Randomized Controlled Trial of the Shauriana Intervention to Integrate PrEP, Sexual Health, and Mental Health Support for Gay, Bisexual, and Other Men Who Have Sex With Men in Kenya

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Contents

1. **Title**: Randomized Controlled Trial of the ***Shauriana*** Intervention to Integrate PrEP, Sexual Health, and Mental Health Support for Gay, Bisexual, and Other Men Who Have Sex with Men in Kenya

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4. **Names and Addresses of Sponsors and/or Funding Agencies:**

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5. Project Abstract: Gay, bisexual, and other men who have sex with men (GBMSM) are at high risk for HIV-1 acquisition, especially in rights-constrained settings such as Kenya, where men's access to HIV prevention has been impeded by homophobia, stigma, and discrimination. Pre-exposure prophylaxis (PrEP) has the potential to greatly reduce HIV acquisition risk in this key population if accessible, sustainable PrEP programming with tailored, effective adherence support can be provided. To this end, close collaboration between PrEP program implementers and GBMSM-led community-based organizations is essential. We have recently completed a project to identify the multi-level barriers and facilitators that influence GBMSM's ability to engage in the PrEP continuum of care through in-depth interviews with 20 peer navigators working to promote HIV testing and PrEP in the community and with 40 GBMSM with different PrEP experiences. Based on this work, we have adapted and enhanced a theory-based and culturally relevant PrEP support intervention that we named ***Shauriana*** ("we counsel each other"). The ***Shauriana*** intervention merges peer navigation and "integrated Next Step Counseling" (iNSC) to promote sexual health protection strategies, including PrEP uptake and adherence, among GBMSM in Kisumu. The present proposal aims to pilot the intervention among 10 participants for 3 months, and then to evaluate the ***Shauriana*** intervention for acceptability, feasibility, safety, and estimated effect on PrEP uptake and adherence, compared to standard of care, in a small randomized, controlled study with 60 participants followed for 6 months after enrollment. We anticipate that results of the proposed research will have high impact by ensuring GBMSM involvement in the scale-up of effective PrEP programming for this key population in Kenya and providing a peer-led PrEP support model for GBMSM and other vulnerable and marginalized populations in African settings.

6. Background:

GBMSM in the Kenyan HIV Epidemic. While GBMSM received late recognition in the African HIV epidemic,[1] numerous studies have since documented their elevated risk of HIV infection. The WHO and most countries in sub-Saharan Africa (sSA) now classify GBMSM as a "key population" at risk for HIV, and donor responses promote inclusion of GBMSM and their emerging organizations in HIV prevention programming.[2] GBMSM in sSA have 2-4 times higher HIV prevalence than the general male population.[1,3-6] In Kenya, HIV incidence among GBMSM north of Mombasa was estimated at 8.6 (95% confidence interval [CI] 6.7–11.0) per 100 person-years of observation (pyo).[7] Among male sex workers (MSW) in Nairobi, HIV incidence was 10.9 (95% CI 7.4 to 15.6) per 100 pyo.[8] In contrast, the estimated HIV incidence in Kenya overall was 0.5 per 100 pyo in the 2012 Kenya AIDS Indicator Survey,[9] highlighting the disparity in risk among GBMSM, especially among MSW. The Kenya National AIDS Strategic Plan has recognized the pivotal role that GBMSM play in the epidemic,[10] since a 2009 *Modes of Transmission study* estimated that 15% of new HIV infections were attributable to male-male sex.[11] Concordantly, the Office of the U.S. Global AIDS Coordinator recently issued its *"Technical Guidance on Combination HIV Prevention for Men Who Have Sex with Men,"*[12] highlighting the urgent need to strengthen and expand prevention interventions for GBMSM globally. This considerable support provides an important opportunity to advance research to determine how HIV prevention services for GBMSM could best be structured, including in rights-constrained settings such as Kenya and other countries in sSA.

In the past decade, numerous GBMSM-focused community organizations have been established in Kenya, especially in the Kisumu area. Umbrella organizations advocating for human rights and access to health care include the Gay and Lesbian Coalition of Kenya (GALCK) in Nairobi, and the NYARWEK (Nyanza, Rift Valley, and Western Kenya) lesbian, gay, bisexual, transgender and intersex (LGBTI) Network in Kisumu. NYARWEK advocates for 23 registered organizations, including MAAYGO (Men Against AIDS Youth Group), and several un-registered organizations in western Kenya. Kenyan GBMSM organizations have also united to form G10, a national research advisory committee that published a roadmap for enhancing and sustaining meaningful research partnerships between the "sexual orientation gender identity and expression" (SOGIE) community, researchers and donors.[13] In 2017, the Kenya MSM Health Research Consortium, of which co-Principal Investigators (co-PI) Graham and Harper are members, trained 27 LGBTI community members on research literacy and ethics; in addition, Dr. Harper trained 25 GBMSM on qualitative research and interviewing skills.

7. Literature Review:

PrEP Delivery to Kenyan GBMSM. The potential impact of daily PrEP with tenofovir-emtricitabine (TDF-FTC) on high-risk populations was demonstrated in the 6-country iPrEx trial, which enrolled 2,499 GBMSM and transgender women, reporting a 44% reduction in HIV acquisition,[14] with up to 90% effectiveness among participants who had measurable drug levels.[15] Overall, PrEP studies have demonstrated effectiveness at reducing HIV infection risk for rectal exposure (relative risk [RR] 0.34, 95% CI: 0.15-0.80) and in men (RR 0.38, 95% CI 0.20-0.60).[16] Repeatedly, post-trial analyses have shown that PrEP efficacy depends on drug detection in serum or tissues.[15,17] In the STRAND trial, in which doses were directly observed,

blood levels of tenofovir diphosphate (TFV-DP) achieved with daily dosing were estimated to provide 99% protection, while ≥4 doses per week were estimated to provide 96% protection.[15] In 2014, the WHO released a strong recommendation to include PrEP as an option in combination prevention packages oriented to GBMSM.[18] In the same year, Kenya incorporated PrEP for key populations into its HIV Prevention Revolution Road Map.[19] Soon afterwards, the Kenya Pharmacy and Poisons Board approved PrEP for HIV prevention,[20] and Kenya officially adopted PrEP in early 2017 as part of combination HIV prevention for individuals at substantial ongoing risk, specifically including GBMSM.[21] Kenya's commitment to PrEP expansion presents an opportunity to conduct research on the effectiveness of this intervention in specific target groups such as GBMSM, as access is now a reality and there is a commitment from the Government of Kenya and several funders to support PrEP availability for this group for the foreseeable future.

Experience is now accruing on PrEP use among Kenyan GBMSM. For example, one small Kenyan trial of intermittent PrEP enrolled 62 GBMSM and demonstrated high acceptability.[22,23] Median adherence to daily PrEP using electronic monitoring was 80% in this study.[24] Lower adherence was associated with travel, transactional sex, and longer follow-up; higher adherence was associated with assignment to daily dosing and higher income.[24] A recent study in Nairobi and Kisumu found that 83% of enrolled GBMSM were willing to take daily PrEP, with higher willingness among bisexual and younger men.[25] While men were motivated to stay HIV negative and protect their partners, a history of poor medication adherence, fear of side effects, and stigma were potential barriers to PrEP adherence.[25] In early data from PrEP rollout among GBMSM on the Kenyan coast where Dr. Graham works with colleagues from the Kenya Medical Research Institute (KEMRI), 112 of 166 eligible men (69.6%) accepted PrEP at first offer and 11 of the 49 who did not initially accept PrEP (22.4%) accepted PrEP after a median of 56 days (interquartile range, 32-83 days). In multivariable analysis, factors associated with early PrEP uptake included younger age (18-24 years) (adjusted prevalence ratio [aPR] 1.3, 95% CI 1.1-1.6), self-reported receptive anal intercourse (aPR 1.5, 95% CI 1.0-2.1), payment for sex (aPR 1.3, 95% CI 1.1-1.7) and group sex (aPR 1.5, 95% CI 1.1-2.0) (Wahome, in preparation).

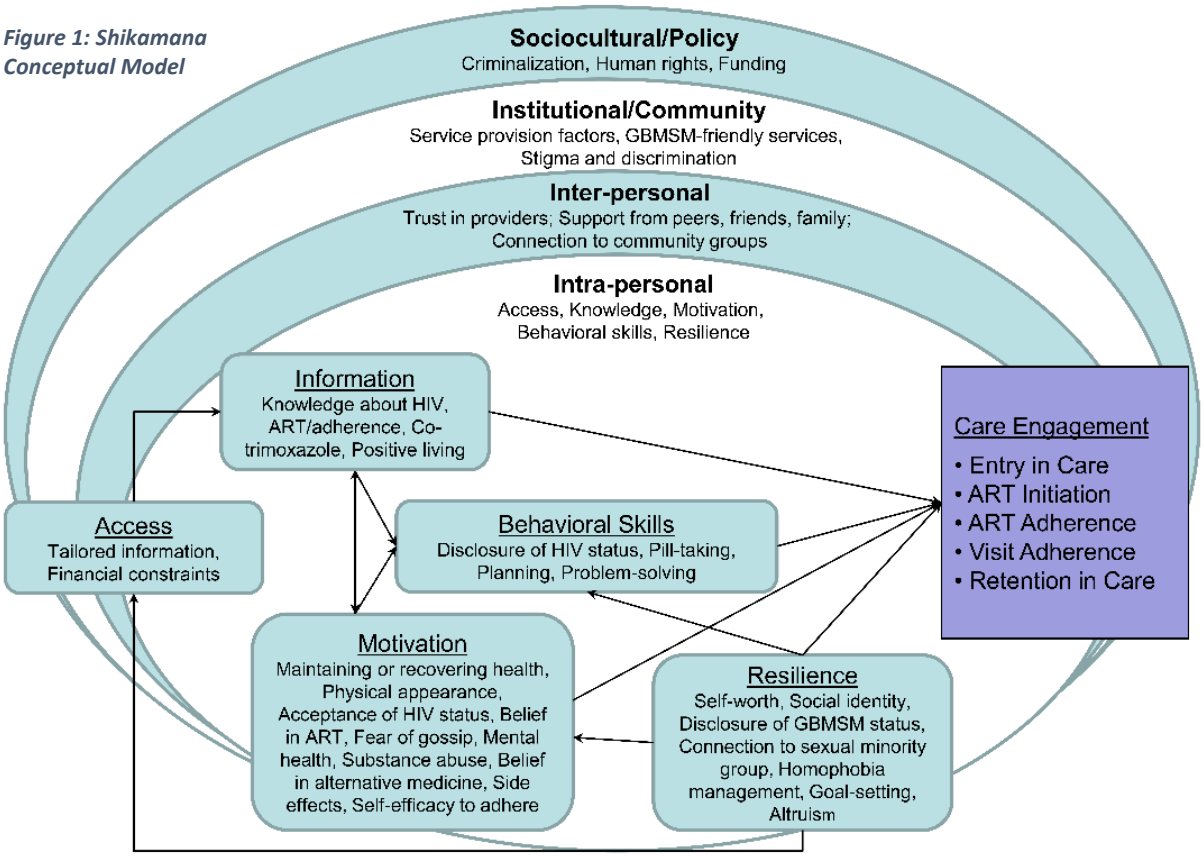
These initial data on GBMSM interest in PrEP informed the ***Anza Mapema PrEP*** cohort that was conducted by our research team in Kisumu (described below), along with several programs offering PrEP to Key Populations including GBMSM. For example, LVCT Health has supported programmatic PrEP delivery at the ***Anza Mapema*** Clinic for over 420 HIV-negative GBMSM. A separate Gates-funded demonstration project "*Bridge to Scale – Jilinde*" provided PrEP to 20,000 adolescent women, fisher folk, female sex workers, injection drug users and GBMSM in 10 Kenyan counties, including Kisumu County, over 4 years, using the same supply chain currently used for ART provision. Such programs have increased demand and availability of PrEP for GBMSM in Kisumu. However, current PrEP programs for GBMSM in Kenya rely heavily on clinic-based support groups, peer outreach workers with limited training, and standard adherence counseling by HIV care providers who often are not GBMSM affirming. This approach too often results in discussions focused on assigning a regimen dose time and informing of need for high adherence, without patient-driven or tailored exploration of potential barriers and facilitators to optimal PrEP use. While standard PrEP programming may work for some, it is clear from our initial work that a tailored approach with more GBMSM input may be required to achieve optimal GBMSM engagement in HIV prevention.

8. Previous Studies & Rationale:

Studies at the Coast, including the *Shikamana* intervention. In 2004, Dr. Graham established a pilot ART program providing treatment to cohort participants. Among 58 participants taking ART from 2004-2006, 40% of GBMSM had <95% adherence, versus 28.6% of heterosexual men and 11.5% of women.[26] Through a 3-year developmental project grant (R34-MH099946, Graham PI), Dr. Graham and the KEMRI team conducted qualitative research investigating facilitators and barriers to ART adherence among GBMSM living with HIV, and developed the ***Shikamana*** intervention to promote ART adherence.[27,28]

Shikamana (Kiswahili for "form a bond or stick together") uses motivational interviewing by counselors combined with peer support from HIV-positive GBMSM experienced in taking ART to promote ART adherence among GBMSM living with HIV. The intervention is based on a conceptual model situated in a socioecological framework incorporating factors on multiple levels that impact GBMSM access to and utilization of services (Figure 1, below). This model was based on qualitative work that demonstrated the relevance of

Figure 1: Shikamana Conceptual Model



basic concepts of an access-information-motivation-behavioral skills (access-IMB) model of ART adherence for this population. Our work demonstrated that this basic access-IMB model should be situated in a context in which stigma is a destructive influence that can be offset by contextual factors such as trust in providers and psychosocial support. In addition, resilience-related concepts such as self-worth, social identity, disclosure of GBMSM status, connection to LGBTI organizations, homophobia management, goal-setting, and altruism were important factors influencing adherence.[29] Our ***Shikamana*** intervention based on this work comprises the

following components: sensitivity training for clinicians and counselors, provider training in patient-centered care, counselor training in motivational interviewing, peer training in basic counseling and support methods, and mental health screening and support. A **provider training manual** includes counseling procedures, role-play exercises, case studies, and hypothetical problem scenarios. A **peer training manual** includes roles and responsibilities, didactic information, and role-playing exercises for skill building. Trainings were supplemented by periodic practice to reinforce skills. A detailed manuscript describing intervention development and pilot testing results has been published, along with the training manuals for peers and providers.[27]

Shikamana* results.** A pilot randomized trial to determine acceptability, feasibility, safety, and initial effect size of the ***Shikamana intervention was recently completed. Sixty men enrolled, of whom 33 (55%) were assigned to standard care including adherence counseling per Kenyan guidelines and 27 (45%) to the intervention. Eight counselors and eight peers were trained to support the intervention; one peer dropped out. In exit interviews, all intervention participants reported finding the counseling acceptable, with several ART-experienced participants noting a difference from standard counseling and a few participants mentioning specific "next steps" they worked on. Three intervention participants withdrew from the peer component for various reasons; in all cases, discontinuation did not engender problems for participants or peers. For the 24 successful peer-participant pairings (89%), acceptability was high and feedback positive. No study-related adverse events occurred. Retention (85% in both arms) and visit attendance (median 7 in both arms) did not differ. Compared to SOC, intervention participants rated higher how well they took their ART (mean 4.80/6 vs. 4.41/6, p=0.002) and how often they took their ART as prescribed (mean 5.25/6 vs. 4.83/6, p=0.001). Plasma viral load suppression was 100% in the intervention and 76.9% in the standard care control at month 3 (p=0.025) and 90.5% in the intervention and 76.9% in the standard care control at month 6 (p=0.20). **In GEE analysis adjusting for baseline suppression (<40 copies/mL), men in the intervention had an increased odds of virologic suppression at months 3 and 6 (aOR, 5.7, 95% CI 1.1-30.7, p=0.04).**[28] This intervention also had a positive impact on depressive symptoms, which may have helped mediate its impact (Graff, in preparation). *This work demonstrates our ability to develop a successful adherence intervention involving both peer and provider components and to engage with members of the GBMSM community to improve service delivery.* While successful in this small trial, the impact of this approach on PrEP adherence is unknown. The change in focus from treatment to prevention may lead to different results; as such, careful adaptation of the ***Shikamana*** materials and evaluation of the acceptability, feasibility, and safety of the resulting intervention to promote PrEP adherence and sexual risk reduction is required.

Studies among GBMSM in Kisumu. In 2010, NRHS completed a respondent-driven sampling study of GBMSM in Kisumu, in collaboration with NASCOP, Population Council, and University of Illinois at Chicago. From 11 original seeds, 415 men aged 18-62 years who reported oral or anal sex with another man in the last 6 months were recruited. HIV prevalence was 4.2% among 18-19 year-olds versus 28.9% among 25-29 year-olds, highlighting the need for prevention in young GBMSM. Factors associated with HIV infection were older age, herpes seropositivity, male sex clients, and unprotected sex with the most recent female partner,[30]

indicating that risk reduction for GBMSM must focus not only on same-sex behavior, but also on sex with female partners. Before and during this work, NRHS founded a support group for GBMSM, called *Kisumu Initiative for Positive Empowerment* (KIPE), which rapidly grew to ≈200 active members. During 2011, KIPE provided HIV counseling and testing to 740 GBMSM in the greater Kisumu area, referring HIV-positive men to an ART clinic run by NRHS or an ART provider of their choice.

This work formed the basis for the CDC-funded ***Anza Mapema*** (Kiswahili for "start early") demonstration project (U01GH000762, Otieno PI, Graham and Bailey co-investigators), which aimed to: 1) find and test 700 GBMSM for HIV; 2) link and retain HIV-positive GBMSM in HIV care including ART; and 3) link and retain HIV-negative GBMSM in an HIV prevention program including quarterly HIV testing and counseling. ***Anza Mapema*** participants were followed for 12 months and benefitted from risk reduction counseling, condoms and lubricants, sexually transmitted infection (STI) screening and treatment, and post-exposure prophylaxis (PEP) as indicated, with ART for HIV-positive participants. In addition, social events such as theatre, movie nights, spiritual meetings, and "Coffee Wednesday" meetings to promote reduction in substance use were offered. Between 8/31/2015 and 9/17/2016, 713 men enrolled, the vast majority of whom (636, or 89%) were HIV-negative.[31] Of note, 36% reported no transactional sex and 24% reported only occasional transactional sex, making this cohort more representative of GBMSM who are not sex workers than most Kenyan cohorts. **Overall, retention is the *Anza Mapema* study was 83% at the month 12 visit.** This retention is high given a young, mobile population with frequent travel in search of work. Twelve ***Anza Mapema*** participants seroconverted during follow-up (≈2.3 cases per 100 pyo). Among men reporting condomless anal intercourse (CAI) at baseline (29%), HIV incidence was ≈4.6 per 100 pyo. Overall, willingness to use PrEP was high (92.3%) and did not vary by risk behavior (unpublished data).

Despite improved access to non-PrEP HIV prevention services in ***Anza Mapema***, only interventions including PrEP are likely to bring HIV incidence below the reproductive threshold in this population. After the main study ended, the ***Anza Mapema PrEP*** cohort enrolled 167 men to receive PrEP services in line with current Kenyan recommendations for key populations,[19] enhanced by the social activities described above. This demonstration program, funded by *Evidence for HIV Prevention in Southern Africa (EHPSA*), aimed to provide evidence on PrEP adherence over 12 months of follow-up, and is cited as part of NASCOP's *Framework for the Implementation of Pre-Exposure Prophylaxis in Kenya*.[21] HIV-negative MSM ≥18 years were enrolled if they reported recent unprotected anal sex, ≥3 male sex partners, STI, transactional sex, or injection drug use. All participants were offered PrEP at baseline, with adherence counselling at each visit. Follow-up occurred at week 2; months 1, 2 and 3; then quarterly for 1 year. Adherence was measured by visual analogue scale (VAS) and qualitative self-rating. Dried blood spots were collected at months 3 and 9 for TFV-DP testing. Generalized estimating equations (GEE) with robust variance were used to detect associations with (1) TFV-DP detection and (2) protective TFV-DP levels (≥700 fmol/punch, compatible with ≥4 weekly doses).

DBS were provided at 275 visits by 161 participants. At baseline, median age was 26, 46.6% reported unprotected anal sex, 86.5% reported ≥3 male partners, 9.8% reported a recent

STI, 66.3% reported transactional sex, and 5.5% reported injection drug use. Median VAS adherence was 98% (IQR 90%-100%), and men reported taking PrEP "most" or "all of the time" at 89% of visits. DBS results showed no detectable TFV-DP at 178 visits (64.7%), and protective TFV-DP levels at only 28 visits (10.2%). In GEE analysis, age, education, occupation, sex with female partners, injection drug use, depressive symptoms, social support, and time were associated with one or both outcomes in bivariable analysis. Only time was associated with TFV-DP detection in multivariable analysis (adjusted odds ratio [aOR] 0.84, 95% confidence interval [CI] 0.78-0.90 per month). Increasing age (aOR 1.12, 95% CI 1.04-1.21), sex with a female partner in the past 3 months (aOR 3.98, 95% CI 1.33-11.9), and lower social support score (aOR 0.97, 95% CI 0.95-0.99) were associated with protective TFV-DP levels in multivariable analysis (Graham, in preparation).

Thus, the ***Anza Mapema*** PrEP sub-study demonstrated that uptake and adherence to PrEP among GBMSM was much lower than desired. Despite high reported adherence, drug levels were undetectable in most participants, and only 10% had protective levels. These results suggest that PrEP adherence is not aligned with risk among GBMSM in Kenya, and that tailored interventions to address PrEP adherence in this population are urgently needed.

Strengthening HIV Prevention for Kenyan GBMSM. Optimizing comprehensive HIV prevention including PrEP delivery requires programs to reach a diversity of GBMSM, including men of different ages, backgrounds, sexual identities, degrees of outness, behaviors, and sex work status. Based on qualitative data about men's concerns,[23,25] GBMSM need skills for problem-solving, developing pill-taking routines, getting on-time refills, sustaining commitment to adhere, disclosing PrEP use, and combatting stigma.[25] Tailored counseling and education on HIV transmission, use of condoms and lubricants, and STI risk is needed while delivering PrEP to GBMSM, to promote comprehensive sexual health.[32] Many of the concerns raised by GBMSM in PrEP-oriented studies of barriers and facilitators are remarkably similar to those raised in the qualitative work used to design the ***Shikamana*** intervention to promote ART adherence,[27,29,33] and are at least partly addressed in the ***Shikamana*** counselor and peer training materials.[27] Our goal with the proposed work is to adapt the ***Shikamana*** intervention from its focus on HIV treatment and enhance and reinforce it for comprehensive HIV prevention including PrEP adherence and sexual risk reduction, through work in collaboration with our GBMSM community partners. Based on our experience with ART adherence promotion and preliminary work on PrEP scale-up, additional intervention components to foster resilience, address stigma, and promote healthy sexual identity development will likely strengthen the intervention and provide more benefit. By providing tailored, affirming support to GBMSM throughout the PrEP care continuum, the proposed research could increase the reach and optimize the impact of HIV prevention services for a high-risk, vulnerable population that has until recently been ignored.

Recent qualitative work. In 2019, our team conducted a series of interviews with 20 peers providing support to GBMSM, as well as 40 GBMSM in the Kisumu area who were purposively samples from the following groups: PrEP-experienced men currently taking PrEP, PrEP-experienced men who have stopped taking PrEP, PrEP-naïve men interested in taking PrEP, and PrEP-naïve men who have no interest in taking PrEP. This work, which was conducted as protocol MSU/DRPI/MUERC/00637/18, had the following aims:

Aim 1: To identify multi-level barriers and facilitators that influence GBMSM's ability to engage in the PrEP continuum of care by examining socioecological factors that impact Kenyan GBMSM's lives, including sexual and PrEP-related stigma, sexual health promotion, and resilience, through qualitative work with PrEP-experienced and PrEP-naïve GBMSM and peers engaged in HIV testing/counseling or PrEP programming.

Aim 2: Following steps 1-6 of the ADAPT-ITT model (assessment, decision-making, adaptation, production, expert review, and integration of feedback)[34] in collaboration with our GBMSM community partners, to adapt and enhance a theory-based and culturally relevant PrEP support intervention that includes peer navigation and "*integrated Next Step Counseling*" to promote sexual health protection strategies, including PrEP uptake and adherence, among GBMSM in Kisumu.

The project team has successfully conducted its Aim 1 qualitative work and has successfully used the ADAPT-ITT process to create a new intervention, called ***Shauriana*** (Kiswahili for "to consult one another"). The ***Shauriana*** **Project** team consists of a close collaboration between our research team and NYARWEK, a GBMSM-led community-based organization based in Kisumu. Trained GBM community members from NYARWEK conducted in-depth interviews with 20 peer educators and 40 community members with and without PrEP experience to identify multi-level barriers and facilitators that influence GBM's ability to engage in the PrEP continuum of care. These interviews examined socioecological factors that impact Kenyan GBM's lives, including sexual and PrEP-related stigma, sexual health promotion, and resilience. In addition, we held a community meeting with 51 representatives from GBM- and sexual minority-led organizations, to identify the barriers and facilities they have noticed in their work on HIV testing and counselling or PrEP programming in the Kisumu area.

Feedback from the interviews and community meeting identified a number of barriers and facilitators influencing GBM's PrEP engagement. Barriers to PrEP awareness included stigma and discrimination, mistrust and myths, and lack of tailored information. Barriers to uptake included fear of side effects, fear of disclosure, the perception that PrEP was only for sex workers and promiscuous individuals, poor ownership, and a feeling of "coercion" by programs perceived as only interested in numbers. Barriers to adherence included forgetting, side effects, pill burden, problems obtaining refills, negative interactions with providers or peers about PrEP, and challenges with substance use. Facilitators to engagement across the continuum included tailored information, feeling safer due to PrEP, support from partners and PrEP champions, theatre and drama with testimonials about personal experiences, community ownership and advocacy, and rapport with GBM-friendly providers and services.

In summary, multiple barriers have limited GBM engagement in the PrEP care continuum, and there is poor community ownership of this intervention. Community-focused efforts and increased ownership are therefore key to improving PrEP engagement by GBM. These results are being used by the team to adapt and enhance a theory-based and culturally relevant PrEP support intervention to combat stigma and promote a more holistic approach to sexual health, including but not limited to PrEP uptake and adherence, among GBM in Kisumu.

9. Research Questions: The current study's research questions are as follows:

1) Will the ***Shauriana*** intervention be acceptable, feasible, and safe?

2) What effect will this intervention have on PrEP uptake and adherence, compared to standard care?

10. Study Objectives/Aims:

Aim 1: To pilot the ***Shauriana*** intervention among 10 participants for 3 months, in order to ensure that intervention and study procedures are optimized.

Aim 2: To determine the acceptability, feasibility, and safety of the ***Shauriana*** intervention and estimate initial effect size compared to standard care on PrEP uptake and adherence assessed by drug levels over 6 months in a pilot randomized controlled trial (RCT).

11. Description of the Study Areas/Regions, Design, Materials and Methods:

Study Sites. Sites engaged in research include the University of Washington, the University of Michigan, Nyanza Reproductive Health Society (NRHS), and the Nyanza, Rift Valley, and Western Kenya LGBTI Network (NYARWEK). Participant recruitment will occur through the NYARWEK Network. Enrollment, all study visits, and clinical care, including PrEP services provided according to the most recent Kenyan Ministry of Health guidelines, will take place in private rooms at the ***Anza Mapema*** Clinic. Intervention delivery will take place at NYARWEK, at private sites used by NYARWEK organizations, or at a meeting space agreed upon and deemed private and safe by both the participant and a ***Shauriana*** peer facilitator trained to deliver the intervention. In-person research team meetings to monitor the study will also be held in private rooms at the ***Anza Mapema*** Clinic, NYARWEK, or at private sites used by NYARWEK organizations. A description of each site's facilities and other resources are included in "Appendix B: Facilities & Other Resources."

Study Population. The proposed Aim 1 pilot will include 10 adult HIV-negative GBMSM. The proposed Aim 2 intervention trial will include a population of 60 adult HIV-negative GBMSM, all of whom will be recruited in Kisumu, Kenya. The study team and peer facilitators trained to deliver the intervention will also participate in data collection, by providing feedback on intervention feasibility at routine study team meetings that will be minuted.

Study Design. The Aim 1 work will be a prospective pilot of the intervention and of study procedures other than laboratory testing, in a small group of 10 men over a 3-month period, with visits at baseline, month 1, and month 3. During this pilot test, intervention and clinic visit procedures, including data collection tools, will be revised and improved as needed according to feedback on feasibility, comprehension, burden on participants, and acceptability among pilot participants. The Aim 2 work will be an RCT of the final ***Shauriana*** intervention, to test its acceptability, feasibility, and safety and estimate its initial effect size compared to standard care. The final phase of this study will consist of data analysis and dissemination activities.

Recruitment. Subjects for the Aim 1 Pilot and the Aim 2 intervention trial will be recruited using existing NYARWEK peer networks, snowballing and venue-based referrals. All interested and potentially eligible subjects identified by the NYARWEK team will be given a business card of

the NYARWEK peer facilitator they were in contact with and referred to the ***Anza Mapema*** clinic for eligibility screening.

Enrolment targets are presented in Table 1. If a participant tests positive for HIV infection at baseline or at any follow-up visit, he will be withdrawn from this study and undergo counselling and referral to the HIV clinic of his choice. Participants who withdraw before or test positive at the month 1 visit will be replaced; replacement participants in the RCT will undergo randomization and not necessarily be assigned to the arm to which the participant they replace was assigned.

Table 1. Overview of Participant Enrolment

Stage	Pilot Test (Aim 1)	Feasibility RCT (Aim 2)
Purpose	Standardization of intervention	Initial testing of feasibility, tolerability, acceptability, and safety; estimate of effect size
Group	10 HIV-negative GBMSM participants	60 HIV-negative GBMSM participants

Eligibility Screening. A brief permission script will be used to confirm consent for screening. Basic sociodemographic data (age, sex), a brief risk behavior assessment, and reasons for screening out or failing to enroll will be noted. Men who are found to be ineligible will be referred by ***Anza Mapema*** staff to HIV prevention or care programming as indicated, including risk reduction counseling, condoms and lubricants, STI screening and treatment, programmatic PrEP if eligible and interested, and HIV care for men who self-report as HIV-positive. Men who are eligible will undergo an informed consent process as described in section 12 (Ethical Considerations).

Inclusion criteria: Men recruited for each study aim must meet all of the following criteria:

- Biologically male at birth and identifies as male, according to self-report
- 18 to 35 years of age
- Resident in the Kisumu area for ≥12 months
- Reports anal intercourse with a man in the past 3 months
- Not currently taking PrEP for HIV prevention in the past 3 months
- Willing to provide complete locator information
- Willing to undergo all study procedures, including HIV testing and counselling
- Not currently participating in any HIV prevention or vaccine study
- Planning to remain in the study area for at least 6 months

For the pilot study only, men will be required to speak English, in order to expedite the study team's analysis of feedback from these participants in preparation for the RCT. Of note, approximately 50%-60% of young MSM in Kisumu speak English.

Exclusion criteria: Men who meet any of the following criteria will be excluded from this study:

- Unable to understand the study purpose and procedures
- Unwilling to adhere to study procedures

- Currently under the influence of alcohol or drugs
- Prior diagnosis of HIV infection

Men who screen out or decline enrolment will be reimbursed KSh 350 for transportation to the clinic. Locator information will be collected from all enrolled participants to ensure they can be traced in the event of a missed visit or lab result needing action. In addition, the Anza Mapema clinic provides the option for participants to use iris scanning rather than a study card with their ID number as a means of identification when they present to the clinic. This biometric identification method has been found to be more acceptable to the target population than fingerprint scanning, and helps avoid duplicate enrolments across studies. For study forms that include the recruitment script and eligibility screener and checklist please see "Appendix C: Eligibility Screener and Checklist."

Aim 1 Procedures: Piloting and Standardization of the Shauriana Intervention*.** The overall objective of this phase is to pilot test and standardize our empirically-based, targeted sexual health intervention for Kenyan GBMSM at risk for acquiring HIV. Objectives of the pilot test phase will be to a) assess acceptability of intervention components to the target population; b) test the adequacy of intervention materials and research instruments; and c) monitor fidelity of provider implementation. We will recruit 10 HIV-negative, PrEP-naïve GBMSM who are willing to undergo all intervention procedures at a scheduled roll-out date and provide detailed feedback after each intervention session. Recruitment will be achieved through outreach by the NYARWEK team, with screening and enrolment at the ***Anza Mapema clinic as described above.

Clinic visits. The 10 field-test participants will undergo all study procedures at baseline, month 1, and month 3 at the ***Anza Mapema*** clinic as detailed below for the aim 2 work. The exception will be specimen collection and laboratory testing, which are currently not included as part of standard of care in Kenyan PrEP programs. Clinic visits will include HIV counselling and testing, screening for STI symptoms, and individual counselling about HIV prevention methods. Standard of care counselling for HIV prevention in Kenya includes general information about HIV transmission and discussions of risk reduction including condom use. PrEP counselling sessions focus on PrEP knowledge, adherence tips, and strategies to address adherence barriers. Our intervention will include this component as standard care at the ***Anza Mapema*** Clinic. After receipt of these services, pilot study participants will complete the detailed ACASI described below for Aim 2, allowing us to identify any technical problems with this data capture and the questions included. Each of the three clinic visits (baseline, month 1, and month 3) will take from 1.5 to 2 hours; participants will be reimbursed KSh 500 for each clinic visit.

Intervention procedures. In addition to this standard of care, men in the pilot study will receive the ***Shauriana*** intervention, which is aimed at promoting sexual health and preventing HIV through a comprehensive prevention toolbox including PrEP. The intervention is adapted to respond to the particular needs of Kenyan GBMSM, as identified in the qualitative research conducted in as protocol MSU/DRPI/MUERC/00637/18. The components of this intervention are: four weekly in-person sessions with a trained peer intervention specialist; optional additional in-person or by phone check-ins after the in-person sessions are delivered; and optional monthly group sessions at NYARWEK. The four in-person health education and coaching sessions will be delivered once per week, by trained peer facilitators who identify as GBMSM. These sessions

will focus on the following topics: sexual health basics (understanding how HIV and STIs are transmitted, prevented, and diagnosed/treated), relationships (types of relationships we have, characteristics of healthy relationships, communication skills), stress and coping (understanding mental health challenges, adaptive and maladaptive coping strategies), and healthy sexuality and empowerment (understanding sexual orientation and gender identity, challenging stereotypes about GBMSM, making sexual choices).

An overview of session content is included in "Appendix D: Shauriana Intervention Draft." Peer facilitators will use a structured counselling format to help participants set specific goals, identify facilitators and barriers, and problem-solve to overcome barriers they anticipate or encounter. One-on-one sessions with peer facilitators will be structured as follows: 15 minutes introduction or review from previous week; 30 minutes didactic sharing of health information; 45 minutes of integrated next step counselling (iNSC) related to the current topic and sexual health. Peer facilitators will document each module administration, which will also be digitally recorded, in order to monitor fidelity of intervention delivery. In addition, participants will be asked to provide both quantitative (i.e., scales) and qualitative (i.e., open-ended questions) feedback on each intervention session delivered. Each session will take from 1.5 to 2 hours; participants will be reimbursed KSh 500 for their time.

A training manual is being designed for the six peer facilitators who will deliver the intervention. This manual will include the didactics and background information necessary to teach the peers the rationale and procedures of the intervention. Training components will be illustrated using role-play exercises, discussion of sample cases, and hypothetical problem scenarios. Peer training will be carried out over 3-4 days at least one week prior to the pilot test, and will include an overview of the study design, theoretical principles, and rationale, as well as step-by-step review of supporting manuals and handouts, practice role-playing exercises, and feedback. Practice sessions will be role-played until each intervention is adequately delivered, as assessed by the research team. We will hold weekly peer facilitator meetings to review study progress, guidelines, and issues that have arisen. Minutes of these meetings will be used to monitor the study and identify needs for revised training or procedures.

Optional intervention components. Once participants have completed the four weekly sessions, peer facilitators will send regular messages to participants to check in with them. If participants choose, they may continue to meet with their peer facilitator for additional iNSC sessions by phone or in-person (this is an optional component of the intervention). Participants may also choose to attend group sessions focused on LGBTI mental health and wellbeing that will be held at NYARWEK (also an optional component of the intervention).

Exit interviews. On completion of each pilot participants' 3 months of follow-up, an in-depth exit interview will be conducted for feedback regarding intervention components and overall study experiences, including any social harms (i.e., inadvertent disclosure, breach of confidentiality) of participation. Participants will be reimbursed KSh 500 for the exit interview. The topic guide for the exit interviews is included in "Appendix E: Shauriana Exit Interview Guide."

Pilot data analysis. Data from the pilot study will be reviewed on a weekly basis and corrections to ACASI skip rules or other data programming problems will be made immediately. Feedback from participants after intervention sessions and notes taken during interviews will be

reviewed by the team and discussed at weekly meetings. At the conclusion of the pilot study, we will assess whether we need to revise the intervention based on pilot test findings. If this is the case, we will submit revisions to the ethical review board at Maseno University and to the human subjects research committee at the University of Washington for approval.

Aim 2 Procedures: RCT of the Shauriana Intervention. Aim 2 work will use an RCT design to test the acceptability, feasibility, and safety of the ***Shauriana*** Intervention compared to standard care and estimate initial effect size. Acceptability will be assessed using Likert scales in participant ACASI questionnaires and qualitative exit interviews with participants in each study arm. Feasibility will be assessed at regular research team and peer facilitator meetings, which will be minuted. Safety will be assessed through careful monitoring of study participants to identify and report any adverse events. Information on perceived or experienced social harms and benefits will be collected by study staff at all clinic visits and assessed in greater depth in qualitative exit interviews. Additional trial outcomes that will be monitored and reported include screening and enrollment numbers, visit and intervention attendance, overall retention, and self-reported PrEP uptake and adherence. At the end of the trial, urine samples will be tested for tenofovir (TFV) drug levels (see Laboratory details, below). Dried blood spots will also be collected and stored for future testing of TFV-DP and FTC-TP levels, should funding permit.

Recruitment. The ***Shauriana*** Intervention pilot RCT will enroll 60 HIV-negative men (30 in the intervention and 30 in SOC) and follow participants for 6 months. We will recruit 60 participants over the course of 3 months; this target is realistic, given enrolment of over 160 men in the ***Anza Mapema PrEP*** cohort within a 2-month period. Potentially eligible participants will be recruited by NYARWEK, then referred to the ***Anza Mapema*** Clinic for screening and consenting, as described on pp. 11-12.

Trial enrollment and randomization. Once consent has been given, participants will be randomized to a study arm. The process of randomization to one of two study arms will be explained carefully and reviewed as part of the informed consent process. Computer-generated randomization will be used to assign participants in a 1:1 ratio to the standard care or intervention group, in blocks of 4, to ensure that equal numbers are randomized across arms. Numbered envelopes indicating the assignment will be prepared in and sealed by the UW CFAR Biometrics Core; study staff will not be aware of an individual's condition until the envelope is opened.

Clinic visits. Consistent with the latest Kenyan guidelines, all trial field-test participants will undergo study procedures at baseline, month 1, month 3, and month 6 at the ***Anza Mapema*** clinic. As for the pilot study, clinic visits will include HIV counselling and testing, screening for STI symptoms, and individual counselling about HIV prevention methods, including standard of care counselling (information, risk reduction, and PrEP counselling). A standardized physical exam will be performed at each visit, and both blood and urine samples will be collected. For participants taking PrEP, medical history will also focus on PrEP side effects and seroconversion symptoms, and PrEP refills will be provided (monthly for the first 3 months then quarterly). After completing these procedures, RCT participants will complete a detailed ACASI described below. Each of the four clinic visits (baseline, month 1, month 3, and month 6) will take from 1.5 to 2 hours; participants will be reimbursed KSh 500 for each clinic visit.

Standard care. All participants will receive standard care at the ***Anza Mapema*** Clinic, including standard counseling as described above; screening for depressive symptoms and substance use disorder; monthly ***Anza Mapema*** peer outreach for education and supply of condoms and lubricants; support group meetings; and social events as described above under "Previous Studies and Rationale." Attendance at ***Anza Mapema*** support groups and social events by ***Shauriana*** study participants will be tracked, as will the content of these group and social events during the study period. To ensure fidelity of delivery for each arm, we will review study progress, procedures, and emergent issues at weekly study meetings.

Clinical outcomes that will be tracked by the Anza Mapema Clinic using existing data collection instruments include visit attendance, attendance at clinic-sponsored support groups or social events, diagnosis and treatment of STI, HIV test results, PrEP refills, and PrEP-related adverse events and their management. Treatment will be provided for STI syndromes and acute illnesses as needed. All non-scheduled clinic visits will be documented. The study team (both clinic staff and intervention facilitators) will refer participants who need services beyond their capacity to mental health, substance use, advocacy, and/or legal services provided locally. All referrals will be documented.

Men who discontinue PrEP will continue follow-up; PEP will be available for men reporting high-risk exposure while not taking PrEP. Men who seroconvert will be withdrawn from the study and linked to HIV care at ***Anza Mapema*** or at another HIV clinic of their choice. As described above under "Recruitment," participants who withdraw before or test positive at the month 1 visit will be replaced; replacement participants in the RCT will undergo randomization and not necessarily be assigned to the arm to which the participant they replace was assigned.

Intervention delivery. Participants assigned to the ***Shauriana*** intervention will be introduced to an assigned peer facilitator on the day of their enrolment visit, after which telephone, SMS, and/or WhatsApp contacts from peers will begin, with in-person meetings per the intervention schedule described above. For the RCT, the intervention has been expanded to include an initial introductory session where peer facilitators spend timing getting to know their assigned participants. Therefore, five core intervention sessions and an optional additional session will be delivered. All peer facilitator contacts with participants and all required and optional intervention sessions will be documented. RCT participants will be reimbursed 350 KSh for their transportation after receiving each of the five core ***Shauriana*** modules, as participants may need to travel to a safe space for intervention delivery to ensure privacy.

ACASI measures and data collection. Due to its enhanced privacy, ACASI will be the main method of data collection, in English, Dholuo, or Kiswahili. This method was successfully used in the ***Anza Mapema*** project. Because participants occasionally have difficulties using ACASI, a research assistant will be available to assist participants if needed. The Anza Mapema clinic has an ACASI in use that includes questions on sociodemographics, sexual history, risk behavior, intimate partner violence, depressive symptoms, alcohol and other substance use, trauma, HIV risk perception, and awareness and use of PrEP and post-exposure prophylaxis for HIV prevention. Data elements that have been added to the ACASI specifically for the ***Shauriana*** study are listed below in Table 2. Our selection of measures for the ***Shauriana*** ACASI has drawn from our conceptual model for the ***Shikamana*** intervention and from the qualitative and intervention development work completed in protocol

MSU/DRPI/MUERC/00637/18. The ***Shauriana*** ACASI will be updated after the Aim 1 pilot test, balancing the need for data collection with the need to ensure a reasonable ACASI length without undue burden on participants. The final ACASI questionnaire is included in "Appendix F: *Shauriana* ACASI."

Table 2. PrEP-oriented and *Shauriana*-Specific Data Elements for Collection by ACASI

Data Element	Content	Method	Frequency
Primary Outcome Variables			
Acceptability	5-point Likert scales evaluating acceptability of the ***Shauriana*** intervention components,[35] exit interviews for detailed qualitative feedback	ACASI, exit interviews	Quarterly
Feasibility	Visit attendance, session delivery, documentation of peer contacts, minutes of research team meetings	Clinic and intervention data, minutes	Ongoing
Safety	Adverse events reported by participants or study staff; self-reported consequences of study participation in exit interviews	Reports at clinic visits, exit interviews	M1 then quarterly
Secondary Outcome Variables			
PrEP uptake	Two questions on past and ongoing PrEP use	ACASI	Quarterly
PrEP adherence	A series of self-report measures we have used in previous work.	ACASI	Quarterly
PrEP refills	Documented at Anza Mapema for each participant	Clinic data	Quarterly
PrEP drug levels	Urine TFV levels[36] DBS TFV-DP and FTC-TP levels (if funding permits)	Laboratory	Quarterly
Potential Correlates of Retention and Adherence			
Risk perception	A question on the participant's self-assessment of his chance of getting HIV/AIDS	ACASI	Quarterly
PrEP knowledge	PrEP knowledge questions (based on relevant literature and completed qualitative research by the team)	ACASI	Quarterly
Motivation/skills	LifeWindows Information-Motivation-Behavioral Skills adherence questionnaire,[37,38] adapted for PrEP use based on completed qualitative research by the team.	ACASI	Quarterly
PrEP distrust	PrEP-related distrust, skepticism, trust in providers, and ownership (championing) per Amico et al.[43]	ACASI	Quarterly
Shared decision making	Participant-reported sharing of decision-making related to PrEP; adapted from Barr et al.[39,40]	ACASI	Quarterly
Social support and loneliness	Multidimensional Scale of Perceived Social Support, a 12-item scale of perceived support from family, friends, others[41]	ACASI	Quarterly
Self-esteem	10-item Rosenberg self-esteem scale,[42] previously used in this population[43]	ACASI	Quarterly
Resilience	Coping self-efficacy scale: 13-item version validated in HIV+ GBMSM with depressed mood[44]	ACASI	Quarterly
Sexual identification	27-item lesbian, gay, and bisexual identity scale (LGBIS),[45] previously used in Kenya[43]	ACASI	Quarterly

Laboratory testing. HIV testing at screening and follow-up visits will be performed with two rapid tests (Determine®, Abbott Laboratories, Abbott Park, IL, USA; and First Response®, Premier Medical Corporation, Kachigam, Nani Daman, India), in accordance with the latest Kenyan HIV testing guidelines. Dried blood spots will be collected per an existing SOP at the

Anza Mapema Clinic, and stored for analysis of PrEP drug levels (i.e., detection of TFV-DP and FTC-TP), should funding permit. Safety monitoring in the RCT will be done at a higher standard than is currently available in Kenya, where costs of lab testing have prohibited routine baseline testing and instead use an approach targeted based on signs or symptoms of kidney or liver disease. Serum will be tested at baseline for creatinine level using the Cobas Integra 400 Plus biochemistry analyzer (Roche, Germany), to document normal renal function prior to PrEP start. Baseline serum will also be tested for hepatitis B surface antigen (HBsAg) using SD Bioline HBsAg WB at the CDC-KEMRI laboratory in Kisumu; men who do not have chronic hepatitis B (i.e., those who are HBsAg negative) will be offered hepatitis B vaccination.

Blood and urine aliquots from baseline, month 3, and month 6 will be stored at -80ºC in the NRHS laboratory in Kisumu. Urine samples will be shipped on dry ice for testing utilizing the liquid chromatography tandem mass spectrometry (LC-MS/MS) urine tenofovir (TFV) assay developed at Philadelphia FIGHT/Children's Hospital of Philadelphia by Dr. Helen Koenig and colleagues, currently performed by Molecular Testing Labs in Vancouver, Washington, USA. This assay detects TFV with greater sensitivity than plasma-based measures, with a detection window within 7 days of the last TDF/FTC dose.[36] In addition, dried blood spots will be shipped to Molecular Testing labs for TFV-DP and FTC-TP quantitation using LC-MS/MS to estimate the number of doses taken in the past 7 days.[15] If any participant acquires HIV during the study, HIV-1 genotypic resistance testing will be conducted on stored samples at the CDC-KEMRI laboratory in Kisumu, to determine whether acquired virus is resistant to TDF or FTC.

Exit interviews. At study completion or any visit on which a participant withdraws, an exit interview will be conducted regarding experiences, including any social harms of participation and feedback on standard care or the ***Shauriana*** intervention. Exit interviews will be conducted by the ***Shauriana*** Project Research Coordinator, who is based at NYARWEK, using a semi-structured exit interview guide. Notes will be taken and interviews will be recorded using a digital recorder. All participants who complete an exit interview will receive KSh 500 as reimbursement for their time and transport. The topic guide for the exit interviews is included in "Appendix E: Shauriana Exit Interview Guide."

Schedule of procedures. A table summarizing procedures for the Shauriana study is included in "Appendix G: Schedule of Procedures."

Power considerations. This project is designed to develop a novel intervention to promote PrEP adherence and sexual health among African GBMSM and to assess its acceptability, feasibility, and safety in a clinical trial setting. It is not designed or powered to determine the overall intervention effect nor the effects of individual components of the intervention. Data on PrEP drug levels and other secondary outcomes in each study arm will help to evaluate whether the intervention is at least as good as standard care and provide some insight into the promise of the intervention to inform larger-scale testing. See Section 13 for statistical analysis plans.

12. Ethical Considerations:

Human Subjects Involvement and Characteristics: The proposed research is non-exempt human subjects research. Prisoners and children under 18 years of age will not be included. Precautions will be taken as below regarding potential subjects with low literacy. All procedures will be conducted in accordance with 45 CFR Part 46. Protocols will be approved by

the Human Subjects Research Committees (HSRC) at the University of Washington (UW) and by the Maseno University Ethics and Research Committee (MUERC) in Kisumu, Kenya. During both research stages (pilot test and RCT), we will actively solicit feedback from GBMSM participants, as well as from the study team (clinic staff and peer facilitators) regarding the feasibility of the intervention components. In addition, we will hold ongoing discussions with the Anza Mapema Community Advisory Board, within the NYARWEK member network, and with our ethical review boards to ensure the relevance and ethical conduct of the research.

The proposed Aim 1 study will include a population of 10 adult HIV-negative GBMSM recruited in Kisumu, Kenya. The proposed Aim 2 study will include a population of 60 adult HIV-negative GBMSM recruited in Kisumu, Kenya. To be eligible for the ***Shauriana*** intervention pilot or trial, men must be biologically male at birth and male-identifying, 18 to 35 years of age, resident in the Kisumu area for ≥12 months, report anal intercourse with a man in the past 3 months, and be willing to provide complete locator information and undergo all study procedures, including HIV testing and counseling (HTC). In addition, men should not be currently participating in any HIV prevention or vaccine study and be planning to remain in the study area for at least 6 months. Men will be excluded if they are unable to understand the study purpose and procedures or unwilling to adhere to study procedures or currently under the influence of alcohol or drugs (assessed by clinic staff during screening) or have a prior diagnosis of HIV infection.

Clinical management of PrEP, including PrEP eligibility and exclusion criteria, will be strictly according to Kenyan Ministry of Health (MoH) guidelines, which closely follow World Health Organization guidelines. While current management is detailed in the study protocol, procedures will be updated if Kenyan MoH guidelines change. PrEP will be supplied by the Kenya National AIDS and STI Control Programme (NASCOP). Syndromic treatment for STI and for minor injuries or illness will be managed at the study clinic free of charge.

Eligible men who consent to pilot study participation will all receive the ***Shauriana*** intervention. Pilot study participants will be followed for 3 months total, attending visits as detailed in the protocol. At each clinic visit, participants will be given 500 Kenyan shillings (Ksh, about $5) to reimburse them for their time and transport expenses. After delivery of each of four intervention modules, feedback on the intervention materials will be elicited and participants will be reimbursed 500 KSh for their time and transport expenses. Men who test positive for HIV during the study will be withdrawn from the pilot study and referred to care at the comprehensive care clinic of their choice, either at the ***Anza Mapema*** Clinic run by the Nyanza Reproductive Health Society (NRHS) or at any of several other clinics providing HIV care and treatment in the greater Kisumu area. All non-scheduled contacts with study staff will be documented. At month 3 or at the time of withdrawal for any reason (e.g., a move from the study area), a semi-structured exit interview will be conducted regarding experiences, including any social harms of study participation. Permission will be requested for digital recording of the pilot test intervention sessions and the semi-structured exit interviews during the consenting process, and confirmed at the time of the interview. Men will be reimbursed KSh 500 for completing their exit interview.

Eligible men who consent to RCT participation will be randomized to receive either standard PrEP counseling and support following Kenyan MoH guidelines or standard care plus

the ***Shauriana*** intervention. RCT participants will be followed for 6 months total, attending visits as detailed in the protocol. At each clinic visit, participants will be given 500 Kenyan shillings (about $5) to reimburse them for their time and transport expenses. RCT participants will be reimbursed 350 KSh for their transportation after receiving each of the four core ***Shauriana*** modules, as participants may need to travel to a safe space for intervention delivery to ensure privacy.

Men who test positive for HIV during the study will be withdrawn from the trial and referred to care at the comprehensive care clinic of their choice, either at the ***Anza Mapema*** Clinic run by the Nyanza Reproductive Health Society (NRHS) or at any of several other clinics providing HIV care and treatment in the greater Kisumu area. All non-scheduled contacts with study staff will be documented. At month 6 or at the time of withdrawal for any reason (e.g., a move from the study area), a semi-structured exit interview will be conducted regarding experiences, including any social harms of study participation. Permission will be requested for digital recording of the semi-structured exit interviews during the consenting process, and confirmed at the time of the interview. Men will be reimbursed KSh 500 for completing their exit interview.

***Research Material Obtained from Participants*:** At study visits, detailed audio computer-assisted self-interview (ACASI) data collected will include sociodemographic background; sexual risk behavior; experience of stigma, discrimination and violence; depression; alcohol and drug use; current physical symptoms; and HIV and PrEP knowledge. Before each PrEP dispensation/refill, data on PrEP status and adherence will also be recorded by ACASI. Names will be included only on a registration form containing information to be used in locating the participant in case of need (e.g., laboratory results requiring follow-up, tracing after a missed visit); this registration form will also be used to prevent duplicate enrolments. Names will not be included in routine data collection forms or in the computer database. Names of sexual contacts will not be collected.

Collection of specimens is for study purposes (e.g., monitoring of outcomes), but results will also be used to provide appropriate clinical care (e.g., PrEP safety monitoring, HIV care referral if indicated). HIV testing using a finger-prick blood sample will be conducted at all study visits, regardless of PrEP uptake or adherence. This testing will be conducted following current Kenyan MoH guidelines. Safety monitoring in the RCT will be done at a higher standard than is currently available in Kenya, where costs of lab testing have prohibited routine baseline testing and instead use an approach targeted based on signs or symptoms of kidney or liver disease. Serum will be tested at baseline for creatinine level using the Cobas Integra 400 Plus biochemistry analyzer (Roche, Germany), to document normal renal function prior to PrEP start. Baseline serum will also be tested for HBsAg using SD Bioline HBsAg WB at the CDC-KEMRI laboratory in Kisumu; men who do not have chronic hepatitis B (i.e., HBsAg positive) will be offered hepatitis B vaccination.

Urine and dried blood spots will be collected and stored for assessment of PrEP drug levels at baseline, month 3, and month 6. Blood draws at the baseline, month 3, and month 6 visits will have a maximum volume of 15 mL, with up to 10 mL for required for laboratory testing and 5 mL to store for assessment of genotypic drug resistance for any participant who acquired HIV during the study. Consent will be obtained prior to all specimen collection.

Recruitment of Subjects and Consent Procedures: Subjects will be recruited by the NYARWEK team using existing peer networks, snowballing and venue-based referrals. All interested subjects will be referred to the ***Anza Mapema*** clinic for study eligibility screening, for which a brief screening consent will be used (Appendix C). If an individual is found to be eligible, he will undergo the informed consent process outlined below. Men who are found to be ineligible will be referred to HIV prevention or care programming as indicated, including risk reduction counseling, condoms and lubricants, STI screening and treatment, programmatic PrEP if eligible and interested, and HIV care for men who test positive. These men will receive KSh 350 for their time and transport to the clinic for the screening process.

Trained ***Anza Mapema*** study staff, fluent in Dholuo, English and Kiswahili, will offer participation to the ongoing study component (i.e., pilot study or RCT participation) using a consent specific to that study component. Each informed consent document will describe the purpose of the specific component of the study described, the procedures to be followed, and the risks and benefits of participation. During the consent process, staff will explain the study procedures, with emphasis on features that differ from routine programmatic services, highlighting the risks and benefits of study participation. Consent documents will be available in Dholuo, English and Kiswahili. If an individual is illiterate, all procedures, risks and benefits will be explained and the individual will be given the option of having a friend or family member or a trained consultant who is not a member of the research staff to be present to further explain the study.

Written informed consent will be obtained from all participants; persons incapable of providing informed consent are excluded. Potential participants who would like to take additional time to consider their enrolment will be encouraged to do so. Participants will be able to opt in or out of optional elements of study participation before signing the consent; these include: iris scanning as biometric identification, text messages as reminders of study visits, digital recording of intervention sessions (pilot test only) and exit interviews (pilot test and RCT). Staff will emphasize that participation is voluntary, and that participants can refuse to answer any question or undergo any procedure or can discontinue participation at any time without penalty. Participants will be informed of the procedures for ensuring confidentiality, including use of unique non-personally identifying ID numbers instead of names on research materials, and the maintenance of data in encrypted computer databases and locked filing cabinets in locked rooms. Enrolled participants will be provided with a signed and dated copy of the informed consent document before they leave the study site.

Risks to Human Subjects: The potential risks of study participation can be divided into risks specifically related to the study and, for those participants who initiate and adhere to PrEP, risks inherent in taking prophylactic antiretroviral medications. The risks associated with taking PrEP are not truly risks associated with the research, since any man who takes PrEP is exposed to these potential complications and inconveniences, regardless of study participation. However, we list them here to be comprehensive.

<u>Risks and Inconveniences Related to Participation</u>

- There is a small risk of loss of privacy or confidentiality for participants related to study visits, exit interviews, or contacts by staff, peers, or field workers. This study will include questionnaires and counselling on sensitive topics including sexual risk behavior.

- Participants may also experience psychological discomfort during discussion and disclosure about stigma, mental health symptoms, and substance use.
- Participants may experience stigma or discrimination if stigmatized sexual risk behavior (e.g., male-male sex) is revealed.
- Potential inconveniences include:
    - Intensive monitoring during study follow-up, and
    - Collection of blood and urine specimens (RCT only).

Risks and Inconveniences Inherent to Use of PrEP

Medical risks associated with PrEP will be no different in this trial than they would be if PrEP were started in a non-research setting according to standard care in Kenya. TDF/FTC or TDF/3TC, the drugs used for PrEP in Kenya, may cause side effects including headache, nausea, diarrhea, vomiting, rash, depression and mild, painless darkening of the skin on their palms and/or soles of feet. Most medication-related adverse effects are mild to moderate, resolve within weeks, and do not require discontinuation of therapy. Rarely, severe side effects including hepatitis and renal failure can occur, and may be life threatening. There is a small risk that men with chronic hepatitis B infection but no evidence of liver disease constituting a medical exclusion at baseline could experience a hepatitis flare upon discontinuation of PrEP. Because reports to date indicate that this risk is minimal, the Kenyan PrEP guidelines do not exclude these men from PrEP programming. There is a small risk that a participant could acquire an HIV-1 strain with antiretroviral resistance, if adherence to PrEP is suboptimal. Other potential risks and inconveniences related to PrEP use include the need for regular HIV testing, collection of blood for safety monitoring, and loss of privacy related to the need for chronic medication. Participants who experience persistent or serious adverse effects of PrEP will be advised to stop this medication and focus on behavioral risk reduction instead. Participants who are diagnosed with HIV infection during PrEP monitoring will receive supportive counseling and referral for HIV care.

Adequacy of Protection from Risks: Every effort will be made to minimize the risks associated with study participation. Experienced research staff will counsel participants prior to enrolment, so that they are aware of the risks described above. We will have strict guidelines and procedures in order to minimize the potential for emotional distress due to questions asked in the ACASI, intervention sessions or participant interviews. Participants will be told during the informed consent procedures that some of the questions asked may cause discomfort or distress. Participants will be assured of their right to refuse to answer any questions they do not wish to answer. Participants will be assured of their right to leave an intervention session or end an interview prior to completion. To minimize the risk of discomfort, assessments, intervention sessions, and interviews will be conducted in private areas. If during the course of an computer-assisted interview, intervention session, or interview, the participant demonstrates or articulates signs of distress, the research staff will be trained to immediately stop the activity taking place. Referral to mental health and other support services will be available onsite or through referrals to local community providers. Research staff members will receive initial and ongoing training in: ethics and confidentiality; study protocols; emergency procedures; mandated reporting procedures; general interviewing skills and data management. We have in place an emergency procedure protocol if the participant reveals information that would require immediate action (e.g., suicidal intent). Drs. Harper and Simoni, both licensed mental health professionals, will be

notified immediately of such events and provide support as needed to the study team for triage and management pending successful referral.

The risk for loss of privacy will be minimized by strict confidentiality procedures. Identifying information collected for tracing purposes will be kept in an encrypted contact information file on a password-protected laptop computer with an encrypted hard drive. A master electronic file including the linkage of names to numbers (used to identify participants who return without a numbered study card) will be encrypted and retained on a single computer at NRHS in a secure location. This master file will be checked each day for duplicates. Consents will be stored in a separate area in a locked file cabinet. All personal identifying information will be destroyed immediately after the study is completed. In addition, privacy will be protected by ensuring that computer-assisted interviews and examinations take place in private rooms. Recordings from pilot test intervention sessions and participant interviews will be transcribed and stored on a password-protected personal computer. Interviews conducted in Swahili or Dholuo will be simultaneously translated into English and transcribed, with back-translation and verification by a different person to ensure accuracy. Participants will not be identified by name in the interview transcripts, rather by study ID. We will also protect privacy by developing individualized procedures for study-related contacts in collaboration with each participant. NRHS study staff and peer outreach workers already have 2-10 years of experience maintaining confidentiality and privacy with GBMSM in Kisumu, and are either from the GBMSM community or face social challenges due to secondary stigma. The NYARWEK research team, including all peer facilitators, similarly have all been trained in human subjects research protections and privacy protections. All newly hired staff and peers will undergo rigorous training on the protection of confidentiality and particular need for discretion in working with this population, whether in the clinic or community.

All study procedures will be conducted according to detailed standard operating procedures that emphasize participant protections and the voluntary nature of participation. All HIV testing will be accompanied by pre- and post-test counselling, in accordance with the latest Kenyan national guidelines. In addition, experienced research staff will oversee all computer-assisted interviews and perform examinations and blood collection. Appropriate clinical and laboratory monitoring will minimize the risk of severe adverse events related to PrEP during clinic follow-up. Participants will be assured that their clinical care will not be affected by their participation status in any component of the study, nor by their responses in questionnaires. Participants will be informed that they have the right to withdraw or refuse an examination or sample collection at any point. All study staff and GBMSM community members involved in research procedures will be required to undergo training in Human Subjects protection certification and in Good Clinical Practice (GCP), and all laboratory staff will be required to undergo periodic training in Good Clinical Laboratory Practice (GCLP).

The District Commissioner, Officer Commanding Police Division, the County Health Director and the District Medical Officer of Health are aware of our GBMSM research activities, and they support non-discrimination based on sexual orientation. While homosexuality is illegal in Kenya, there are strong passages in the constitution protecting human rights, and judicial, police and health authorities have chosen to emphasize human rights as protecting LGBT, including in Kisumu County. This does not mean, however, that there are no risks to disclosure

of same-sex sexual behavior, and this study will do everything possible to maintain confidentiality and anonymity of study participants. We have an established community advisory board (CAB) at ***Anza Mapema*** to advise us on risks to participants related to study procedures and to assist in monitoring social and psychological harm resulting from study participation. This CAB is currently composed of Mr. Onyango (Executive Director, NYARWEK), an additional GBMSM community representative, a lawyer with experience in defending GBMSM in the courts, a religious leader, and the Kisumu District AIDS and STI Control Officer (DASCO).

All participating men will receive a comprehensive package of services, including HIV testing and risk reduction counseling, condoms and lubricants, and screening and treatment for syndromic STI, regardless of whether they initiate and continue PrEP. For men who initiate and continue PrEP, appropriate clinical and laboratory monitoring will minimize the risk of severe adverse events. Men in the standard care and intervention arms will receive regular PrEP adherence support, according to detailed procedures for each study arm. There will be no charge to participants for the medications or services provided. Men may withdraw from the study at any time. For any man who withdraws from the study, we will ask him to complete a withdrawal survey regarding his reason for withdrawal, any care and referral needs, and intent to establish care elsewhere. Men who withdraw will also be invited to participate in an exit interview, if willing. Of note, PrEP is available in a non-research (program) context at several sites in Kisumu including the ***Anza Mapema*** Clinic, should men be eligible for and interested in PrEP but not want to participate in this research study.

Potential Benefits to the Subjects and Others: Benefits of study participation include the following:

1. All study participants may benefit in terms of access to risk reduction counseling, periodic STI screening and HIV testing, and PrEP programming.
2. For study participants who initiate and adhere to PrEP during follow-up, there is the potential to avoid HIV acquisition while working to reduce behavioral risks.
3. Pilot study participants and those assigned to the ***Shauriana*** intervention group in the randomized trial may benefit from a GBMSM-affirming, tailored approach to PrEP provision with activities to promote resilience, decrease stigma, and improve sexual health.
4. All participants will contribute to a study that will evaluate ways of increasing access to HIV prevention services tailored to the needs of Kenyan GBMSM.

<u>Potential Benefits to Others</u>

1. From the perspective of the population from which participants be recruited, this study offers the potential for GBMSM to benefit from the testing and evaluation of a GBMSM-affirming, tailored approach to HIV prevention.
2. This study has the potential to reduce HIV transmission in the Kisumu area by reducing HIV transmission in a key population that is estimated to account for ≈15% of new HIV infections in Kenya.

The proposed work will help us to adapt and enhance a promising intervention for this at-risk population. Given the low likelihood of significant risks to participants, the risks seem reasonable in relation to anticipated benefits.

Importance of the Knowledge to be Gained: Results of this study will be applicable to the development and scale-up of HIV prevention programs for GBMSM in Kenya and other East African countries, and could serve as a model for peer-led approaches to HIV prevention for vulnerable and marginalized populations. In addition to the general applicability of the results, this project will help to develop capacity in Kenya to scale-up PrEP for this target population and to promote GBMSM leadership and input into research and programs.

Trial Registration: The trial will be registered with ClinicalTrials.gov upon ethical approval of a final protocol.

Consent Form: For participant screening materials and consent form, see "Appendix C: Eligibility Screener and Checklist," "Appendix H: Pilot Study Consent," and "Appendix I: RCT Consent."

Other Institutional Ethics Reviews Received*:* The IRB at University of Washington has approved this research protocol, along with the screener and two consents. Documentation is attached with this application.

13. Data Management & Statistical Analysis Plans:

Data Management Plan: Recruitment, consenting, and data collection will be monitored carefully to ensure the confidentiality and safety of participants, as detailed in our Human Subjects statement.

Statistical Analysis Plan: Data analysis will include both quantitative and qualitative components.

Qualitative analyses. *Clinic staff and intervention team feedback* from meetings will be monitored in real time, to identify any problems needing correction, and then analyzed at the end of the study, to assess feasibility of the intervention, should scale-up for a larger trial seem warranted. *Pilot study feedback and pilot/RCT exit interviews* will be analyzed to evaluate men's views regarding the acceptability and overall value of the intervention vs. standard care. In addition, we will review exit interview transcripts to identify best practices for engaging and retaining GBMSM in the ***Shauriana*** intervention and for optimizing adherence to a daily PrEP regimen and uptake of other HIV prevention services. Notes and tapes from exit interviews will be translated and transcribed into English, then reviewed to identify and code salient themes. NVivo software will be used to facilitate qualitative analysis.

Primary quantitative analyses. *Acceptability* of intervention procedures will be assessed by comparing month 3 and month 6 Likert scale scores for the acceptability of study participation across study arms, using Mann-Whitney U tests. Likert scale scores for ***Shauriana*** intervention components will be summarized using medians, interquartile ranges, and ranges for intervention participants. *Social harms and benefits* reported by participants in each arm will be tallied and described in report form.

Secondary quantitative analyses. Participant characteristics in the two study arms will be presented using counts and percentages for categorical variables and means and standard deviations or medians and inter-quartile ranges (IQR) for continuous variables. Descriptive statistics will be used to evaluate distributions of the measures assessed at each time-point. To determine validity of the scales used, item scores will be evaluated using Cronbach's alpha and factor analysis, then compared to published scale psychometrics in African populations if possible. The temporal stability of scales will also be investigated to ensure reliability. These

approaches will help assess the utility of the instruments used for future analyses and research in HIV-negative Kenyan GBMSM.

Given the preliminary nature of this work and the small sample size dictated by time and budget limitations, secondary analyses will focus on obtaining estimates of Table 2 secondary outcomes (PrEP uptake, adherence, refills, and drug levels) in each group and characteristics associated with these outcomes, for use in design of a larger study. Retention will be compared across study arms using uncorrected Chi square tests in an intent-to-treat analysis. Rates and patterns of self-reported PrEP adherence (defined as taking 4 or more doses per week) will be examined, and assessment methods will be compared using bivariate analyses (e.g., Spearman correlation coefficients for continuous variables). Sociodemographic and other potential cofactors will be evaluated for associations with adherence measures and other outcomes (e.g., urine TFV levels, dried blood spot TFV-DP) using Wilcoxon rank sum or independent-sample t tests, Spearman or Pearson correlations, and chi-square tests as appropriate. Multivariable analyses will adjust for sociodemographic and other potential cofactors. Parsimonious model testing will explore potential intervention efficacy.

14. Laboratory Specimens and Biohazard Containment:

Laboratory Specimens: The following specimens will be collected for the tests to be conducted for the randomized trial:

- Blood (15 milliliters) for creatinine and hepatitis B surface antigen testing at baseline and dried blood spots plus storage at baseline, month 3, and month 6
- Urine (10 milliliters) for PrEP drug level testing

Research staff will adhere to standards of good clinical laboratory practice, and local SOPs for specimen management, including proper collection, processing, labeling, and transport of specimens to the CDC-KEMRI laboratory for testing or the UNIM Research and Training Centre for storage.

Biohazard Containment: Transmission of HIV and other blood borne pathogens can occur through contact with contaminated needles, blood, and blood products. Appropriate blood and secretion precautions will be employed by all personnel in the collection of clinical samples and the shipping and handling of all clinical samples and isolates for this study, as currently recommended by the World Health Organization and the Kenyan Ministry of Health. After all requisite permissions are obtained, urine and dried blood spot samples will be shipped to Dr. Graham at the University of Washington and then forwarded to Molecular Testing Labs in Vancouver, Washington, USA, for PrEP drug level testing. All specimens will be shipped using packaging that meets requirements specified by the International Air Transport Association Dangerous Good Regulations for UN 3373, Biological Substance, Category B, and Packing Instruction 650. In addition, all infectious specimens will be transported in accordance with United States regulations (42 CFR 72).

15. Study Limitations/Possible Complications and How to Minimize Them:

This proposal includes an ambitious research plan and timeline, based on the urgency of the problem addressed. We acknowledge several potential complications:

1. Research involving GBMSM in Kenya can be sensitive, and a good relationship with the key stakeholders (e.g., Ministry of Health, police, media) will be critical to ensure safety. While male-male sex is illegal in Kenya, the Kenyan courts recently ruled against forced

anal examinations at police stations. We have safely conducted multiple studies with GBMSM participants in Kenya since 2005, and have taken measures in Kisumu to ensure we have assistance should any problems arise (e.g., the ***Anza Mapema*** CAB has successfully resolved sensitive situations through dialogue). In addition, security is a pillar of NYARWEK's work, and includes GBMSM sensitivity training for local police and judiciary. We also have the endorsement of the Kisumu County Ministry of Health for the proposed work, and confer with County Health officials periodically and when issues arise.

2. We do not anticipate that recruiting and retaining participants for the Aim 1 pilot and the Aim 2 trial will be difficult. The >600 HIV-negative participants recruited and high retention achieved in ***Anza Mapema***, support from GBMSM partners, and a strong community outreach program suggests recruitment of 60 GBMSM participants not currently taking PrEP will not be challenging.
3. Because we will conduct the intervention trial in a single community with overlap in social and sexual networks, there could be contamination of arms, with participants in the standard care arm receiving some intervention components. We will address this risk by locating all intervention procedures outside the ***Anza Mapema*** Clinic, monitoring standard care at the ***Anza Mapema*** Clinic, and strict adherence to trial protocols. We had success with such monitoring in the ***Shikamana*** trial, in which audits of recorded counseling sessions found minimal contamination of standard vs. intervention approaches. Manipulation checks will also be included in exit surveys to identify potential crossover contamination.
4. We also acknowledge that there may be differences in attention due to increased peer contact or counseling efforts in the intervention arm. We will monitor data on ***Anza Mapema*** Clinic visits (planned study visits and interim visits), ***Anza Mapema*** social activities, and all ***Shauriana*** intervention contacts with participants, to assess differences in attention across study arms.
5. Finally, the HIV prevention landscape is constantly changing and injectable PrEP may be on the horizon. Even if injectable PrEP replaces oral PrEP and reduces the burden on participants to adhere to daily therapy, GBMSM in Kenya and other rights-constrained settings will continue to face stigma and discrimination that may affect uptake and maintenance of HIV prevention. Hence, a holistic approach to sexual health such as that provided by the ***Shauriana*** intervention would still be pertinent and needed.

16. **Timeline/Time Frame**:

Aims 1 and 2 of the project (pilot phase and trial of the ***Shauriana*** intervention) will occur over an 18-month period, from the time all ethical approvals are in place. Piloting will take place in months 1-5 of the proposed work, after training of the peer facilitators and of the Anza Mapema Clinic staff on the research protocol. Recruitment for the RCT would take place over months 6-12, with 6-month follow-up for each enrolled participant. As work progresses, we will present abstracts at international and national conferences and submit manuscripts to top-tier journals with an audience inside and outside of Africa.

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18. Budgetary Estimates

Budget, Year 1

Budget Category	Amount in USD
Personnel	$54,215
Research Travel (US to Kenya)	$15,000
Supplies	$20,000
Nyanza Reproductive Health Society Subcontract (includes NRHS personnel, NYARWEK personnel, travel, supplies, clinic and community costs, and other study expenses)	$85,784

Budget Justification

The provided budget sufficiently covers the expenses required to conduct the proposed research. This budget includes salary support for investigators and other personnel at Maseno University (PI Dr. Wilson Odero), the University of Washington (Co-PI Dr. Susan Graham, adherence expert Dr. Jane Simoni, grants administrator Yvonne Zhang, and biostatistician Sarah Holte), the University of Michigan (Co-PI Dr. Gary Harper, counseling expert Dr. K. Rivet Amico, and research manager Laura Jadwin-Cakmak), Nyanza Reproductive Health Society (Research

Director Dr. Fredrick Otieno and other staff), and Nyanza Rift Valley LGBTI Network (NYARWEK; Daniel Onyango). The budget also includes international travel funds for Drs. Graham, Harper, Amico, and Ms. Jadwin-Cakmak to travel from the U.S. to Kenya for study activities. Finally, the budget includes a subcontract to NRHS that includes salary support for personnel, travel, supplies, clinic and community costs, and other study expenses.

19. Appendices

Appendix A: Investigator Biosketches / CVs

Appendix B: Facilities & Other Resources

Appendix C: Eligibility Screener and Checklist

Appendix D: Shauriana Intervention Draft

Appendix E: Shauriana Exit Interview Guide

Appendix F: Shauriana ACASI

Appendix G: Schedule of Procedures

Appendix H: Pilot Study Consent

- ***English***
- ***Dholuo***
- ***Kiswahili***

Appendix I: RCT Consent

- ***English***
- ***Dholuo***
- ***Kiswahili***

Appendix J: University of Washington IRB Approval Letter

Appendix K: Ethics Certificates

SHAURIANA TRIAL CONSENT

PARTICIPANT INFORMATION & CONSENT FORM

The Shauriana Program: A Community Participatory Approach to Integrating PrEP, Sexual Health, and Mental Health Services for Gay, Bisexual, and Other Men Who Have Sex with Men in Kenya

Investigators:

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Wilson Odero, MD, MSc, PhD, Dean of School of Medicine, Professor of Public Health, Maseno University, phone: +41 057-351622; email: wodero@gmail.com

Study Location: Kisumu, Kenya

Study Sponsor: National Institutes of Mental Health (NIMH), USA

Why am I being asked to participate?

You are invited to be a part of a research study. Gay, bisexual, and other men who have sex with men (GBMSM) are at higher risk of HIV infection compared to other men. To prevent new HIV infections among GBMSM and their partners, it is important to ensure that GBMSM are connected to HIV prevention and services and given the option to start pre-exposure prophylaxis (PrEP). PrEP is a medication that can reduce HIV risk by over 90% if it is taken as prescribed. It is also important that HIV prevention services, including counselling related to PrEP use, be culturally appropriate and meet the needs of GBMSM in Kenya.

The objective of this study is to test a tailored sexual health program called "***Shauriana***" that has been developed specifically by and for Kenyan GBMSM. ***Shauriana*** aims to help men improve their sexual health and reduce their risk of HIV acquisition using available tools. We are conducting a study to determine the feasibility (can we do this?), acceptability (will GBMSM like this?), and safety (will this be safe for GBMSM?) of the ***Shauriana*** program. We are recruiting 60 HIV-negative GBMSM for this study, and will randomly assign 30 men to the ***Shauriana*** program and 30 men to standard care at the ***Anza Mapema*** clinic in Kisumu.

We are asking your permission for you to participate in this study.

What will happen during the study?

This study will last for 6 months from the time you enrol. You will be asked to attend three additional clinic visits after today's visit: at months 1, 3, and 6 after enrolment. If you enrol in the study, we will reimburse you KSh 500 for time and travel expenses related to each scheduled study visit, beginning with today's visit.

SHAURIANA TRIAL CONSENT

If you are randomly assigned to the ***Shauriana*** program, you will be introduced to a trained peer facilitator. You will meet with this peer at agreed-upon safe spaces in the community weekly during the first several weeks of the study (5 weekly sessions). You will be reimbursed KSh 350 after completing each of the 5 ***Shauriana*** sessions with the facilitator.

At the end of the study, we will ask for your feedback in an in-person exit interview. You will be reimbursed KSh 500 after completing the exit interview.

If you participate, you will be informed of any changes made to the study after you enrol or any new information that becomes available pertinent to HIV prevention or PrEP that may affect your health or study participation.

Procedures at Scheduled Clinic Visits
At each clinic visit, you will receive standard HIV prevention care at the ***Anza Mapema*** clinic, including HIV testing and counselling, screening for symptoms of sexually transmitted infections, and counselling about HIV prevention methods. If you test positive for HIV infection, you will be counselled and referred to the HIV clinic of your choice and withdrawn from this study.

You will be offered condoms, lubricants (when available) and PrEP free of charge. At each visit, the clinic counsellor and other providers will talk with you about: how PrEP works and why it might be right for you, your pill-taking practices, potential barriers and facilitators to your adherence, problem management skills, and strategies for remembering pills.

At the baseline visit, we will collect your contact information so that we can reach you in case of a missed visit or a laboratory test that needs follow-up. At baseline, month 3, and month 6, you will undergo blood collection (5 mL, ≈1 teaspoon) and urine collection (4 ounces in a collection cup). These samples will be used for PrEP monitoring and safety. In addition, we will test your blood at baseline to see if you may benefit from hepatitis B vaccination.

At each clinic visit, you will undergo a computer-based questionnaire, in which you will be asked questions about your general health, sexual behaviour, substance use, mood, social support, and medication-taking. This computer-based questionnaire will take approximately 1 hour to complete.

Shauriana **Program Procedures**
If you are randomly assigned to the ***Shauriana*** program today, we will introduce you to the ***Shauriana*** facilitator who will work with you. This facilitator is a peer from the GBMSM community who has helped to develop the ***Shauriana*** program and received training in counselling and sexual health. You will meet with the facilitator once a week for the first month. After each session, we will get your feedback on how it went and whether you felt it was helpful.

After you have completed the 5 weeks of weekly intervention sessions, you will have the option to meet in person with the peer facilitator once a month for the last two months of the study if you like (this is optional), and you can contact him as many times as the two of you agree upon by phone or SMS. You will also be invited to attend an optional group session on mental health at NYARWEK, our community partner for the ***Shauriana*** program. There will

be no reimbursement for these optional components of the interview, but we encourage you to participate if you find these programs offerings helpful.

Exit Interviews
After completing the study or if you need to withdraw before completing the study, you will be interviewed about how your study participation went, and asked to provide any feedback you have about the clinic procedures. If you were assigned to the ***Shauriana*** program, we will also ask for your feedback on the program and how it was delivered. With your permission, we will record this interview.

Iris Scan
To help the Anza Mapema clinic keep track of who is enrolled in this and other ongoing studies, we will ask you to look into a binocular. This machine will scan your iris in less than 2 seconds. This is a painless exercise and will not cause eye damage. The scan will translate into a unique identification number that will be added to your study ID card, and will be accessible only to the Anza Mapema clinic staff. At each subsequent clinic visit, an iris scan will be done at the reception desk to ensure that we identify you as a ***Shauriana*** study participant.

SMS Reminder Messages
If you would like, we can send you reminder messages for your scheduled clinic appointments one day in advance. If you do not want to receive such messages, please let us know either now or at any time in the future.

After the Study
After the research study ends, you may continue to receive care at the Anza Mapema clinic or can transfer to any other GBMSM-friendly clinic or program in the Kisumu area. In case there will be another research study for which you are eligible, you will be informed of this and requested for consent to enrol.

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

What are the potential risks and discomforts?
There is a small risk of loss of privacy or confidentiality related to study visits or contacts by research staff or peer facilitators. We take this risk seriously, and have protocols in place protect participants' confidential data, including HIV status and MSM behavior. Our priority for every participant is their well-being. Drawing blood may cause pain, and a bruise may form where the needle enters the vein. When blood is collected, there is a minimal risk of infection at the site – if this occurs, you will receive treatment at the clinic. Questionnaires and counselling may be stressful for some people. Each of the four clinic visits (baseline, month 1, month 3, and month 6) will take from 1.5 to 2 hours of your time. Each ***Shauriana*** session (5 weekly sessions over the first 5 weeks) will take from 1.5 to 2 hours of your time.

To protect against these potential risks and discomforts:
Our research team members, including the peer facilitator, will all treat your information as private and confidential. An independent committee will monitor this research continuously to ensure participant's safety and rights are respected at all times. If for any reason the research team thinks you would benefit from leaving this study, they will recommend this and ensure that you receive care outside the study.

Are there benefits to taking part in this study?
By participating in this research, you may learn more about your own barriers and facilitators to sexual health including HIV prevention, and may as a result start to use PrEP or increase your PrEP adherence. However, it is also possible that you will have no direct personal benefit and will only contribute to an increase in knowledge about sexual health for GBMSM in the community. You will also help us learn about factors that help and hinder sexual health for GBMSM in Kisumu.

What will happen if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time. In addition, you may refuse to answer questions or provide samples at any time. If you would not like to participate, this will not affect your relationship with or services received at ***Anza Mapema*** or NYARWEK network organizations. If you withdraw from the research project after enrolling, we will ask you to complete an exit interview regarding your reason for withdrawal, care and referral needs.

What about privacy and confidentiality?
All our research records are stored securely in locked cabinets and password-protected computers. Your information will be kept in your study file and be marked with your study ID number. To protect your confidentiality, your name will not appear anywhere in this file. Your signed consent and the information you provide at registration will be locked separately from your file. If we do need to contact you, your confidentiality will be strictly protected by our staff.

Audio recordings of interviews will be stored securely in locked cabinets and on password protected computers. The audio files will be destroyed after completion of the research and expiration of the records retention period required by our funder.

When the study ends and the records retention period has expired, we will destroy the evidence that links your name with your study ID number. We will not publish or discuss in public anything that could identify you. We plan to publish results of this study, but we will not include any information that would identify you. No personal information about you will be given to any person or agency without your written permission.

There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including the ethics review boards at Maseno University and/or the University of Washington. Because this study explores sensitive topics, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies to make sure everyone is safe.

SHAURIANA TRIAL CONSENT

What will happen to my samples?
Blood samples will be tested locally for hepatitis B exposure and kidney function at baseline. Any remaining blood and all urine collected will be stored for analysis of PrEP drug levels at the end of the study. These samples will be sent to two different laboratories in the United States (one for the blood and one for the urine) that specialize in the detection and quantification of PrEP metabolites in blood and urine.

Will I receive any compensation for helping with this study?
After you complete each clinic visit, you will receive 500 KSh to thank you for your time and participation. Reimbursement for all clinic visits will total 2,000 KSh: 500 KSh today if you complete the enrolment visit, 500 KSh after the month 1 visit, 500 KSh after the month 3 visit, and 500 KSh after the month 6 visit. If you are assigned to the intervention, you will receive 350 KSh after completing each of the 5 ***Shauriana*** program sessions with your assigned peer facilitator. All participants, regardless of whether they are assigned to the intervention, will receive 500 KSh after the exit interview.

What are my rights as a research subject?
If you have any concerns or questions about your rights as a study participant, please contact:

- ✓ The Secretary, Maseno University Ethics Review Committee
  Private Bag, Maseno
  Telephone numbers: 057 -51622, 0722203411, 0721543976, 0733230878
  Email address: muerc-secretariate@maseno.ac.ke; muerc-secretariate@gmail.com

You may also contact the University of Washington's Human Subjects Division (HSD) at +1-206-543-0098 or e-mail HSD at hsdinfo@uw.edu.

Who should I contact if I have questions?
If you have any questions concerning the study or your role as a participant or if you wish to report a research-related injury or harm, please contact the following person:

- ✓ Fredrick O. Otieno, Research Director, Nyanza Reproductive Health Society (NRHS); telephone: +254 57 2023903 (Kisumu); 0721-759867 (cell phone)

Remember: Your participation in this research is voluntary. If you decide to participate, you are free to withdraw at any time.

You will be given a copy of this form for your information and to keep for your records.

This research is supported by the United States National Institute of Mental Health. 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 you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

SHAURIANA TRIAL CONSENT

Statement of Consent

I have read this participant information and consent form. I have had the chance to discuss this research study with a study assistant. I have had my questions answered by him or her in language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential. I authorize the inspection of records that relate to this study by the Maseno University and University of Washington ethics boards, and/or their funding agencies for quality assurance purposes.

By verbally consenting to participate in this study, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study as it has been explained to me	Yes	No
I agree for my 6-month exit interview to be audio recorded	Yes	No
I agree to scanning of the eye (iris scan) when I attend clinic visits	Yes	No
I agree to receive text reminders for clinic visits	Yes	No
I agree for my blood and urine samples to be stored for future testing	Yes	No
I agree for my blood and urine samples to be shipped for further study either elsewhere in Kenya or overseas	Yes	No

Participant Name Printed: _____

Participant Signature: _____ Date_____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his consent.

Staff Signature: _____ Date _____

Staff Name Printed: _____

Witness Signature, if necessary: _____ Date _____

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP