Uganda, 2016).

Study population
Adults accessing routine HIV testing at Nakivale Health Center III, Kibengo Health Center II and Juru Health Center II will be invited to participate. These are established study enrollment sites from prior research conducted in Nakivale by our research team. The study population will include adult refugees and Ugandan nationals. Those that test positive for HIV will be invited to participate in the Early Community Client-Led ART Delivery group intervention.

Study design
Enrollment: Individuals will be offered research participation which will include an intake survey, an HIV test, and the option to participate in early community client-led ART delivery (early CCLAD) groups if diagnosed with HIV. The consent process will occur before HIV testing, so some of those consenting for the research will not have the option to participate in early CCLAD intervention. This method of consenting prior to HIV testing is a method we have used for years in our research in Nakivale as it permits us to ask questions that may be otherwise answered differently if someone was just diagnosed with HIV (i.e. sensitive screening surveys on depression, anxiety, PTSD, social support and perceived stigma). Those interested in participating will have a consent form read aloud to them by a Research Assistant before being tested for HIV. Consent forms will be available in 4 languages: Runyankore, Kinyarwanda, Kiswahili and English, and will be read by multi-lingual Research Assistants. These individuals will be told at the outset that they can alternatively access free HIV testing at the outpatient department clinic if they prefer to not participate in any aspect of the research. Those accessing testing through the outpatient department clinic can do so after consultation with a clinical officer (then obtaining referral to the lab) or by going to the HIV clinic to request at an HIV test from the HIV clinic staff.

Intake survey: After consent but prior to HIV testing, we will conduct a baseline survey. This method of obtaining consent prior to HIV testing has been effective in prior research in Nakivale as it allows for baseline data collection before individuals learn of a new HIV diagnosis which could alter their survey answers. This will include collection of contact information, demographic information, physical assessment (height, weight, blood pressure), migration patterns (e.g. country of origin, years in Nakivale, recent time away from Nakivale), HIV testing history, perceived stigma, screening for mental disorders (PTSD, depression, anxiety), and assessment of social support (see Appendix I: "Survey"- Runyankore, Kinywarwanda, Kiswahili, English). The purpose of the intake survey is to understand if any of these factors are associated with uptake of or engagement in the Early CCLAD groups as a means to enhance engagement in care in the future. Like the consent process, the survey will be available in 4 languages: Runyankore, Kinyarwanda, Kiswahili or English, and will be read aloud to participants with responses entered directly into a passcode-protected electronic tablet.

Early Community Client-Led ART Delivery (Early CCLAD) intervention: Willing participants newly diagnosed with HIV will be placed into a Community Client-Led ART Delivery group. The goal will be to place participants into groups within the first month of diagnosis. We will attempt to ask participants what their ideal group would look like (i.e. sex of other group members, proximity of house to other group members, country of origin of other group members, size of group), and we will work to place participants in groups that they anticipate will work best for them. We anticipate groups will range in size from 3-12 participants. As enrollment permits, we will invite participates to indicate their preferred group size and group characteristics (sex, age, country of origin of participants). We will not initiate a participant into group after 90 days of diagnosis. To facilitate linkage to the Early CCLAD group, clients will be linked to an expert client peer navigator. The

expert client peer navigators will be tasked with supporting the Early CCLAD intervention groups and helping provide psychosocial support to newly diagnosed individuals and helping them seamlessly integrate with their group.

HIV clinical care for "Early CCLAD" participants: The *first meeting* of each Early CCLAD group will include an HIV clinic clinician (most likely an HIV RN as is standard in HIV clinics in the refugee settlement). Most commonly this first meeting will be for all participants in a single group. In unique circumstances, we may have an individual meet with the HIV clinician on their own for their first meeting and then join an existing group (e.g. if it is difficult to find a group that fits in terms of location and group characteristics). The first meeting is the one time in the intervention where participants will be compensated for their transportation to the clinic or to the meeting site (20,000 USH will be provided for each participant who attends this meeting). The HIV clinician, who will have been trained in the Early CCLAD group intervention, will help individuals in the group to understand their roles and responsibilities (as guided by the Ugandan Ministry of Health "Implementation Guide for Differentiated HIV Services in Uganda" (20), pages 58-59). The group will work together to plan future meeting dates and locations. They will decide if they would like to support the person responsible for picking up the ART each month (e.g. money, transportation, childcare, food). They will specify which dates they will be responsible to attend HIV clinic and pick up ART for the group. They will discern if they would like to identify a connecting activity to be integrated into their group (e.g. exercise, faith, livelihood, craft). The group will select a Team Leader to coordinate communication between the group and the healthcare facility. Finally, an important part of this first meeting is that the HIV clinician will conduct a standard comprehensive clinical exam and will refer each person for any necessary laboratory testing.

Monthly "Early CCLAD" meetings: The "Early CCLAD" intervention will require monthly group meetings. This is intentionally more frequent than is suggested in the Ugandan Ministry of Health guidelines (which recommends visits every 3 months) as this intervention will occur at the time of diagnosis rather than when a person is deemed "stable" in care. Before the designated individual goes to clinic in any given month, they will be responsible for connecting with each group member to ask about how they are feeling and to see if they have any questions to ask of the HIV clinic staff. That individual will then attend HIV clinic and communicate about the status of each group member. They will collect useful information from the clinic and pre-packed ART for each group member. ART may be distributed in MEMS Cap bottles if these are available and if the participant is willing. These allow for transmission of the date and time of bottle opening to research staff only to better monitor medication adherence. The "Early CCLAD" group will then meet at their predetermined location so that the individual who attended clinic can share information from the clinic and can distribute the ART to each person in the group.

Anticipated annual health care visit schedule*:
Month 1: ART start for group + comprehensive clinical exam + laboratory testing as needed
Month 2: ART refill (in community)
Month 3: ART refill (in community)
Month 4: ART refill (in community)
Month 5: ART refill (in community)
Month 6: ART refill for group + clinical review + laboratory testing as indicated/needed
Month 7: ART refill (in community)
Month 8: ART refill (in community)
Month 9: ART refill (in community)
Month 10: ART refill (in community)

Month 11: ART refill (in community)
Month 12: ART refill for group + clinical review + laboratory testing as indicated/needed

*Alternatively, some groups may decide to rotate and have group members attend clinic in 6-month intervals but not necessarily with other group or with all the group members.

Additional clinic attendance: All participants assigned to an "Early CCLAD" group will be expected to attend HIV clinic in person twice yearly for a clinical evaluation and a viral load check. The HIV clinician will work with the team to decide if they prefer their twice annual HIV clinic visits on the same day but individually, on the same day as a group, or individually on different schedules from others in the group. Additionally, individuals will attend clinic in person when they do not feel well, when they have any questions they prefer to ask the clinicians directly, when additional laboratory testing is required, and when requested by HIV clinic staff to optimize their medical care. In cases where the participants are deemed clinically unstable and are in need of regular clinical follow up (e.g. develops an opportunistic infection, develops other co-morbidity, has a viral load > 1,000 copies/mL), clients will be asked to attend the clinic monthly with the rotating group member collecting group ART refill or to step in as the group member responsible for attending clinic that month. Individuals "Up referred" by HIV clinic staff to monthly HIV clinic visits should still participate in the "Early CCLAD" groups to receive psychosocial support and other benefits of community group care.

Option to stop the "Early CCLAD" group at any time: Participants can opt to stop Early CCLAD participation at any time. If willing, they will be asked to participate in a brief exit interview so we can better understand what aspects of the intervention were acceptable or not acceptable to them. If necessary, we will restructure Early CCLAD groups to maintain a minimum of 3 per group.

"Early CCLAD" groups and HIV clinic connectedness: To ensure the Early CCLAD intervention participants remain well integrated into HIV clinic, the research staff will meet regularly with the HIV clinic staff to update them on the intervention and to discuss specific problems and specific individuals needing specialized care. Additionally, efforts will be made so that participant HIV clinic files and pre-packed medications are ready for the visit of the individual Early CCLAD group member each month. Finally, participants will be reminded frequently that they are expected and welcome to attend clinic when they do not feel well or when they have any questions or needs that are not being met through group care.

Follow-up data collection: Early CCLAD group participants will be given components of the intake survey (i.e. to assess mental health screening, perceived stigma, and social support) again 6-months after they began participation in the intervention. Additionally, data will be collected to assess retention in group care, ART medication pick-up, and HIV clinic outcomes.

Sample size determination

From our routine HIV testing study conducted at Nakivale Health Center III in 2013 (O'Lauglin et al, JAIDS 2014), we found an HIV prevalence of 4.5%. With a current population of about 110,000 (https://reliefweb.int/sites/reliefweb.int/files/resources/69449.pdf), this means approximately 4,950 in Nakivale are living with HIV. As this is a pilot study, sample size determination is not applicable. However, to assess the feasibility and acceptability of this intervention, we aim to enroll approximately 70 individuals into the early community client-led ART delivery (early CCLAD) intervention. To reach this number, we plan to enroll 3,000-4,000 individuals to participate in the initial survey and HIV test.

Sampling method and procedures
We will invite all individuals newly diagnosed with HIV to participate in the intervention. There will be no randomization.

Outcomes and Variables to be measured in the study
Primary outcome:

- Linkage to HIV clinical care: attendance of one Early CCLAD group meeting within 90 days of study initiation

Secondary outcomes:

- Retention in care: Early CCLAD group meeting attendance each month
- ART medication pick-up
- Date and time ART medication bottle is opened (if the client is willing to use a MEMS Cap bottle which will record this information)
- HIV clinical outcomes (CD4, viral load, clinic visits outside required visits)
- Variables collected in the intake survey (and 6-month survey for those in Early CCLAD groups):
    1. Demographic information (i.e. refugee status, marital status)
    2. Non-communicable disease screening
    3. Migration patterns
    4. Perceived health
    5. HIV testing history
    6. HIV-related stigma
    7. Patient health questionnaire depression assessment (PHQ-9)
    8. Generalized anxiety disorder (GAD-7)
    9. Post-traumatic stress disorder (PCL-6)
    10. Social support (BS6)

Process outcomes:

- Uptake/Acceptability: number offered Early CCLAD, number accepted Early CCLAD (and reason for not accepting for those unwilling to participate), number placed into an Early CCLAD group, number attending first Early CCLAD meeting, number retained in Early CCLAD meetings.
- Early CCLAD group characteristics: size, sex of group, age of group, country of origin of group, location of group meetings, time of group meetings, group leader characteristics, choice of whether or not/how to support individual attending clinic monthly, group connecting activity, the frequency of "up referral" and retention in group care for those referred to resume monthly clinic visits in person
- Assessing Early CCLAD group intervention feasibility and fidelity:
    1. Group size remains between 3-12
    2. First group meeting to include the following components:
        - Includes all team members
        - Occurs within 90 days of initial diagnosis for all team members
        - Is led by the clinic HIV RN
        - Plan made for future meetings dates/locations
        - Decision made about whether or not to support group member attending clinic each month and in what way to support them

- Specify the clinic attendance schedule for the next 6 months
- Choose whether or not to have a "connecting activity"
- Select a Team Leader
- Each individual to have a comprehensive clinical exam and any necessary laboratory testing

3. Monthly group responsibilities (to be checked each month):
   - A representative group member scheduled to attend clinic that month is to check in with each individual prior to going to clinic
   - A group representative attends HIV clinic and picks up ART for the group
4. Monthly group meeting to include the following components:
   - Meet as a group in the selected location at the predesignated time and distribute ART

i. Note: The Team Leader for each Early CCLAD group will be responsible for collecting and submitting the following information to the research team each month: Date of meeting (and was this the originally planned date, if not, why/how did it change)
ii. Time of meeting (and was this the planned time, if not, why/how did it change)
iii. Location of meeting (and was this the planned location, if not why/how did it change)
iv. Number of participants in attendance (record de-identified code for each participant in attendance)
v. Length of meeting (in minutes)
vi. Estimate of time spent discussing information from clinic (in minutes)
vii. Estimate of time spent discussing family/friends/life/suggestions about living with HIV (in minutes)
viii. Was a Connecting Activity a part of this meeting (yes/no; if so, how much time was spent with this and what was it)
ix. What else did the group spend time on (estimate of time in minutes, specify the other topic/activity)

- With permission from the group, we will intermittently observe group meetings. Research staff will seek to learn from group members about facilitators and barriers to engagement in the intervention. We will collect feedback from participants, Team Leaders, HIV clinic staff, expert peer-client navigators and Research Assistants to help refine the intervention. We will document changes to group sizes and to any program adaptations needed.

Eligibility criteria *(inclusion and exclusion criteria)*

- Adults ≥ 18 years of age
- Newly diagnosed with HIV (within last 90 days) but not yet engaged in HIV care
- Able to provide informed consent
- Willing to share HIV test results and HIV clinic follow-up data for research purposes
- Willing to participate in community client-led ART group
- Willing to have information about group activities and group participation collected for research purposes

Data collection methods and procedures
As we have done previously for research in Nakivale, we will collect data off-line onto passcode protected electronic tablets (e.g. mobile REDCap). In regular and frequent intervals, we will push the data to a secure web-based platform.

Regarding HIV testing, for those diagnosed HIV negative, repeat testing shall be conducted based on client's level of recent exposure and or ongoing risk of exposure to rule in or rule out sero-conversion. Additionally, all individuals newly diagnosed with HIV shall be re-tested before ART initiation. This second HIV test will be conducted on the same day as the initial test and will be performed by the health center laboratory staff. The ART treatment guidelines used will be those approved by the Ugandan Ministry of Health (Consolidated Guidelines for the Prevention and Treatment of HIV and AIDS in Uganda, September 2018).

Quality control measures
The data will be reviewed at least twice monthly by the research team to ensure the validity and integrity of the data as well as adherence to the IRB-approved protocol. In addition, data will be reviewed no less frequently than monthly by the PI (Dr. O'Laughlin). If there are any deviations from the IRB-approved protocol, the PI will be notified immediately, and the study will be stopped. The research team will closely monitor the study to ensure the safety of subjects. The Head Research Assistant (i.e. Project Manager) will conduct safety reviews twice monthly at the study site. HIV counselors will attend periodic training sessions to assist them in their role and to ensure quality procedures are used when conducting rapid HIV tests. Study staff will use precautions when conducting HIV testing and all materials will be disposed of in a secure fashion using biohazard containers as is the protocol in Nakivale. Research assistants will receive specific training in data security and methods to ensure safety of subjects and they will be given information on proper expectations regarding reporting of adverse events. The study will be monitored closely for any breaches in confidentiality. In the event of any of the problems described above, the study staff will notify the PI (Dr. O'Laughlin) and she will intervene to correct the problem.

Data management and analysis
Data will be stored and reviewed in the web-based data storage platform (e.g. REDCap). Data analysis will be conducted in conjunction with a biostatistician at the University of Washington. All data shared with biostatisticians, or anyone outside of the immediate research team, will be deidentified prior to transfer.

Dissemination plan
During the study period, the Head Research Assistant and the PI will discuss the study with stakeholders at the clinic and will share regular feedback about the progress of the study. Upon study conclusion, the PI will meet with stakeholders to share the study findings. If the accepted, the results will also be presented at international conferences and published in a peer-reviewed journal.

Study laminations
Not applicable.

Ethical considerations
Risks and Discomforts: There is minimal anticipated discomfort due to finger prick for the HIV test. The surveys used for data collection will may cause distress, however, research staff can refer participants to non-research clinic staff for counselling as the need arises. While patients choosing to

test for HIV may experience stress and anxiety related to the testing process and receipt of the result, the research assistants will be trained to provide support and all clients with a positive test will be encouraged to meet with an HIV counselor in the HIV clinic that same day and will be offered participation in the group-based intervention. The counselors will remind each person that they are free to decline to participate in the survey and they may leave any or all answers blank if they do not feel comfortable answering a question. Patients will also be reminded that they can change their mind regarding HIV testing and study participation at any time. Care will be taken to protect the confidentiality of the data collected and all data will be stored in a locked location or on password-protected computers equipped with anti-virus software. Clients participating in the Community Client-Led ART Delivery groups are at greater risk for breaches in confidentiality as family or neighbors may hear or see them communicating with other group members. However, we will counsel all study participants at the outset regarding the importance of maintaining confidentiality among the group and respecting others' wishes regarding if they are willing or not to have their HIV status disclosed in the community.

Potential Benefits: The study provides additional measures to protect the rights and welfare of refugees by working to ensure that HIV services are more readily available for them. The hypothesis of this intervention study is that this intervention will increase the number of individuals linked to HIV treatment. If this is found to be the case, then the intervention will help ensure their right to HIV care and will allow individuals to obtain treatment for HIV improving their own health and decreasing the chance that they will expose their sexual contacts to HIV. This study may have important individual benefits to participants who chose to participate in the ART treatment groups. Those testing positive will be able to access Community Client-Led ART Delivery, allowing them to attend HIV clinic less frequently while still accessing ART. Those testing negative may benefit from psychological relief as well as from the opportunity to increase knowledge about risk factors and HIV prevention strategies. This study has important benefits to healthcare delivery in the refugee setting as it will provide scientific evidence regarding the feasibility, acceptability, and impact of an HIV linkage intervention in this population.

Study budget

This study is funded by a K23 award titled, "Linking Refugees to HIV Care in Uganda," from the National Institute of Mental Health (PI: Dr. Kelli O'Laughlin; K23 MH108440-01A1). Funds from this grant that will be spend towards this project are approximately $41,543 and cover the costs of the research staff ($35,543), study supplies ($2,000), transport for study staff ($3,500), and compensation to research participants ($500).

Study timeline

This study will be implemented as soon as all necessary approvals are obtained, likely in January of 2020. We will enroll participants into groups until near the end of 2020. We will continue to monitor the intervention and collect process data and HIV clinic data through 2021.

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APPENDICES

Consent Forms

Appendix 1a. Consent Runyankore
Appendix 1b. Consent Kinyarwanda
Appendix 1c. Consent Kiswahili
Appendix 1d. Consent English

Survey

Appendix 2a. Survey Runyankore
Appendix 2b. Survey Kinyarwanda
Appendix 2c. Survey Kiswahili
Appendix 2d. Survey English