A MEDICAL RESEARCH COUNCIL (MRC)/UGANDA VIRUS RESEARCH INSTITUTE (UVRI)/LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE (LSHTM) UGANDA RESEARCH UNIT COLLABORATIVE STUDY

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Study title: Improving uptake and adherence to HIV prevention services with PrEP and HIV self testing for HIV negative high risk young women aged 15-24 in Kampala, Uganda

Short title: The POPPi (Prevention on PrEP) study

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LIST OF ABBREVIATIONS

ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CAB	Community Advisory Board
FGD	Focus group discussion
FP	Family planning
FSW	Female sex worker
G/C	Gonorrhea / chlamydia
GCP	Good Clinical Practices
GHWP	Good Health for Women Project
HIV ST	HIV Self Test
HTC	HIV testing and counseling
IEC	Independent Ethics Committee
IPV	Interpersonal violence
IRB	Institutional Review Board
KII	Key informant interview
LSHTM	London School of Hygiene and Tropical Medicine
PCR	Polymerase chain reaction
PE	Peer educator
PMTCT	Prevention of mother-to-child HIV transmission
PrEP	Pre-exposure prophylaxis
RCT	Randomized Controlled Trial
REC	Research and Ethics Committee
SMS	Short messaging system
SOC	Standard of care
SOP	Standard operating procedure
SRH	Sexual and reproductive health
sSA	Sub-Saharan Africa
STI	Sexually transmitted infection
UCSF	University of California San Francisco
UNCST	Uganda National Council for Science and Technology
UVRI	Uganda Virus Research Institute
YAB	Youth Advisory Board
YWHR	Young women at high risk
WHO	World Health Organization

SUMMARY OF PROPOSED WORK

Background: Sub-Saharan Africa (sSA) is home to the fastest growing and youngest population in the world and includes countries with the highest HIV prevalence globally. More than half of sSA's population is under 25 years of age. Men and women aged 10-24, defined as 'young people' by the United Nations Population Fund (UNFPA), represent one third of the sSA population and this proportion continues to grow. Young sex workers, new to sex work, are much more vulnerable than their older colleagues to violence, STIs and HIV. The illegality of sex work in Uganda contributes to the risk these young women face. Effective STI and HIV prevention, care, support, and reproductive health services are critical to keeping this young vulnerable population healthy. Evidence on interventions that address uptake and adherence to HIV prevention services for high-risk populations is limited, and interventions that address young women at high risk (YWHR) are almost non-existent.

We propose to develop and conduct a pilot intervention trial including PrEP and HIV self-testing for HIV-uninfected women 15- to 24-years old who engage in high-risk sexual activity in Kampala, Uganda, and to evaluate its feasibility, acceptability and potential effect on PrEP uptake and adherence as well as repeat HIV self-testing. We will embed this study within our existing cohort study (NIMH R01 HD085805-01, PI King) that has revealed the need for greater attention to young sex workers soon after their initiation into the work. The intervention will focus on increasing initiation of PrEP among HIV-uninfected YWHR with enhanced adherence support, uptake of and adherence to repeat HIV self-test, and motivation to adopt and sustain sexual risk reduction behaviors for STI, HIV, and unplanned pregnancy.

Aims and Objectives: The main aim is to develop and assess an intervention to enhance initiation and adherence to PrEP among HIV negative YWHR. The specific aims are (1) To conduct formative research to enhance our understanding of the dynamics of the social and sexual networks, and context of young HIV-uninfected women (aged 15-24) engaged in high risk sexual behavior in Kampala, Uganda (2) Document barriers and opportunities for PrEP uptake and adherence as well as repeat HIV testing by self test; (3) To develop and test a socially and culturally acceptable and feasible prevention intervention on uptake and adherence to PrEP and HIV self-testing for young women at high risk for HIV; (4) to translate lessons learned from the pilot study to the design of a larger RCT.

A. BACKGROUND

Sub-Saharan Africa (sSA) is home to the fastest growing and youngest population in the world and includes countries with the highest HIV prevalence globally. More than half of sSA's population is under 25 years of age; men and women aged 10-24, defined as 'young people' by the United Nations Population Fund, represent one third of the sSA population and this proportion continues to grow.[1]

Young women in sSA who are economically and educationally disadvantaged are at high risk of engaging in transactional sex. Transactional sex is a spectrum of economic interactions that varies from gift-giving to formal commercial sex work.[2] Factors such as age difference[3] and power disparity[2,4,5] between couples exist in most transactional sex situations. In some cases, sex work is the only source of family income, while in others, women use informal-transactional sex to supplement income or to augment social-status or material gain.[6] Transactional sex may be situational or temporary, associated with acute shortfalls in cash, need for school fees or food insecurity.[7] The prevalence of transactional sex varies by country and urban context in sSA,[8] with approximately 11.8% of girls and adolescent females reporting some exchange of sex for material goods in Uganda.[9-11]

Young women aged 15- to 24-years old involved in transactional sex work must be considered one of the highest risk populations in high HIV prevalence countries.[12,13] Globally, female sex workers (FSW) of all ages are over 10 times more likely to be infected with HIV than women in the general population.[14] In sSA in 2012, the average HIV prevalence among FSW was greater than 35%.[14] Throughout the world, 20-40% of sex workers enter sex work as adolescents with a mean age of entry of 16 years, and those under 16, new to sex work are much more vulnerable than their older colleagues to violence, STIs and HIV.[15-21] The illegality of sex work in Uganda further enhances the risk these young women face. Young people in Uganda have an HIV prevalence of 3.7% nationally,[22] yet young FSW have about a four to seven times higher prevalence of HIV.[22,23] Despite rising numbers of young FSW and their recognized vulnerability, there have been very few interventions globally that have targeted this group.[21]

Adolescent and young women in Uganda are highly vulnerable to HIV, unplanned pregnancy and poor reproductive health outcomes. Adolescents are at especially high risk of maternal mortality, miscarriage and other complications in pregnancy.[24] Young Ugandans have less access to health services than adults, and even less so to HIV prevention

and care services.[25] Awareness of and knowledge about HIV transmission, reproductive health and contraceptive methods are poor among HIV-positive adolescents.[10,11] The large and growing population of young Ugandans face a range of social, economic, and health challenges,[26,27] yet their concerns may sometimes be overlooked in health agendas and programs.

This project is set within the Good Health for Women Project (GHWP), a study set up to investigate HIV and STI epidemiology and to enhance prevention strategies among women involved in high-risk sexual behavior in Kampala which has provided important data on the prevalence of HIV among this population and barriers faced by the young women engaged in high risk sexual activity. In 2011, the GHWP reported an HIV prevalence of 37%, among a cohort of 1,027 FSWs; of these, only 58% knew their HIV status at time of enrolment; 53% reported consistent condom use with paying clients in the last month.[28] Other studies have reported similar HIV prevalence and found young age to be a strong predictor of greater vulnerability to HIV, STI and violence.[15-21] [28,29] GHWP results have shown high rates of STI,[30] the complexity and risks associated with sex work location, young age and FSW capacity to reduce harm,[6,29] how gender inequities have led to sex work and limited FSWs' ability to protect themselves.[31] Currently, GHWP participants 15-24 years old have an HIV prevalence of 28% and 24% report consistently using condoms. HIV incidence was 3.66/100 person-years (PY) and declined from 6.80/100PY in the first calendar year of the study enrollment.[29] HIV/AIDS is now the leading cause of death for women aged 15–29 years in sSA.[32-34] There is a dearth of evidence for effective interventions to increase HIV testing, prevention, adherence, retention in care amongst adolescents.[33,34] It is widely recognized that adolescents are difficult to reach as they often fall between pediatric and adult care.[35,36] To adequately reach youth, integrated structural, behavioral and biomedical, multi-level approaches will be required. Thus, combining biomedical approaches such as PrEP and HIV self-test with a prevention package, including behavioral and structural components as part of a comprehensive approach delivered by peers and counselors, could help to reduce HIV infection in young sex workers in diverse settings worldwide.[37]

Trials among different high-risk populations have demonstrated high efficacy of tenofovir-based PrEP in reducing HIV transmission.[38,39] [40]Thus, the 2015 WHO guidelines recommend PrEP for HIV-negative partners of HIV-infected individuals or populations engaged in high-risk behavior in settings with ≥3% annual HIV

incidence.[41]. A recent study in South Africa and the US reported that adherence to daily PrEP is more difficult for younger populations, and low adherence was associated with decreased efficacy in all PrEP trials. [42] Barriers at the individual level included limited familiarity with antiretroviral-based prevention, stigma, storage, and social support, as well as structural hurdles including healthcare financing for PrEP, healthcare provider bias and ease with PrEP drugs, and the lack of youth-friendly health services. In its 2016 Consolidated Guidelines for HIV Prevention and Treatment, Uganda has approved PrEP for demonstration and pilot studies specifically for high-risk populations such as sex workers.[43]

HIV self-testing (HIVST) was recommended by WHO in the 2014 comprehensive HIV care guidelines, and HIV testing guidelines from the Uganda Ministry of Health (2016), for use in demonstration projects. HIVST is defined as an individual performing and interpreting his/her own HIV test[44,45]. It has the potential to be implemented at a wide scale with a minimal requirement for trained health-workers, and would thus be highly suited for FSW with low access to services. In addition, it is convenient since individuals perform HIVST in their own time, without having to present to a clinic at fixed hours. HIVST has been shown to be acceptable in a wide array of populations globally [46-54]. It has recently been assessed in a number of settings in sub-Saharan countries, where it was found safe and accurate among the general population. Interest and acceptability in self-testing (HIV ST) is highest among high-risk groups[55-57]. In Malawi, 92% of adult participants in a high prevalence setting opted for supervised self-testing over provider-delivered tests.[58] Respondents from a range of studies report that self-testing would reduce HIV testing stigma, a significant barrier to testing among young people. We will adapt a protocol that is being tested in Kenya among adult sex workers in Nairobi and Kisumu that found a high (98%) acceptance, gave accurate results and helped linkage to care. HIV ST could increase convenience and confidentiality, which are important testing barriers and can be especially useful for repeat testing in high HIV prevalence and incidence groups who may not visit health facilities regularly for long-term follow-up.[56,57,59,60] Repeat HIV self-tests can be empowering, can be a motivator to remain healthy and HIV-free, and can fit perfectly with PrEP. The Kenyan FSW study found that peers were able to assist with the tests, found no reports of harm, and that tests were empowering to users and can be cost-efficient.[61]

Peer educators (PE) have an important role in health promotion for HIV prevention and PrEP**.** Numerous studies

have demonstrated that young people want information especially from trusted sources such as health care providers or teachers.[62,63] Acting as a bridge between communities and health facilities, Peer leaders and peer educators s can provide education, expedite access to the clinic, and promote adherence to health recommendations. Studies in Uganda have shown that community members view PE as knowledgeable and trustworthy in matters of health and would seek their advice if they had a medical problem.[64] Using peers in studies among young people have revealed that peer support as part of a comprehensive strategy to provide cognitive-behavioral counseling by a trusted adult has been effective.[65] Identifying effective strategies for improving uptake of adolescent HIV testing and re-testing for high risk groups[66] as well as successful uptake and adherence to effective prevention means including PrEP is critical for the survival of high risk youth and for the prevention of onward HIV transmission. This study could play a key role in understanding the complex connections between high risk sexual behavior, sexual relationship dynamics, socio-cultural relationship bargaining and sexual partnership decision-making that result in protected and unprotected sex in this highly vulnerable population. It will also help designing more effectively tailored interventions for HIV prevention and treatment for YWHR. Combining effective biomedical, behavioral and structural approaches is of key interest to Uganda's Ministry of Health as a potentially efficient way to reach marginalized populations at high risk for HIV acquisition. We propose to develop and pilot test a multi-component intervention to improve uptake and adherence to PrEP and repeat HIV self-testing by HIV-negative YWHR 15- to 24-years old who are highly vulnerable to STI and HIV in Kampala, Uganda. We hypothesize that, combined with knowledge, skills and health-related self-efficacy, access to PrEP and HIV self-testing will act synergistically to prevent HIV and improve health outcomes of YWHR. Targeting young women who are initiating sex work will enable us to understand ways to enhance the potential impacts of a combined structural-behavioral intervention on health outcomes to be tested in a larger clinical trial. The study will provide important evidence to inform Uganda's HIV counseling and testing policy for adolescents and key populations, and will offer essential information for other countries striving for UNAIDS 90-90-90 target. In sum, this study could play a key role in understanding the complex connections between high-risk sexual behavior, sexual relationship dynamics, socio-cultural relationship bargaining and sexual partnership decision-making that result in protected and unprotected sex in this highly vulnerable population. It will also help designing more effectively tailored interventions for HIV

prevention and treatment for YWHR.

B. RATIONALE

Targeting young Ugandan women at high risk for HIV (YWHR) and their social and sexual networks represents an innovation over traditional individual, partner or age-limited categories. Descriptive data that have been gathered on adolescent and young women engaged in high risk sexual activity in high HIV prevalence settings in sSA, though limited, reveal that they remain one of the most neglected, vulnerable, and underserved populations with regards to sexual and reproductive health (SRH) and HIV prevention services.[67,68]

Combining the network and peer-led approaches that together put HIV combination prevention fully in control of women by using PrEP and repeat HIV self-tests may increase empowerment, acceptability, and penetration into networks and ultimately increase effectiveness in reaching this highly marginalized population. We believe it is key to focus our intervention on these women as soon as possible after they enter the sex trade in order to effect primary HIV prevention rather than wait until they attend the clinic after they may have already been infected. Preceding the design and pilot of our intervention with an in-depth qualitative formative phase will allow us to optimize the early identification of these women in their community, the delivery of interventions and the design of our study based on a more thorough understanding of the location, mobility and networks of young women at risk in Kampala.

We propose to use an innovative approach to linking HIV-negative YWHR to PrEP. Our participatory co-design approach is to engage YWHR in dialogue with researchers to co-develop intervention content and materials that are responsive to the needs of the target group. We propose to use established co-design strategies to refine aspects of the intervention and related materials to tailor them to our population. We will engage in conversation young women who represent the intervention target population as well as individuals with biomedical, and program expertise and experience with ‘communities’ who do not generally meet and discuss together. This participatory design process will ensure YWHR the opportunity to engage meaningfully in designing an intervention that is responsive to their needs and concerns.

Our study will be the first to use HIV self-tests for repeat testing among YWHR in sub-Saharan Africa. Few adolescent friendly services are available in Uganda, and stigma towards adolescent sexuality is pervasive among health workers. Self-test is a novel option that may allow a substantial proportion of these women to retest with the

help of a trained peer. There are limited data available on self-testing among similar groups, but what exists show a high level of acceptability[69] and low levels of social harm.[70,71]

HIV testing in urban hotspot areas will enhance effectiveness of these strategies in complex contexts and social environments, and will help overcome two key challenges of PrEP delivery; (1) identifying the most vulnerable communities to use PrEP and (2) enhancing adherence through repeat self-tests in a very high-risk population. It is premised on the hypothesis that offering acceptable strategies for HIV retesting by YWHR coupled with motivation to remain HIV negative through a peer-led community-engaged approach using a PrEP/repeat self test will empower YWHR to adopt risk reducing behavior**.**

C. AIMS

We propose to design and refine key elements of our intervention components in order to maximize the probability of success in a definitive trial. The goal of the study is to develop and pilot test a multi-component structural and behavioral intervention targeting HIV-negative young women (15- to 24-years old) who engage in high-risk sexual activity in Kampala, Uganda, in order to increase uptake of, and adherence to combination HIV prevention services using PrEP, HIV self-tests, condoms and family planning. As currently conceptualized, the planned intervention will be delivered in two group sessions followed by two one-on-one counseling sessions. We will conduct the study in three integrated phases over 3 years:

Phase 1: will consist of formative research to enhance our understanding of barriers and opportunities for PrEP and HIV testing uptake and adherence as well as to better understand the dynamics of the social and sexual networks, mobility and context of young women (15- to 24-years old) engaged in high risk sexual behavior in Kampala, Uganda. In our current R01 study (A Cognitive Behavioral And Structural HIV Prevention Intervention for Young Ugandan Sex Workers) we have found that hot spots are not static and must be identified regularly with the input of key informants who are peers of our target population. We will collect qualitative data using in-depth interviews and focus group discussions with key stakeholders: a) HIV-positive YWHR, b) HIV-negative YWHR, c) male partners of YWHR, d) peer educators, e) health workers and f) policy makers (including ministry of health officials). The objective of these discussions will be to identify the opportunities and multiple levels of barriers to specific HIV prevention services as well as the acceptability, feasibility, challenges to our preliminary intervention

components (Table 1). We will examine our planned approach with respect to social and cultural relevance as well as necessary resources, and how to operationalize the intervention components most efficiently considering existing services, the knowledge, capacity and attitudes of potential participants, as well as the different contexts they are living in (eg cramped shared housing; high mobility). We will use participatory co-design methods to produce and pilot a training curriculum and associated materials for use in intervention group sessions. These materials will be refined with input from a youth advisory board (YAB) in a second series of focus group discussions with members of the target population.

Phase 2: Will be informed by Phase 1. We will conduct a small pilot RCT study (N=60) to assess the feasibility, acceptability, and preliminary effects of the intervention on PrEP uptake and adherence.

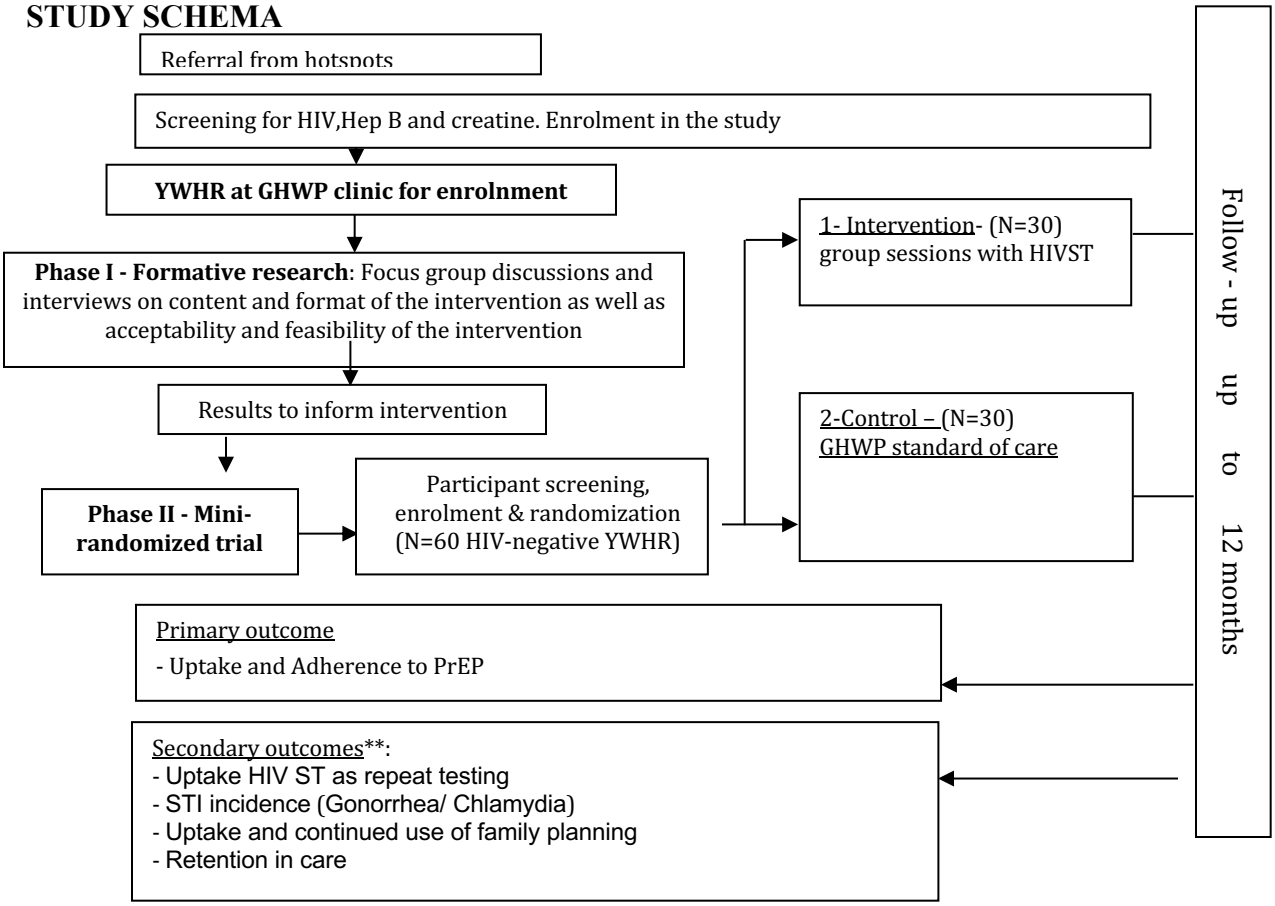
Phase 3: We will review qualitative and quantitative data on intervention feasibility, acceptability and potential effectiveness from Phase 2 in collaboration with the Community Advisory Board (CAB) and Youth Advisory Board (YAB) to seek consensus about refinements to be made for formulating an R01 application to assess the efficacy of the intervention in a larger RCT. The setting, conceptual framework and activities of each phase are described below.

D. STUDY DESIGN AND METHODS

OVERVIEW OF STUDY DESIGN

In this pilot study, we propose to conduct formative research and then develop and evaluate a combination prevention intervention through a randomized controlled trial comparing intervention vs GHWP care among high-risk young people.

STUDY SCHEMA



Phase III – Develop R01

D.1 Study setting

We will conduct this study at the GHWP Clinic in Kampala. The GHWP clinic is located in a densely populated slum area of southern Kampala with retail shops and roadside kiosks selling general merchandise, and bars, which are the main hotspots in the area. The current HIV prevalence among women in the cohort who are 15-24 years is about 31% and 38% in all participants. The GHWP clinic currently provides mobilization, testing and counseling, and ART.[28,72] At GHWP, all eligible participants receive HIV care and treatment, including ART, in accordance with Uganda MoH Guidelines. Peer educators associated with the clinic visit YWHR to provide information, education and referral related to uptake and retention to clinic services according to established visit protocols. The existing GHWP infrastructure, highly skilled staff, and proven recruitment system[31,73,74] are strong assets to this study. Participants will be recruited from hotspots (generally bars and lodges) in Kampala according to established and tested protocols. The clinic currently provides free medical and counseling services, free male and female condoms, HIV and STI testing and treatment to all high risk women, their partners and their children under 5 years

of age. GHWP has over 4358 enrolled FSW, 36% of whom are under 24 years of age, and enrolment is open and ongoing. However, currently there are limited specialized services for *young* women engaged in some form of transactional sex at GHWP apart from our parent study (NIMH R01 HD085805-01 PI King**)** and neither PrEP nor HIV self-testing are currently offered as standard services.

D.2 Intervention Components

The content and structure of the intervention will include at a minimum 2 group sessions and 2 counseling sessions with YWHR (Table 1), which will be facilitated by trained peers and counselors. Group sessions will be limited to 8 participants, last about 2- 3 hours, be participatory, youth-centered and include modeling, role plays, story-telling, and body-mapping – all strategies that we have previously found to be highly engaging with young people and lower literacy populations. As our population has low literacy, our techniques will be highly visual to ensure accessibility to information and avoid stigmatizing participants who cannot read. Sessions will be conducted in Luganda and/or English at the clinic, as it is comfortable and private and is where we conduct the intervention for our current R01. The clinicians will be blinded to the intervention. Google mapping of hotspots will be done at every scheduled visit . This intervention format will be revised based on findings of Phase 1 formative research

INTERVENTION FLOW DIAGRAM

Table 1: Intervention Components

Screening: HIV counseling and testing either in the community hot spots or in the clinic followed by:

TWO GROUP SESSIONS covering multi-level factors *informed by formative phase and parent study*:

1. **Health empowerment**: Barriers and strategies for health seeking, benefits, process and efficacy of PrEP, adherence support guidance, safer sex, HIV and reproductive health including STI prevention and treatment, family planning, child spacing & contraceptive methods; *Curriculum to be drawn from existing resources (current R01 + PrEP demonstration project; Dr Katabira)*
2. **Initiating daily PrEP** following MOH guidelines (300mg TDF + 200mg FTC)
3. **Social/Contextual empowerment**: building a support network using SMS reminders designed by peers from parent study; focusing on gender and social norms; training in HIV self-testing; exploring issues around education and life ambitions, vocational training and alternative livelihoods; *To be drawn/adapted from existing curricula*

TWO INDIVIDUAL COUNSELING SESSIONS covering:

Personal history; cognitive behavioral therapy (CBT) as relevant ; HIV/STI transmission risk at multiple levels; Uptake of PrEP, safer sex, family planning, violence prevention ; Adherence to PrEP, safer sex, family planning, clinic visits; Remaining HIV negative: re-testing using HIV self-test; Exploring education and life ambitions, and alternative livelihoods

D.3 Procedures - Phase 1

D.3.1 Conduct facility site assessments to assist future randomization procedures and power calculations.

As part of Phase 1 and during the first year of the R34 project, a field team will conduct detailed mapping of all current hot spots for young women in urban Kampala including areas where high-risk youth congregate with their social networks. Ten communities with separate catchment areas and similar baseline characteristics will be identified as study sites (for the future R01 application) through qualitative and quantitative data collection using a mapping protocol that we have used in previous studies.[75] Briefly, this protocol involves showing the participant a map of Kampala on Google-Maps and them pinning their hotspot(s). In-depth and key informant interviews and focus group discussions will assess acceptability, feasibility, challenges and potential uptake of the proposed strategies. We will examine the social and cultural relevance and how to operationalize the procedures considering the knowledge, attitudes and context of the target population. The maps will be kept highly confidential and anonymous in a locked cabinet in the study office. Only study IDs will be used; no names and no telephone numbers will be connected to study participant information. In addition, we will collect information on predefined criteria (e.g. number and ages of potential participants at a given hotspot at the time of the visit, willingness to be enrolled, location, description of site [e.g., bar, lodge], and availability of space suitable for outreach testing). Site assessments will also serve as an opportunity for mobilization team to familiarize themselves fully for a smooth transition from the pilot to the proposed RCT. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify the participant. At most, the web site will include a summary of the results.

D.3.2 Qualitative data collection on risk, barriers to HIV prevention services and intervention content.

Table 2: Qualitative Data Collection

Group	Topic		Method	# participants
	Risk	Intervention		
HIV negative YWHR	x	x	FGD, Interviews	8x2= 16 8
HIV positive YWHR	x	x	FGD, Interviews	1x8=8 8
Peer educators		x	FGD	8
Male partners	x		FGD	8
Key Informants (health workers, policy makers)		x	Interviews	8
TOTAL				**64**

Focus group discussions will be organized with HIV negative and positive YWHR, Peer Educators, male partners and other key stakeholders (Table 2) to inform the content and form of the intervention group discussions. The discussions will be held in the clinic and notes will be taken immediately. With YWHR, discussions will assess both the areas of risk behavior and barriers to accessing HIV prevention services as well as feasibility, acceptability and refinement of the intervention design and materials to be used in the next phase as well as documenting most relevant strategies for the target group. Discussions will focus on possible pathways of effectiveness such as

knowledge, social support, motivation and skills. With PE and other key informants, the discussion will focus on topics surrounding how to develop and implement the intervention in the most effective, targeted manner. With YWHR, PE and key informants, we will explore the following alternatives to simple self-report through group discussions and interviews with participants:

1) Assisted ST; at the time of receiving the HIV ST, participants will be offered to perform it in the presence of their counselor who can then directly counsel the participant according to her questions and/or test result

2) Delivery of the HIV self-test (ST) result strip into a labeled box just inside the clinic gate; each HIV ST strip will have a bar code on it and participants can drop their strip into the box as they enter or exit the clinic. At enrolment, these procedures would be explained in detail

3) Participants with phones can report their HIV ST experience on a four-question phone-based short messaging system (SMS) survey: (Did you use your test? Was it easy or difficult? Would you use it again? Would you like help?) and upload their responses into a simple web-based portal. We are using web-based portals in other studies as well as on a national level for Ugandan PMTCT data entry and the development and use of the portal have proven simple, user-friendly and functional [76].

D.4 Phase 2; Pilot RCT

The pilot RCT will assess intervention feasibility/acceptability and control conditions to be used in a subsequent larger trial. We will examine preliminary impact on mediators and outcomes of interest.

F. TIMELINE

Table 6: Outline of Project Activities by Year and Quarter

	Year 1 Oct 17-Sept 18				Year 2 Oct 18-Sept 19				Year 3 Oct 19-Sept 20			
Activities / **Quarter**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Planning & staff recruitment; Assemble YAB,												
Phase 1: Formative research												
Phase 2: Screening & enrolment Pilot Study												
Phase 2: Follow-up Pilot												
Phase 2: Analysis												
Phase 3: Translate results (feasibility and												

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