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**Complete Intervention Research Protocol**

Title: ***"Gwan Enjoy Life*: Protocol for a Randomized Controlled Trial to Test a Peer-Supported Mental Health Intervention to Improve Engagement in Care for High Priority Sexual Minority Men Living with HIV in Jamaica"**

Submitted By

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## 2. Abstract/Summary

In Jamaica, an estimated 27,000 to 33,000 adult men who report same-sex sexual behavior are living with or face elevated likelihood of acquiring HIV infection. HIV prevalence in this group is estimated at approximately 33%, substantially higher than the 1.8% observed in the overall population. The parishes of Kingston and St. Andrew, St. James, and St. Ann account for some of the highest HIV case concentrations in the country. Psychological distress, social isolation, and exposure to interpersonal violence are associated with reduced engagement in HIV medical care and suboptimal treatment outcomes. Individuals experiencing these stressors demonstrate higher rates of depressive and anxiety symptoms, reduced adherence to antiretroviral therapy (ART), lower retention in care, and decreased rates of viral suppression. Interventions addressing psychological well-being have demonstrated improvements in emotional functioning; however, prior studies have shown inconsistent effects on HIV treatment outcomes, limited integration of stress-related care components, and minimal adaptation to local service delivery environments. There remains a need to develop and evaluate a sustainable peer-delivered behavioral intervention designed to strengthen psychological functioning and improve HIV care engagement outcomes, including social isolation, depressive symptoms, ART adherence, appointment adherence, and viral suppression. This proposal will develop and implement a structured peer-delivered behavioral support program to improve care engagement among adult men living with HIV in Jamaica. The study has the following aim: **Aim 1.** Assess feasibility, acceptability, and preliminary clinical impact (depressive symptoms, anxiety symptoms, social isolation, ART adherence, clinic attendance, and viral suppression) of the intervention. Guided by the Information–Motivation–Behavioral Skills (IMB) model and incorporating evidence-based stress-response management strategies, the *Gwan Enjoy Life* program will be a multi-session intervention delivered by trained peer community health workers (peers) living with HIV. The program is designed to strengthen coping skills, improve treatment adherence behaviors, and increase sustained engagement in care. Feasibility will be evaluated using predefined recruitment, retention, and implementation benchmarks. Acceptability will be assessed through structured exit interviews. Clinical impact will be evaluated through survey measures and medical records review, including virologic and immunologic indicators. The intervention will be conducted in partnership with Jamaica AIDS Support for Life (JASL), a community-based HIV service organization. Sixty participants will be randomized in a 2:1 ratio (40 intervention; 20 control) and assessed at baseline, 24 weeks, and 12 months using structured surveys and clinical record abstraction. The overall objective is to pilot and evaluate a scalable peer-delivered behavioral support program that improves clinical outcomes and strengthens long-term HIV treatment engagement in a high-burden setting, consistent with national and international HIV control priorities.

## 3. Introduction/Literature Review

### 3*A.* Background:

In 2018, sexual and gender minority (SGM) people (people who are non-heterosexual and/or who have a gender different from that assigned at birth) comprise 27,000 - 33,000 Jamaicans who are at greater risk for health disparities, including very high rates of HIV and mental health conditions.[35] **Jamaica's HIV/AIDS epidemic among SGM is the most severe in the Caribbean in breadth and consequences.** Approximately 34,000 people are living with HIV, with a significant proportion being men who have sex with men (MSM) and transgender women (TW).[41–43] Also, HIV prevalence among MSM is estimated at 33% and 51% among TW, which is alarmingly higher than that in the general adult population (1.8%)[8,34,35]. Compounding the high HIV prevalence in these groups are the many social vulnerabilities they experience, including stigma, discrimination, violence, poverty, limited education, homelessness, and criminalization of same-sex sexual behaviors.[36,43–45]

**Violence against Jamaican SGM is a key driver of high prevalence of HIV infections.** Intersectional stigma, often related to intersecting forces of stigma and oppression (e.g., HIV stigma, homophobia, and transphobia), increases the risk of violence for SMM in Jamaica. Exposure to crime and violence among people living with HIV (PLWH) is associated with HIV stigma, ART non-adherence and poor treatment engagement in low-resource settings similar to Jamaica.[46–50] In a recent study of Jamaican SMM, verbal assaults and physical and sexual violence were common.[35] Community violence, a common form of violence perpetuated as mob-style attacks, drive many SGM from their homes.[8,10] Additionally, gender nonconforming individuals are exceptionally vulnerable to gender-based violence such as sexual abuse and assault.[2] Moreover, police abuse and harassment are common; over half of TW reporting spending one or more otherwise unjustified nights in jail.[10,35,51] Due to the pervasiveness of violence toward TW, many forgo gender-affirmation by appearing more masculine, which limits the health benefits of gender affirmation and harms mental health.

**SGM LWH in this social context have reported higher rates of depression, post-traumatic stress disorder (PTSD), and anxiety compared to those in the general population**.[52] SGM LWH have higher rates of exposure to traumatic events and PTSD than the general public, with negative consequences on HIV care outcomes. A recent study involving individuals seeking treatment for HIV in Jamaica revealed high rates of PTSD, substance misuse, and depressive symptoms.[53] PTSD was also found to be associated with non-adherence to ART, depression, anxiety, polyvictimization, and suicidal ideation.[53–55] Moreover, almost 80% of those that screened positive for mental health disorders had never seen a mental health professional, which in part due to societal and cultural stigma around seeking mental health care.[56,57] In this social/cultural context, very little is known about the experience of intersectional stigma and violence among SGM LWH in the Caribbean and the associated impacts on their mental health and HIV care engagement.[58] **ART adherence** and engagement in care are the most important determinants of viral suppression, morbidity, and mortality among people living with HIV (PLWH). To capture ART benefits, SMM LWH in Jamaica must successfully navigate a complicated landscape (e.g., discrimination and violence) across the HIV continuum of care.[59]

**Examination of the role of intersectional stigma, violence, and poor mental health may improve our understanding of factors affecting HIV care engagement in Jamaica.**[60,61] In

Jamaica, prior research has demonstrated a link between socio-ecological factors and high-risk sexual behaviors among SMM;[17] however, the interplay of intersectional stigma, violence, and mental health on HIV care engagement among SMM remains a significant knowledge gap. Additionally, prior research also suggested that those with identities at the most marginalized intersections experience social vulnerabilities that impact their decisions to seek sexual health services.[8] Research on the broader aspects of HIV care engagement has failed to adequately investigate the role of intersectional stigma and how it intersects with structural factors (e.g., poverty, provider attitudes, healthcare delivery).[62,63] New measures have been proposed to advance intersectionality-based research by furthering an understanding of how oppressive forces (e.g., HIV stigma, homophobia, transphobia) drive stigma that people with intersecting identities must overcome.[64–66] These new measures can improve our understanding of the role violence and other social vulnerabilities play in determining HIV care outcomes, yet they have not been adapted or tested in the Jamaican context.[2,35,53] In Jamaica, a comprehensive understanding of the impact of intersectional stigma, violence, and other barriers and facilitators affecting HIV care engagement is needed to develop effective interventions.

**Trauma-focused cognitive behavioral therapy (TF-CBT) interventions have the potential to improve HIV care engagement**. Across many settings, CBT interventions are a proven approach for reducing HIV risk behavior, improved mental health, and building resilience among PLWH.[67,68] In the United States, the provision of social support, self-awareness, depression screening and counseling, disease management, and multicultural adaptions to psychotherapy in TF-CBT interventions for PLWH demonstrated significant improvements in depression symptoms and ART adherence.[68,69] In the Caribbean, no TF-CBT interventions have been employed to improve engagement in care. Therefore, interventions that utilize TF-CBT approaches to harness the powerful role of social support and resiliency are urgently needed.[70] There is strong evidence that culturally-tailored, TF-CBT interventions targeted towards specific populations and containing structural components are far more effective than generic interventions focusing on individual-level behavior change only.[71–73]

Guided by the Information-Motivation-Behavior (IMB) skills theoretical framework and incorporating evidence-based stress-response management strategies informed by cognitive behavioral therapy (CBT), the ***Gwan Enjoy Life*** program is designed to address a critical gap in HIV care engagement among men who have sex with men in Jamaica by targeting the intersecting forces that shape health behavior. The Gwan Enjoy Life intervention is a 6-session choice-based program where participants can self-select to either participate with the intervention content 1-1 with a peer facilitator or as part of group with other sexual minority men (SMM) living with HIV. Participants will be instructed that they can self-select out of the group if they do not want that option or engage with the peer mental health mentor 1-1 if they missed any group sessions. Existing research shows that intersectional stigma, violence, traumatic or adverse life events, and poor mental health significantly influence engagement in care, yet their combined impact remains underexplored, particularly within the Jamaican context. Sexual minority men (SMM) living with HIV at the most marginalized intersections often face compounded social and structural barriers, including poverty, discrimination, and negative healthcare experiences, which can discourage care-seeking and sustained engagement. By incorporating an intersectionality-informed framework, the intervention seeks to better understand and intervene on these layered influences. To directly address these challenges, *Gwan Enjoy Life* utilizes a culturally tailored, trauma-focused cognitive behavioral therapy (TF-CBT) intervention delivered by trained peer community health workers living with HIV. The intervention is designed to strengthen coping skills,

improve treatment adherence behaviors, and increase sustained engagement in care. This evidence-based strategy targets mental health, builds resilience, and strengthens coping in the face of stigma and violence to improve HIV clinical care outcomes. While TF-CBT interventions have demonstrated success in improving mental health outcomes and antiretroviral therapy adherence in other settings, they have not been implemented in the Caribbean for this purpose. By integrating social support, trauma-informed care, and structural awareness, this randomized controlled trial intervention aims to improve engagement in HIV care in a way that is both contextually relevant and responsive to the lived experiences of Jamaican SMM. The intervention will be conducted over six sessions in partnership with Jamaica AIDS Support for Life (JASL), a community-based HIV service organization. Sixty participants will be randomized in a 2:1 ratio (40 intervention; 20 control) and assessed at baseline, 24 weeks, and 12 months using structured surveys and clinical record abstraction. Recruitment will occur across JASL clinic sites in Kingston and St. Andrew, St. James, and St. Ann.

The overall objective is to pilot and evaluate a scalable peer-delivered behavioral support program that improves clinical outcomes and strengthens long-term HIV treatment engagement in a high-burden setting, consistent with national and international HIV control priorities.
Thus, these results along with the proposed intervention (*Gwan Enjoy Life)* will provide valuable insights on how to improve HIV care engagement among SMM LWH in low-resource settings, by providing some of the first data on impacts of intersectional stigma, violence, and poor mental health on HIV care cascade. We also hope that these data will inform policy as well as programmatic changes to promote engagement in care.

### 3B: Conceptual Model and Preliminary Studies

**Conceptual Framework**: We constructed a conceptual framework that serves as the project's theoretical foundation. It draws upon (**1***)* Hatzenbuehler's Psychological Mediation Framework[77], **(2)** Turan *et al.'s* framework (co-developed by co-investigators Weiser and Johnson), and **(3)** the Social-Ecological Model,[74,78] linking HIV-related stigma, treatment adherence, and health outcomes[79] to explain how multiple forms of intersectional stigma and violence intersect to influence mental health and HIV care engagement (***Fig*** 1). The original models posit that SGM experiences with stigma and HIV are linked in a harmful cycle via poor mental health[77] and other behavioral pathways.[79] The framework centers on using a holistic approach to explore the various experiences of stigma, violence, and their associated impacts on mental health and HIV care engagement. As represented by the broken lines in ***Fig*** 1, we hypothesize that SGM with intersecting identities experience stigma and violence and have poorer mental health outcomes, which may have an adverse effect on their levels of engagement in HIV care. This pathway will serve as the key area of focus for our proposed TF-CBT intervention using a

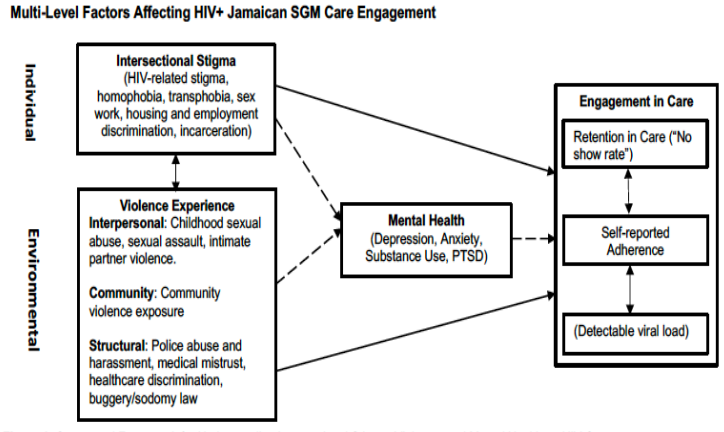



**Figure 1.** Conceptual Framework for Understanding Intersectional Stigma, Violence, and Mental Health on HIV Care Engagement (adapted from Hatzenbuehler, 2009 and Turan et al. 2017)

strengths-based approach that draws on the resilience of the community. Overall, we *hypothesize* that intersectional stigma and violence operate at the individual and environmental levels to impact HIV care engagement. We also *hypothesize* that intersectional stigma and violence operate via mental health pathways to influence engagement in HIV care.

**Preliminary Studies.** From our prior research, we found that sexual decision-making and access to sexual health services in Jamaican SGM were amplified by the trauma they have experienced, including engagement in survival sex, childhood sexual abuse, violence, and homophobia.[1,2,15] Preliminary data from our Integrated Biobehavioral Surveillance study involving (*n* = 652) Jamaican SGM showed that interpersonal violence were commonly reported in the last 12 months among participants. More recently, through funding from the UCSF AIDS Research Institute, Dr. Sharlene Jarrett and Dr. Orlando Harris as PIs conducted a qualitative exploratory study among TW in Jamaica where we explored barriers and facilitators in accessing sexual health services. Preliminary results suggest that TW experience with gender-based violence and discrimination are different; but include overlapping elements (i.e., sexuality-related violence and HIV stigma) that can be addressed in an intervention that is informed by those differences. Our preliminary evidence also suggests two different associations: (1) between HIV status and violence, and (2) experiencing SGM-specific violence and being linked to care. These two projects involved extensive collaboration with Jamaica AIDS Support for Life (JASL), where we worked in the past on other research and programmatic activities for SGM. Therefore, the proposed project is a natural extension of previous research and allows the ability to build on findings for the studies described above.

## 4. Aims/Objectives

**4A. Aim 1:** Implement and assess the feasibility, acceptability, and preliminary clinical impact (depressive symptoms, anxiety symptoms, social isolation, ART adherence, clinic attendance, and viral suppression) of the *Gwan Enjoy Life* intervention among Sexual Minority Men Living with HIV/AIDS (N= 60) in a pilot randomized trial. We will test the feasibility of the intervention (based on defined metrics), acceptability (via qualitative exit interviews), and clinical impact (i.e., virologic/immunologic outcomes from chart reviews) with participants randomized to intervention (N= 40) or control (N= 20).

## 5. Methods

### 5A. Study Design

The proposed research is a piloted randomized controlled trial intervention developed for sexual minority men living with HIV in Jamaica, randomized to either treatment or control. The piloted intervention will assess the feasibility, acceptability, and preliminary impact of the intervention to improve HIV care engagement among SMM LWH. The investigators will randomize 60 individuals in a 2:1 ratio to intervention or control conditions and follow SMM individuals over a 12-month period (i.e., baseline, 24 weeks, and 12 months) with surveys and medical chart reviews to access intervention impacts. Based on our previous research with this population, our findings indicate a need for interventions tailored towards addressing the needs of SMM LWH in Jamacia. Thus, in collaboration with the local community we have designed an intervention that addresses trauma, violence, and mental health, in order to increase engagement in HIV care. The proposed research will

be conducted within JASL, a community-based health organization with operating three sites island-wide, providing direct HIV prevention and treatment services to members of the target population. JASL's three sites include: (1) Kingston & St. Andrew, the region with the highest concentration of HIV infections and population of sexual minority men; (2) St. Ann's Bay, a semi-rural part of the island; and (3) Montego Bay, St. James, the second largest city on the island with a significant tourist dependent economy. There are over 1,000 people living with HIV (PLWHIV) that are accessing services from all three JASL locations, with over 75% of those identified persons identifying as sexual minority men. Thus, JASL's infrastructure and our prior collaborative experiences will provide excellent synergy for ease and support in executing the proposed research activities (see **Appendix 9**).

**5B. Study Population & Sampling**

**5B1. Study population and Sample:** The intervention will involve sexual minority men (SMM) living with HIV and peer mental health mentors who are also living with HIV as session facilitators. The category of sex minority men includes individuals such as men who have sex with men, gay and bisexual men, and those who may identify as nonbinary but was assigned sex at birth. The peer mental health mentor (PMHM) facilitator will either be a peer from the community (sexual minority community [i.e., identify as either gay, bisexual, nonbinary, lesbian]), living with HIV, trained in human subjects protection and confidentiality, and providing peer-level mental health support. The PMHM will be a peer navigator, community facilitator, or adherence or retention counselor, all of whom work with the community within JASL. In our formative work over 40 sexual minority men, participants from the target community were given four choices to choose from to determine which of the four individuals would be best to serve as a mental health mentor and facilitate the intervention. The four choices presented to participants were: (1) a mental health mentor who is a peer from the community, living with HIV, trained in confidentiality, and providing mental health support?; (2) a nurse trained in mental health, not living with HIV, and not form the community; (3) a social worker trained in mental health, not living with HIV, and not form the community?; (4) a psychologist, not living with HIV, and not form the community? The overwhelming majority of participants voted for number one, indicating a strong preference for the intervention to be facilitated by peer who is from the community and trained in delivering the intervention content.

**5B2: Sampling:**

This study will enroll a total sample of 60 participants for the randomized controlled trial titled *"Gwan Enjoy Life: Protocol for a Randomized Controlled Trial to Test a Peer-Supported Mental Health Intervention to Improve Engagement in Care for High Priority MSM Living with HIV."* Eligible participants will be adult sexual minority men living with HIV and currently engaged, marginally engaged in care (defaulters and serial missed appointments), loss to follow-up, or eligible for HIV treatment care services. Of note, an individual is not considered a defaulter if they miss their appointment within 30 days and come back. In this case they are not considered missed. On the other hand, if it is within 30-90 days then that individual is considered default. After the 90 days, they are considered lost to follow-up. At that point, they would be at month 7 mark without a doctor's exam. Patients are given 3 months' worth of medication at a time in order to expand access. However, after that 90-day period, they are in that lost to follow-up category. The organization provides a buffer with writing patients prescription, in essence providing a 4-month supply. Moreover,

lost to follow-up is a public health term utilized by HIV/STI program and does not refer to clients who cannot be located. Many of these clients are in contact with the clinical sites but do not meet the public health definition of being retained in care. For example, a client can be in regularly contact with our patient counselor but has not seen a clinician in the last 6 months to update their ARV prescription. Thus, classifying the as lost to follow up. While they are not actively engaged in clinical care, they're in regularly contact with a member of the psychosocial support team, which facilitates their ongoing engagement with the clinical site. Contact is maintained with the clients through the use of regular wellness calls among other efforts to have them reinitiated. This reinforces that clients are always welcomed to return to clinical care whenever they choose.

We will randomize sixty participants in a 2:1 ratio (40 intervention; 20 control) and assessed at baseline, 24 weeks, and 12 months using structured surveys and clinical record abstraction. Specifically, 40 participants will be assigned to the *Gwan Enjoy Life* intervention arm, and 20 participants will be assigned to the control arm, which will receive standard of care services available to them at JASL. Randomization will be conducted using a computer-generated random allocation sequence to ensure rigor and to minimize selection bias. The computer-generated sequence will utilize the list of all persons living with HIV. The data manager (Mr. Biggs; non-clinic staff) will then prompt the computer using the inclusion criteria to identify by random SMM individuals for potential recruitment. If needed to ensure balance across recruitment sites, randomization will be stratified by site (Kingston, St. Ann's Bay, Montego Bay). This 2:1 randomization approach is intentional and allows for greater exposure to the intervention, enhancing feasibility, acceptability, and preliminary estimates of effect, while maintaining a sufficient comparison group to assess study outcomes. The sample size is appropriate for a pilot randomized controlled trial and is designed to generate effect size estimates, assess feasibility and acceptability, and inform the design of a larger, fully powered efficacy trial to be submitted at a later date. We anticipate the following characteristics for study participants in terms of sample size and inclusion and exclusion criteria (see Table 1 in Recruitment and Consent Section). HIV status and prescription of ART will be determined through JASL clinic records by JASL clinic staff. **No external (foreign and local investigators) collaborator will have access to any patient identifiable information**.

Power and Sample Size: As the primary aim of this pilot study is assess feasibility and acceptability of the research protocol for a future R01 clinical trial, the sample size of $N$=60 individuals were set primarily for practical reasons and not driven by hypothesis testing or estimating precision of effect size estimates. Effect sizes used to inform power analysis for a future full-scale RCT will be taken from the literature and based on clinically important differences. The sample of 60 individuals is proposed to provide a sufficiently large number of SGM to obtain reasonable descriptive estimates and to enable us to test our data collection instruments and procedures and recruitment methods with a sufficiently large sample supplying a variety of responses as well as to obtain a rich set of qualitative exit interview data. However, to supply additional information, we conducted several power analyses and determined that at N=60 the proposed pilot study is powered to detect small to medium distances to confidence limits for descriptive statistics to assess feasibility and acceptability (the primary goal of this pilot study) and large effects for preliminary effectiveness effects (the secondary goal of this pilot study), though, formal hypothesis testing will not be the focus of this pilot study.

**5C: Recruitment & Consent**

**5C1. Recruitment**: Participants will be recruited from all three clinics sites operated by the Jamaica AIDS Support for Life (JASL), a trusted community-based organization providing HIV prevention, treatment, and support services to sexual minority men across Jamaica. Recruitment will occur across three key service locations: Kingston, St. Ann's Bay, and Montego Bay. These sites were selected to ensure geographic diversity and to capture variation in social and structural contexts that may influence stigma, violence exposure, and engagement in care. Participants will be recruited through engagement with members of the care or support service team. Active recruitment will be conducted through one-on-one engagement with a member of the clinic team via phone calls or in person. Clinic staff will introduce the study to potentially eligible clients during routine care visits. We will also use passive recruitment strategies by invoking the help of the research team to locate those who have fallen out of care and encourage participation in the study. We have successfully used similar eligibility criteria in HIV[14] and MSM[2] research in Jamaica. The study team will ask clients to repeat back what we are asking of them in terms of participation and remind clients they do not have to answer right away (give time to client to decide). If clients decide to participate, the team will encourage them to come in on a non-clinic day to refrain from mental pairing. Interested persons will be assessed for eligibility using a brief screening assessment consisting of three questions administered by a study staff member. Prospective participants will be asked: (1) are they a person living with HIV? (2) were they assigned sex at birth? And (3) are they at least 18 years of age? While the clinic staff and the Data and Evaluations Manager will already have this information, we will still ask these three screening questions as another opportunity to confirm that we are selecting the right individuals for the intervention. Following screening, eligible participants will complete the informed consent process and baseline assessment. Upon completion of baseline procedures, participants will be randomized to study condition. The PMHM and the PIs will be responsible for obtaining informed consent from the all enrolled participants.

While JASL clinic research staff will be coordinating with those who wish to participate in the study, to safeguard against undue influence or the risk of coercion, clinical providers (i.e., doctors, nurses, social worker, psychologist, etc.) who are directly engaged in patient care will not participate in the recruitment of participants. This will ensure that potential participants' care is not prejudice by their willingness to or unwillingness to participate in the study. See sampling recruitment script, which will be read by the PMHM to the participant (see **Appendix** 1). Additionally, Drs. Sewell and Harris will not be involved in recruitment of clients for participation in the study. JASL staff will identify, recruit, and preliminarily screen for eligibility and interest for participating in the study. At this point, participants who express willingness to participate, will be consented for inclusion. This gives potential participants a second opportunity to decline participation if they wish. JASL will remind all screened participants, whether they consent or not, that their participation in the study is voluntary and will not impact the services available to them at JASL. Drs. Sewell and Harris will not have access to clients' personal identifiable information. Additional procedures for participant recruitment are detailed Recruitment Plan (see **Appendix 2**).

The study will adhere to the following recruitment enrollment targets. We will adjust those targets based on the time in which the study is approved from the relevant Ethics oversight bodies:

- Enrollment Date:
    - Enrollment of the first participant (Study Start Date) = 7/31/2026

- 25% of planned enrolled recruited by = 8/15/2026
- 50% of planned enrolled recruited by = 8/15/2026
- 75% of planned enrolled recruited by = 8/30/2025
- 100% of planned enrolled recruited by = 9/15/2026
- Completion of primary end point data analysis = 8/30/2027
- Reporting of results in ClinicalTrails.gov = 9/30/2027

**5C2. Consenting Procedures:** Potential participants will be provided with a copy of the informed consent form. The form contents information related to the background and purpose of the study, a description of the study procedures, confidentiality statement, risk of participation, benefits of participating in the study, who to contact to learn more about their rights, and compensation. We will ask participants the following questions in order to determine their eligibility (1) are they a person living with HIV? (2) were they assigned sex at birth? And (3) are they at least 18 years of age? Once they have been deemed eligible, either the PMHM or one of the study investigators will review the consent form with them. Before signing the consent form, each participant will be asked to repeat back what they have read to determine comprehension and ask if they have any additional questions before they engage with any study activity.

**5C3: Eligibility**

**Inclusion criteria:** Sexual minority men will be eligible to participate if they: (a) Self-identified as a cisgender man who have sex with men or nonbinary (assigned male sex at birth); (b) age 18 and older; (c) living in one of the 14 parishes; (d) ability to offer informed consent; (e) provide consent to review medical records; and (f) living with HIV and currently prescribed ART. See **Table 1** for a list of the inclusion and exclusion criteria.

**Exclusion criteria**: a) self-reported participation in another care engagement study; b) unable to understand the consent process; and c) planning on relocating out of the country over the next 12 months. Unwillingness to be recorded is not a criterion for exclusion from participation in the study. For the acceptability qualitative interviews, participants can refuse to be audio recorded. In these instances, the research team will take notes alternatively. This will not prejudice their participation.

| Table 1: Characteristics of study population | |
|---|---|
| | **Aim 1: Intervention Implementation** |
| Sample Size | N= 60 sexual minority men |
| Age | 18+ |
| Inclusion Criteria | Self-identified as a cisgender man who have sex with men, transgender woman, nonbinary (assigned male sex at birth)<br><br>Age 18 and older, living in one of the 14 parishes, ability to offer informed consent<br><br>Living with HIV (currently engaged, marginally engaged, and not engaged in care)<br><br>Provide consent to clinic staff to review medical records. |
| Exclusion Criteria | Self-reported participation in another HIV care engagement study<br><br>Unable to understand the consent process<br><br>Planning on relocating out of Jamaica over the next 12 months. |

## 5D: Data Collection, Management, Storage and Analysis Procedures

### 5D1: Procedures (detailed the approach to obtaining data including how measures will be conducted and by whom)

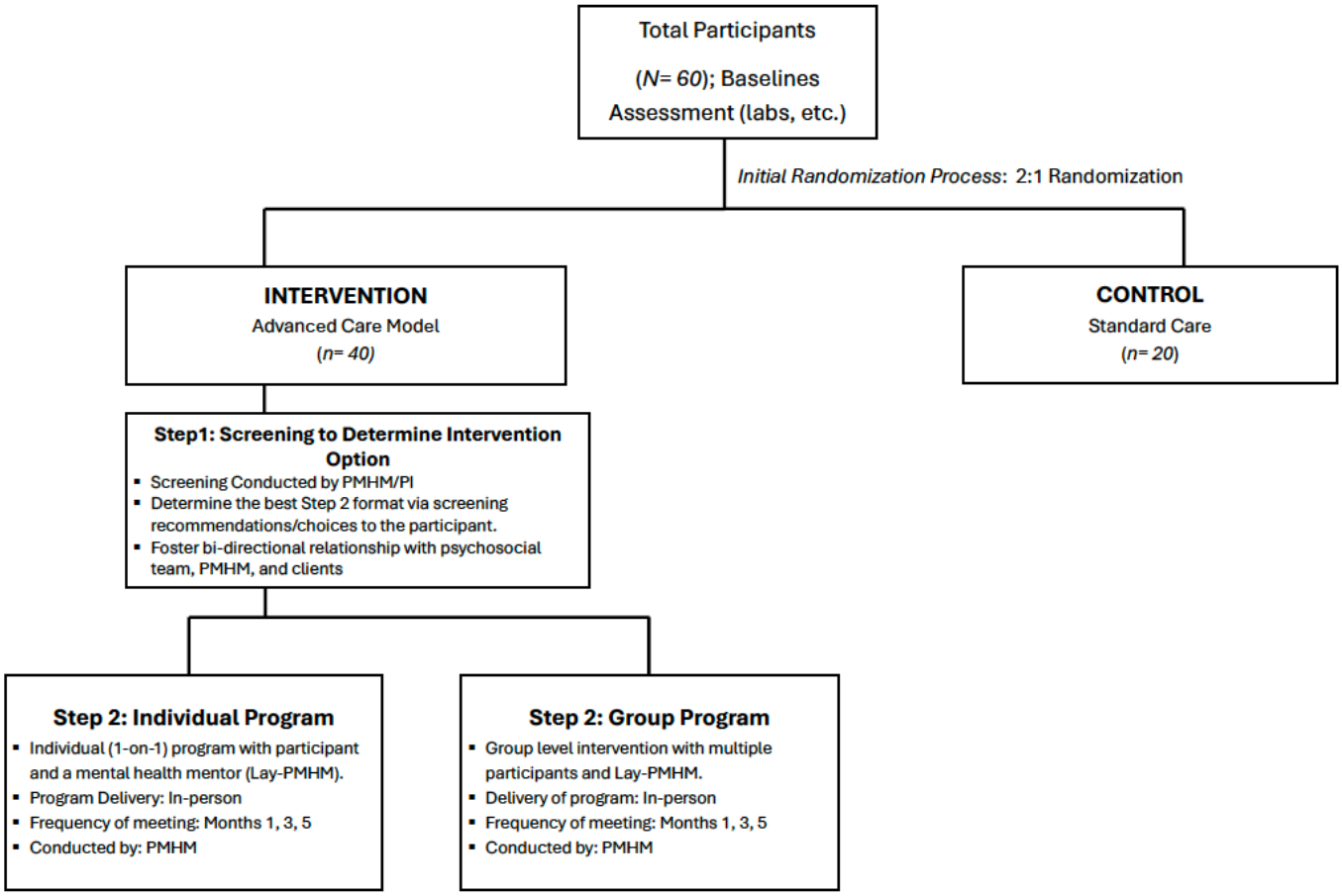
Guided by the Information-Motivation-Behavior (IMB) skills theoretical framework and incorporating evidence-based stress-response management strategies informed by cognitive behavioral therapy (CBT), the ***Gwan Enjoy Life*** program is designed to address a critical gap in HIV care engagement among sexual minority men in Jamaica by targeting the intersecting forces that shape health behavior. The Gwan Enjoy Life intervention is a 6-session choice-based program in partnership with Jamaica AIDS Support for Life (JASL), a community-based HIV service organization, where participants self-select to either participate with the intervention content 1-1 with a peer mental health mentor (PMHM) or as part of group with other sexual minority men (SMM) living with HIV. Participants will be instructed that they can self-select out of the group if they do not want that option or they could engage with the peer mental health mentor 1-1 if they missed any group sessions. The intervention is designed to strengthen coping skills, improve treatment adherence behaviors, and increase sustained engagement in care.

**Randomization:** Sixty participants will be randomized in a 2:1 ratio (40 intervention; 20 control) and assessed at baseline, 24 weeks, and 12 months using structured surveys and clinical record abstraction. This 2:1 randomization approach is intentional and allows for greater exposure to the intervention, enhancing feasibility, acceptability, and preliminary estimates of effect, while maintaining a sufficient comparison group to assess study outcomes. Participants will be recruited across the three JASL sites (Kingston, St. Ann's Bay, and Montego Bay). Specifically, 40 participants will be assigned to the *Gwan Enjoy Life* intervention arm, and 20 participants will be assigned to the control arm, which will receive standard care available to them at JASL. Randomization will be conducted using a computer-generated random allocation sequence (available via Microsoft Excel) to ensure

rigor and to minimize selection bias. The computer-generated stratification sequence will utilize JASL's list of all sexual minority men living with HIV who access care at the facility. Mr. Biggs, JASLs Data Manager will be the only person who have access to this list of persons. The Data Manager (Mr. Biggs; non-clinic staff) will then prompt the computer using the inclusion criteria (see Table 1 in Recruitment and Consent Section) to identify by random and select every third person on the list for potential recruitment. Interested persons will be assessed for eligibility using a brief screening assessment consisting of three questions administered by a study staff member (PMHM). Prospective participants will be asked: (1) are they a person living with HIV? (2) were they assigned sex at birth? And (3) are they at least 18 years of age? While the clinic staff and the Data and Evaluations Manager will already have this information, we will still ask these three screening questions as another opportunity to confirm that we are selecting the right individuals for the intervention. Following screening, eligible participants will complete the informed consent process and baseline assessment survey. Upon completion of baseline procedures, participants will be randomized using the same computer-generated sequence to treatment vs. control. To ensure recruitment and randomization balance across recruitment sites, randomization will be stratified by site (Kingston, St. Ann's Bay, Montego Bay). For example, in the intervention group, we will randomize 20 SMM from Kingston, 12 from Montego Bay, and 8 from St. Anns Bay. In the control group, we will select 10 SMM from Kingston, 6 from Montego Bay, and 4 from St. Ann's Bay. As an intervention pilot, there will be no blinding of participants or PMHM. To control for bias in the fair selection of participants, the PMHMs or the study investigators will not have access to the randomization allocation sequence. Specifically, Drs. Sewell and Harris will not be involved in recruitment of clients for participation in the study.

**Choice Format**: The Gwan Enjoy Life intervention is a choice-based program where participants can self-select to either participate with the intervention content 1-1 with a peer facilitator (PMHM) or as part of group with other sexual minority men (SMM) living with HIV. Participants will be instructed that they can self-select out of the group if they do not want that option or engage with the peer mental health mentor 1-1 if they missed any group sessions. After the randomization process, the intervention group will be screened by the PMHM or the PIs to determine the best intervention option (see Figure 2). The screening and engagement will also foster bi-directional relationship with the clinic psychosocial team, PMHM, and clients. While participants can choice which format they would like to receive the intervention, the content and approach for both the individual and group format will be the same. For example, the program will be delivered in-person, conducted by a PMHM, and will meet at month(s) one, three, and five. Follow-up assessments will occur at 24 weeks after the month 1 (baseline) and final assessment completed in 2027 (12 months after baseline).

**Figure 2: A Peer-led Mental Health Mentoring Intervention to Enhance Engagement in HIV Care Among Jamaica SMM**




**Intervention structure:** Participants in the intervention arm of the study, will be engaged over 6 sessions. At baseline (month 1), participants will engage with the PMHM over a half day period (3-4hrs) and receive sessions 1 and 2 divided over 1.5 to two hours each. At month 3, participants will also receive sessions 3 and 4, divided over 1.5 to two hours each. Sessions 5 and 6 will also be delivered together and divided over 1.5 to two hours each. Below is an outline of each of the sessions and the context that will be covered (modules) for in each session (see **Appendix 3**):

**Session 1: Introduction, identity, and risk**
Module 1. Introduction and Overview to the Gwan Enjoy Life Intervention
Module 2. Sexual Orientation & Discrimination
Module 3. Sexual Behavior and Risk (STI 101; importance of screening and treatment; men's health/healthy sexuality)
Module 4. Substance Use and HIV

The objective of Session 1 is to allow participants an opportunity to understand the purpose and structure of the intervention, identify how sexual orientation and discrimination affect health, and recognize links between sexual health, substance use, and HIV risk.

**Session 2: Understanding HIV and Engagement in Care**

Module 1. Living with HIV and understanding the pathways for treatment: When treatment work and when it doesn't

Module 2. Understanding the importance of engagement with HIV care (adherence, retention, and viral suppression) and supportive programming.

Module 3. Isolating common Barriers to care engagement: Mental Health, adherence, support systems (lack of adequate support), and disclosure.

Module 4. The building rapport and trust with your care team: Understanding the concept of trust and respect with your HIV Care.

Module 5. Overview: HIV 101 & the importance of knowing your numbers (what your numbers mean and your specific line of treatment?)

Session 2's objective is to help participants understand how HIV treatment works and what "viral suppression" means. Participants will also learn how to interpret their own clinical markers (viral load, CD4 count, and treatment regimen). The participant will also learn how to identify barriers and facilitators to staying engaged in care.

**Session 3: Mental Health, Trauma, and HIV**
Module 1. Mental health and HIV: Understanding the role of mental health in HIV care engagement (anxiety, depression, loneliness, etc.)
Module 2. How adverse life experiences can impact HIV care: The interplay between trauma, negative childhood experiences (ACEs), and negative self-image on HIV care engagement.

The primary objectives of Session 3 are to help participants recognize symptoms of depression, anxiety, and loneliness. Participants will also learn how trauma and adverse experiences affect mental health and identify how mental health impacts HIV care engagement. This session acknowledges that poor mental health and lack of retention and engagement in care are both on the pathway to impacting HIV viral suppression. While a person can be virally suppressed, they can also have poor mental. Viral suppression without improving mental health symptoms is not sustainable because it can cause shocks resulting in disengagement from care and variations in viral suppression status. Without adequate psychosocial support, viral suppression is not sustainable on its own.

**Session 4: Stigma, Violence, and Human Rights**
Module 1. Intersectional and HIV-related stigma
Module 2. The Experience of violence
Module 3. Human rights 101: Legal literacy & legal protections available to persons living HIV

The objectives for Session 4 include identifying different forms of stigma (HIV-related, sexual identity, and structural stigma), understand the impact of violence on health and care engagement, and increase awareness of legal rights and protections.

**Session 5: Resilient Coping, Social Support, and HIV Disclosure**
Module 1. Coping and resilience
Module 2. Social support systems (Peer navigation; peer mentoring and support)
Module 3. HIV Disclosure: Challenges and Opportunities

This session is geared towards skills building where participants will develop resilient coping strategies, identify and strengthen social support systems, and explore safe and strategic HIV disclosure assets.

**Session 6: Integration and Moving Forward**
Module 1. Tying it all back together: An overview of topics and testing of knowledge
Module 2. Wrap-up and expectations for follow-up

The objective of this final session is to integrate all the key lessons learned from all sessions, demonstrate understanding of HIV care engagement strategies, and develop a personal plan for continued care and well-being.

**Control group:** While not part of the intervention arm of the study, participants in the control group will still have access to usual care services available at all three JASL sites. For example, those in the control group will still have access to psychosocial support, nutritional support, adherence counseling, care packages, social worker, case management, stipend support, case management, legal support, legal literacy training, gender-based violence support, and other skills building support services. The intervention will not restrict their access to any of these services. Those in the intervention group can also access these services as well while still in the intervention and the PMHM can make referral to any of the additional psychosocial support services available within JASL. To ensure continued access and sustainability, once the intervention is completed and proven to be efficacious, JASL will have access to all intervention materials that can be integrated as part of the care offered at JASL. This will grant access to all patients seen in any of the three JASL clinics.

**Study Activity Completion Time**: Participation in the study will take approximately 2.5hrs to 3hrs for each monthly session for a total of 7.5 to 9 hours total for the intervention. This includes the time for the consenting, completion of the demographic survey, and participation with the intervention content. The intervention will last at least 1 year, with no follow-up after.

**PMHM Selection Process:** The peer mental health mentor is a lay community health worker who is also living with HIV. These lay community health workers have experience working as a community facilitator, retention navigators, adherence counselors, or peer navigators. Community facilitators are assigned by the Jamaica Network for Seropositive (JN+) to work with JASL clients who are living with HIV. Retention navigators, adherence counselors, or peer navigators are either employees of JASL or assigned by the Ministry of Health and Wellness to work with JASL. These individuals have a relationship with the clients and experience in conducting patient support groups as part of their regular duties The PIs in collaboration with JASL leadership will identify two persons from each of the three sites to facilitate both the individual and group sessions. The St. Ann’s Bay and Montego Bay sites only have two lay community health workers at each site. Thus, both will be selected to facilitate the group or individual sessions. While Kingston as four lay community workers, only two will be trained on how to deliver the intervention. Dr. Harris has co-facilitated support groups with many of these individuals before and have complete confidence in their ability to carry out the intervention content with full fidelity.

**PMHM Facilitator Guide and Training:** Before the start of the intervention all identified PMHM will be trained on how to administer the intervention. Dr. Harris and Sewell will conduct a half day training with the team to orient them to the Gwan Enjoy Life Facilitator Training Manual. They will be trained on understanding the goals of the intervention, build on existing facilitation skills (active listening, group dynamics, good facilitation), how to deliver the sessions with fidelity, setting ground rules, mental health, trauma, adverse life events, and all aspects of HIV care engagement (an area that they know very well) (see **Appendix 4**).

**Feasibility:** To understand the feasibility of implementing the intervention, we have identified several feasibility benchmarks/metrics. For recruitment, we will assess the number of clients opting to participate in the study and compare that data to those eligible. We anticipate that at least 70% or greater participation among those being recruited and eligible. In terms of enrollment, we will measure the number of participants enrolled per week and number of those who started the intervention. We anticipate an average of 7-8 persons per week over 1 month, resulting in about 80% of participants enrolled by month 1. The next feasibility metric we will assess is retention in both arms of the study. We will do this by collection data on retention rates and reasons for dropout. The team will work to retain a minimum of 80% of participants at 24 weeks and 12 months. We will also collect data on adherence to the intervention protocol through attendance at individual or support group meetings (a total of three meetings). Finally, we will collect information on intervention fidelity via successful implementation of training curriculum indicated by fidelity score (see **Appendix 5**). We have created a fidelity checklist, which will be completed by each PMHM.

**Table 2:** Feasibility metrics and descriptive statics used to examine feasibility

| Feasibility Metrics | Descriptive Measures | Threshold |
|---|---|---|
| Recruitment | # opting in among those eligible | At least ≥70% among those being recruited and eligible |
| Enrollment | # enrolled per week and # starting the intervention. | Average of 7-8 per week over 1 a month, 80% enrollment rate to achieve n= 40 intervention and n= 20 controls |
| Retention in both arms | Retention rates; reasons for dropout | Minimum of 80% retention at 24 weeks and 12 months |
| Adherence to intervention protocol | Attendance at group peer mentoring sessions and individual peer mentoring sessions (total of 3) | ≥80% of participants complete ≥75% of group meeting times or individual peer support/mentoring sessions<br>≥80% of participants complete group or individual peer support/mentoring sessions |
| Intervention fidelity | successful implementation of training curriculum indicated by fidelity score | Fidelity checklist completed for each PMHM; median score ≥3.5 on 4-point scale; Fidelity of intervention delivery by the interventionist(s) |

These benchmarks will be used to determine whether the intervention and study procedures are sufficiently feasible to support a future fully powered trial.

## Acceptability

Acceptability: We will evaluate acceptability of intervention activities using an acceptability theoretical framework for healthcare interventions[137], which conceptualizes acceptability as a multi-dimensional construct reflecting participants' cognitive and emotional responses to an intervention. The TFA includes seven domains: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. Quantitative acceptability data will be collected using Likert-scale items mapped to each domain, supplemented by qualitative interviews to explore participant experiences, perceived cultural relevance, and barriers to engagement. This approach will allow for a comprehensive assessment of intervention acceptability and inform refinement for a future fully powered trial. Participants will be able to report any problems at any time during the study. In

addition, we will have monthly check-ins with participants during which we will ask about general acceptability. These check-ins will also help to increase engagement with the study and reduce loss-to-follow-up. At 6 and 12 months, we will conduct exit interviews with n=20 intervention participants. During the interviews, we will assess acceptability of the intervention. Participants will be asked to complete the assessment tools. Additionally, participants' perceptions of the intervention (negative/positive) will be assessed during the qualitative interviews. At least 80% satisfaction will be considered acceptable. During the interview, we will ask about: (1) technical issues, such as problems with the intervention; (2) likelihood of continued care engagement outside of our study; (3) content they would change, add, or eliminate; (4) likelihood of participating in other interventions; and (5) suggested modifications to increase engagement and maintain attention. We will also interview HCPs, in which we ask about the burden/ease of the study, the process, pros/cons of the intervention, time commitment and potential impact on daily clinical work, potential benefits to patients, and prospects of recommending it to other clinicians.

According to the Theoretical Framework of Acceptability (TFA) developed by Sekhon and colleagues, acceptability is defined as the extent to which people delivering or receiving an intervention consider it appropriate, based on anticipated or experienced cognitive and emotional responses. In other words, it is not just "did participants like it?" it is how they think and feel about the intervention across multiple dimensions. Thus, participants will be asked the following questions in order to access acceptability:

1. How did participant feel about the intervention? Did they like it? Did they feel supportive or burdensome?
2. Was participation too time-consuming or emotionally taxing? What was the level of perceived effort required?
3. Did they feel as though the intervention improved their mental health or care engagement? Do you believe that the intervention work?
4. Did the intervention feel respectful, safe, and culturally appropriate in Jamaica? Did the intervention fit with participants' values and cultural context
5. Did participants understand why peer support and coping strategies were being used? Did they have a clear understanding of how the intervention works
6. What did you have to give up to participate in the intervention? (Missed work, travel, competing responsibility)
7. Did you feel capable of completing sessions and applying the skills you learned around ways of improving your mental health? How was your confidence in engaging with the intervention?

The TFA allows us to demonstrate that we will be evaluating the implementation of the intervention rigorously, identifying why the intervention work or did not work, and provide enough evidence to prepare for scale-up in a larger intervention trial.

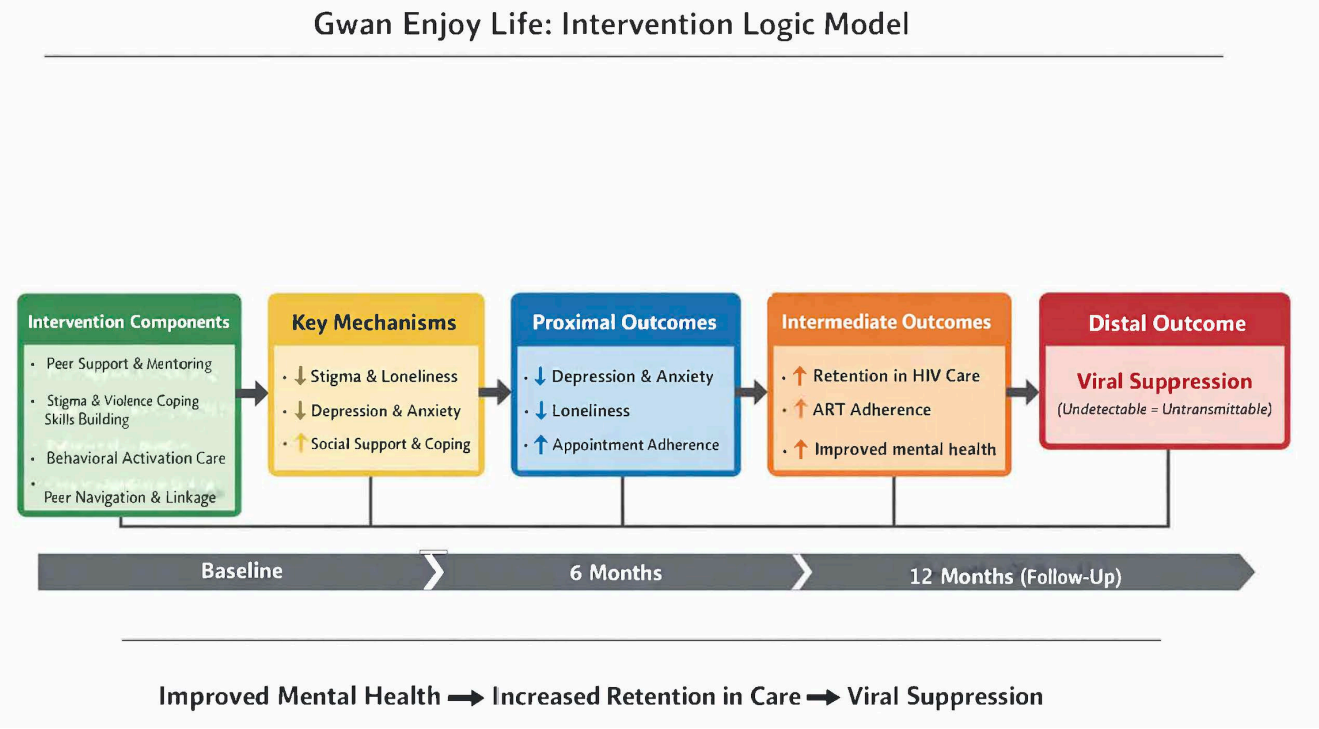
Acceptability will be assessed using the Theoretical Framework of Acceptability (TFA), which conceptualizes acceptability as a multi-dimensional construct reflecting participants' cognitive and emotional responses to an intervention.

Preliminary Clinical Impact: At baseline, 6, and 12 months, we will abstract the following data from participants' medical records: appointment attendance, progress notes that document adherence, mental health variables, and laboratory data including viral load (plasma HIV RNA and CD4+ cell count; see **Appendix 6**).

Pilot primary outcome measures: We will assess feasibility, acceptability, and preliminary impact of the Jamaica Cares intervention via the following metrics: Feasibility: *Table* 2 summarizes feasibility

constructs, measures, and thresholds for feasibility; all procedures (including sample size determination) are based on standardized feasibility procedures outlined in the literature[132–136]

Figure 3




**5D2: Instruments (Questionnaire, data extraction forms)**

**5D2A: Conceptual definition of and Operationalization of Variables**

The team will employ the use of several validated instruments for the purposes of assessing participants mental health, adherence to HIV treatment, and viral suppression. We will also collect sociodemographic survey data in addition to these other instruments. In section 5D3, we have detailed each other the core measurements to be used in the study. We have included a the study demographic and behavior survey that will be used at baseline, 24 weeks, and 12 months (see **Appendix 7**).

**Rationale for Chosen Instruments**: The variables below were chosen because our preliminary studies conducted with the same population at JASL demonstrated that a peer supported intervention was needed that target intersectional stigma, violence, trauma, and mental health (i.e., loneliness, depression, anxiety, etc.) to increase engagement in care.

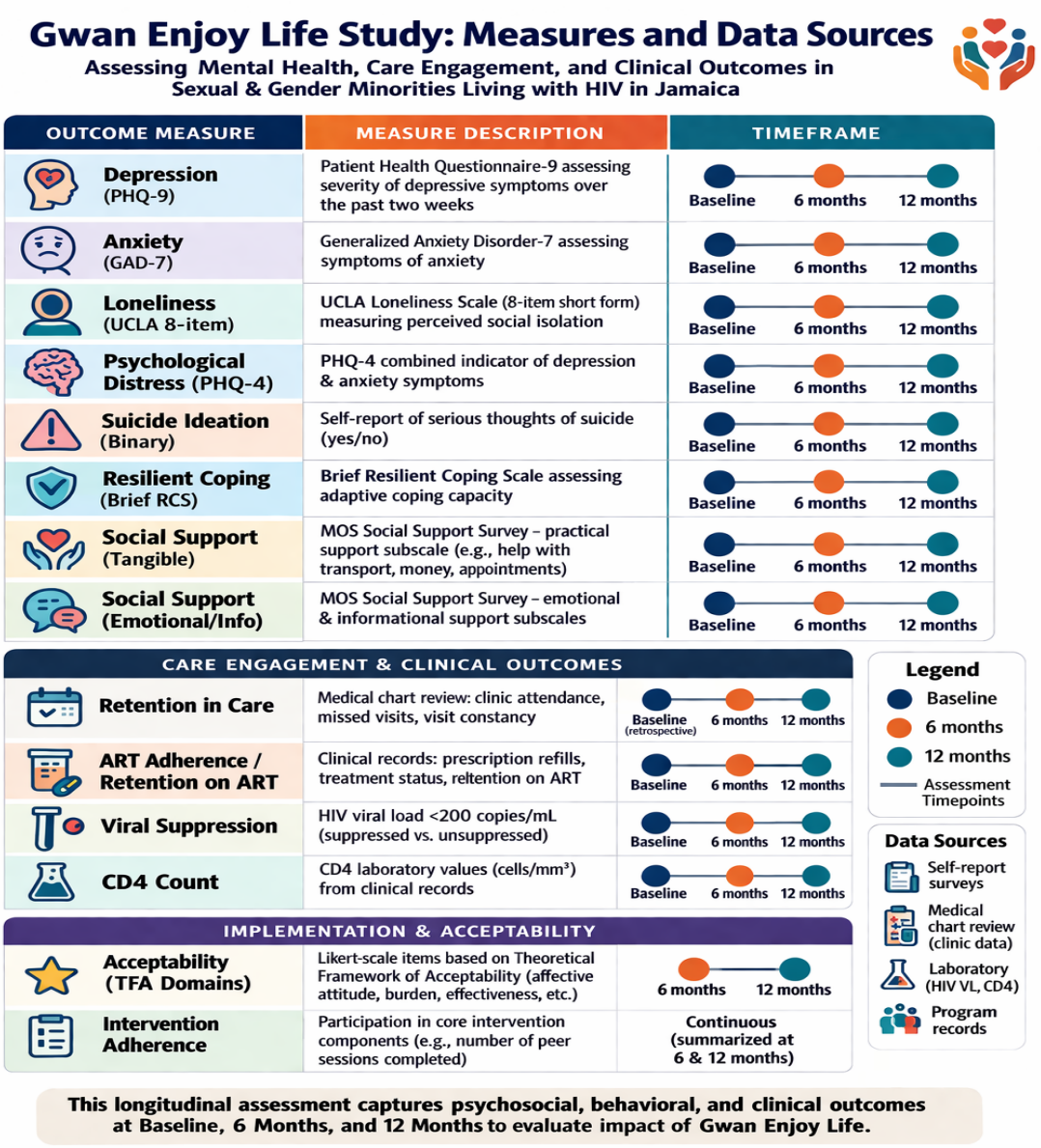



Figure 4: Gwan Enjoy Life: Measures and Data Sources

**Preliminary Study 1:** Sexual minority men (SMM) experiences with sexual violence are poorly understood within the Caribbean context. Childhood sexual assault (CSA) is a known risk factor for poor mental health and loneliness in adulthood. However, little is known about how CSA affects different levels of these outcomes, particularly among SMM living with HIV in Jamaica. We used quantile regression to examine whether CSA is differentially associated with loneliness and poor mental health across the distribution of these outcomes. We conducted a cross-sectional survey among 350 SMM adults living with HIV in Jamaica. Participants were recruited from a community-based HIV clinic between January and May 2024. The sample was described using summary statistics. Multiple linear regression (MLR) with bootstrap standard errors (5,000 replications) estimated average associations, while quantile regression with jittering (5,000 samples) examined whether associations varied across the loneliness and depression/anxiety distributions at the 50th, 75th, and 90th percentiles. We

performed all analyses in STATA version 18. Participants ranged in age from 18 to 71 years (mean age of 33). The majority of the sample identified as male (90%), and not college educated (70%). CSA was associated with higher loneliness in the MLR model (B = 2.903, SE = 0.528, $p < 0.001$), with quantile regression revealing heterogeneous associations across the distribution: the association was larger at the median (B = 4.089, SE = 1.069, $p < 0.001$), similar in magnitude to the average at the 75th percentile (B = 2.064, SE = 0.765, $p < 0.01$), and non-significant at the 90th percentile (B = 2.040, SE = 1.183, $p = 0.085$). CSA was also associated with higher depression/anxiety symptoms in the MLR model (B = 1.953, SE = 0.377, $p < 0.001$), with quantile regression indicating relatively consistent associations at the median (B = 2.365, SE = 0.715, $p < 0.001$) and the 75th percentile (B = 2.213, SE = 0.830, $p < 0.01$), and a notably larger association at the 90th percentile (B = 3.775, SE = 1.354, $p < 0.01$). CSA is linked to more depression/anxiety symptoms among SMM living with HIV in Jamaica. Our findings support targeted clinical and structural interventions for SMM who experienced CSA. The diffused pattern of loneliness also suggests the need for broader, low-threshold social support responses.

**Preliminary Study 2:** Sexual minority men living with HIV experience elevated levels of psychological distress and suicide ideation due to intersecting social stressors such as HIV-related stigma, minority stress, and early-life trauma. While psychological distress is a key risk factor for suicide ideation, less is known about the extent to which resilient coping and social support resources may buffer this association among Sexual Minority men living with HIV in Jamaica. We conducted a cross-sectional survey among a sample of 350 sexual minority men living with HIV in Jamaica. Participants were recruited from a community-based organization operating three HIV clinics island-wide between January and May 2024. Suicide ideation was modelled as a binary outcome using linear probability models (LPM) with robust standard errors. Psychological distress was defined as symptoms of depression and anxiety (PHQ-4). Resilient coping was assessed using the Brief Resilient Coping Scale, and several dimensions of social support resources were measured using the Medical Outcomes Study Social Support Survey. Models included interaction terms to test moderation effects and adjusted for childhood sexual assault and sociodemographic covariates. Analyses were conducted using Stata version 18. Approximately 19% of the participants seriously considered committing suicide (suicide ideation). Psychological distress was positively and significantly associated with a higher probability of suicide ideation ($\beta = 0.23$, $p < 0.001$). Resilient coping and tangible social support resources moderated this association. Specifically, individuals with average levels of resilient coping exhibited a significantly weaker association between psychological distress and suicide ideation compared with those with low resilient coping ($\beta = -0.21$, $p < 0.05$), while a similar but weaker effect was observed for high resilient coping ($\beta = -0.14$, $p < 0.10$). In addition, tangible social support significantly attenuated the positive association between psychological distress and suicide ideation ($\beta = -0.43$, $p < 0.05$), whereas other social support dimensions (e.g., emotional support) showed weaker or inconsistent moderating effects. Resilient coping and tangible social support resources reduce the probability of suicide ideation associated with psychological distress among sexual minority men living with HIV in Jamaica. These findings highlight the importance of strengthening coping capacities and access to practical social support programs for this population.

### 5D2B: Medical Chart Review (Data Extraction)

Participants will be informed that during their participation in the Gwan Enjoy Life intervention, clinic staff will extract several different information from their medical chart. As part of the *Gwan Enjoy Life* intervention, clinical outcome data will be obtained through structured medical chart reviews conducted by a designated member of the Jamaica AIDS Support for Life (JASL) clinical team. This individual is embedded within the clinical care system and authorized to access patient records as part of routine care, thereby ensuring that data extraction is conducted in accordance with organizational policies and local regulations. The chart review will systematically extract the following variables relevant to HIV care engagement and clinical outcomes: (1) next clinic appointment date; (2) last expected clinic appointment date; (3) last antiretroviral (ARV) prescription date; (4) current

ARV regimen (last ARV line); (5) first CD4 test date and corresponding result; (6) most recent CD4 count and result; (7) previous viral load date and result; (8) most recent viral load date and result; (9) and indicators of care engagement, including (11) retention in care, (12) retention on ARV therapy, (13) and viral suppression status. All extracted data will be de-identified prior to transfer to the research team with the Data Management and Evaluation manager serving as the reviewer to ensure all de-identification has taken place. No direct identifiers (e.g., names, addresses, medical record numbers) will be collected, and study data will be linked only through unique participant study IDs. Members of the research team will not have access to identifiable patient information at any stage of the study. All study procedures will comply fully with the Jamaica Data Protection Act and applicable organizational data governance policies. Data will be securely stored on password-protected, encrypted systems, and access will be restricted to authorized study personnel. These procedures are designed to ensure the confidentiality, privacy, and security of all participant data while enabling rigorous assessment of clinical outcomes.

**5D3: Measurements**

**5D3A: Clinical Outcomes Measures and Their Significance**

The “Gwan Enjoy Life” intervention is grounded in the premise that addressing intersectional stigma and violence will lead to improvements in both mental health and HIV-related clinical outcomes among sexual minority men living with HIV in Jamaica. To rigorously evaluate this premise, the study focuses on three interrelated domains of clinical outcomes: (1) mental health, (2) retention in HIV care, and (3) HIV virologic suppression. All three of these areas are hypothesized to improve engagement in HIV care.

**Mental Health Outcomes (Depression, Loneliness, and Anxiety)**

Mental health outcomes, including depression, loneliness, and anxiety, are central to the conceptual model underlying the intervention. Sexual and gender minority men in Jamaica experience disproportionately high levels of psychological distress due to chronic exposure to stigma, discrimination, and violence. These stressors contribute to elevated depressive and anxiety symptoms, as well as social isolation, all of which have been shown to undermine engagement in HIV care and treatment adherence. **Depression** may reduce motivation to attend clinic visits or adhere to antiretroviral therapy (ART), while **anxiety** can heighten fear of disclosure and healthcare-related stigma. **Loneliness**, as a marker of social disconnection, further exacerbates these challenges by limiting access to supportive networks. By targeting these mental health outcomes through a peer-supported, strengths-based approach, the intervention aims to alleviate psychological distress, enhance coping, and improve participants’ capacity to engage consistently in care.

Mental health will be assessed across three domains: depression, anxiety, and loneliness, each measured using standardized, validated scales:

- **Depression:** The Patient Health Questionnaire-9 (PHQ-9) will be used to assess depressive symptom severity over the past two weeks. The PHQ-9 is widely used in HIV research and global health settings, with strong reliability and validity, and is sensitive to changes over time.

- **Anxiety:** The Generalized Anxiety Disorder-7 (GAD-7) will measure symptoms of generalized anxiety. This brief, validated scale has demonstrated strong psychometric performance across diverse populations and is appropriate for repeated assessments in intervention studies.

- **Loneliness:** The UCLA Loneliness Scale (long-form version) will be used to assess perceived social isolation and connectedness. Loneliness is a critical construct in this population given the role of social exclusion and stigma, and this scale has been widely validated across cultural contexts. The UCLA Loneliness Scale was selected because it balances low participant burden with greater content coverage and sensitivity than ultra-brief screeners, making it well suited for a pilot randomized trial evaluating psychosocial mechanisms of intervention effect.

These measures were selected due to their brevity, strong psychometric properties, and prior use in HIV and global mental health research, making them well-suited for longitudinal assessment in this trial (see Table 3).

**Table 3: Gwan Enjoy Life Study: Outcome Measures, Descriptions, and Timeframe**

| Outcome Measure | Measure Description | Timeframe |
|---|---|---|
| **Depression** | Assessed using the Patient Health Questionnaire-9 (PHQ-9) to measure severity of depressive symptoms over the past two weeks | Baseline; 6 months; 12 months |
| **Anxiety** | Measured using the Generalized Anxiety Disorder-7 (GAD-7) to assess symptoms of anxiety | Baseline; 6 months; 12 months |
| **Loneliness** | Assessed using the UCLA Loneliness Scale (8-item short form) to measure perceived social isolation | Baseline; 6 months; 12 months |
| **Psychological Distress** | Measured using the PHQ-4 as a brief combined indicator of depression and anxiety symptoms | Baseline; 6 months; 12 months |
| **Suicide Ideation** | Assessed using a binary self-report measure of serious thoughts of suicide | Baseline; 6 months; 12 months |
| **Resilient Coping** | Measured using the Brief Resilient Coping Scale to assess adaptive coping capacity | Baseline; 6 months; 12 months |
| **Social Support (Tangible)** | Assessed using the Medical Outcomes Study (MOS) Social Support Survey subscale capturing practical support | Baseline; 6 months; 12 months |
| **Social Support (Emotional/Informational)** | Assessed using MOS Social Support Survey subscales for emotional and informational support | Baseline; 6 months; 12 months |
| **Retention in Care** | Measured via medical chart review: clinic attendance, missed visits, and visit constancy | Baseline (retrospective); 6 months; 12 months |
| **ART Adherence / Retention on ART** | Assessed via clinical records including prescription refill data and treatment status | Baseline; 6 months; 12 months |
| **Viral Suppression** | HIV viral load (<200 copies/mL) extracted from medical records to determine suppression status | Baseline; 6 months; 12 months |
| **CD4 Count** | Immune status measured via CD4 laboratory values from clinical records | Baseline; 6 months; 12 months |
| **Acceptability (TFA domains)** | Assessed using Likert-scale items mapped to the Theoretical Framework of Acceptability (affective attitude, burden, perceived effectiveness, etc.) | 6 months; 12 months |
| **Intervention Adherence** | Participation in core intervention components (e.g., number of peer-support sessions completed) | Continuous; summarized at 6 months and 12 months |

**Retention in HIV Care (Clinic Attendance and Engagement)**

Retention in care, operationalized as adherence to scheduled clinical appointments and ongoing engagement with HIV care services, is a critical intermediary outcome linking mental health to HIV treatment success. In contexts characterized by stigma and violence, missed appointments and disengagement from care are common, as individuals may avoid healthcare settings due to fear of discrimination or breaches of confidentiality. Improving retention in care is essential because consistent engagement with healthcare providers facilitates routine monitoring, timely management of comorbid conditions, and sustained access to ART. The "*Gwan Enjoy Life*" intervention is designed to strengthen retention by addressing psychosocial barriers, enhancing trust in care systems through peer support, and fostering a sense of belonging and accountability. Improvements in retention are expected to serve as a key pathway through which the intervention influences downstream biological outcomes.

Retention in care will be measured using objective clinical indicators derived from medical records, supplemented where necessary by participant self-report:

- **Clinic attendance:** Number and proportion of scheduled HIV care appointments attended over the study period, abstracted from clinic records (baseline, 24 weeks, and 12 months).
- **Missed visits:** Number of missed or delayed appointments (e.g., no-shows or visits outside recommended intervals).
- **Visit constancy:** Presence of at least one completed visit within each predefined interval (e.g., quarterly), consistent with standard retention metrics in HIV care research.

These indicators align with established definitions of retention in HIV care and provide objective, clinically meaningful measures of engagement.

**Viral Suppression (Undetectable HIV Viral Load)**

Viral suppression, defined as achieving and maintaining an undetectable HIV viral load, is the primary clinical endpoint and the gold standard indicator of effective HIV treatment. Sustained viral suppression not only improves individual health outcomes by preventing disease progression and reducing morbidity and mortality but also eliminates the risk of sexual HIV transmission (i.e., **U**ndetectable = **U**ntransmittable; U=U). However, achieving viral suppression requires high levels of ART adherence and consistent engagement in care, both of which are compromised by untreated mental health conditions and structural barriers such as stigma and violence. By improving mental health and strengthening retention in care, the intervention is expected to indirectly but meaningfully increase the likelihood of viral suppression. Thus, viral suppression serves as a critical downstream indicator of the intervention's overall effectiveness in improving both individual and public health outcomes.

Viral suppression will be assessed using laboratory-confirmed HIV viral load data extracted from medical records:

- **Primary indicator:** Proportion of participants achieving viral suppression, defined as HIV RNA <200 copies/mL, consistent with international clinical guidelines.
- **Secondary indicator:** Maintenance of viral suppression across consecutive measurements, where available.

Viral load is the gold standard clinical endpoint in HIV research and provides an objective measure of treatment effectiveness. It is also directly aligned with public health goals, including treatment as prevention (**U**=**U**).

### Overall Measurement Strategy

Together, these measures capture a coherent pathway linking psychosocial well-being (mental health), behavioral engagement (retention in care), and biological outcomes (viral suppression). The use of validated, widely accepted instruments and objective clinical indicators enhances the scientific rigor of the study and ensures that findings will be comparable to existing literature and informative for future large-scale trials.

**Table 4: Gwan Enjoy Life: Intervention Logic Model, Outcomes, and Evaluation Plan**

| Intervention Components | Key Mechanisms of Action | Proximal Outcomes (0–3 months) | Intermediate Outcomes (6-12 months) | Distal Outcomes (12 months) | Measures & Data Sources | Analytic Approach |
|---|---|---|---|---|---|---|
| Peer-supported mental health mentoring (structured sessions, peer navigation, social support) | Increased social support; reduced loneliness; improved coping skills | ↓ Loneliness; ↑ perceived support | Sustained reductions in loneliness; improved engagement with peers | Improved psychosocial resilience | UCLA Loneliness Scale (self-report) | Mixed-effects linear models; mediation analysis |
| Stigma and violence coping strategies (skills-building, safe disclosure, resilience framing) | Reduced internalized stigma; improved coping with discrimination and violence | ↓ Anxiety; ↓ psychological distress | Sustained reductions in anxiety; improved coping behaviors | Improved mental health stability | GAD-7 (self-report) | Mixed-effects models; exploratory moderation by exposure to stigma/violence |
| Mental health support and behavioral activation | Improved mood; increased motivation for self-care | ↓ Depressive symptoms | Sustained reductions in depression; improved daily functioning | Enhanced capacity to engage in care | PHQ-9 ( self-report) | Mixed-effects models; effect size estimation |
| Peer navigation and care linkage support | Increased trust in healthcare systems; reduced barriers to care | ↑ Appointment scheduling; initial engagement | ↑ Retention in care; reduced missed visits | Sustained engagement in HIV care | Clinic records (attendance, missed visits, visit constancy) | GLM (Poisson/negative binomial); logistic regression |
| Integrated support addressing stigma + mental health + care engagement | Improved ART adherence via enhanced mental health and care engagement | Early adherence behaviors | Sustained adherence and care engagement | Viral suppression (HIV RNA <200 copies/mL) | Clinic/medical records (viral load) | Logistic regression; GEE for repeated measures; mediation analysis |

**5D4: Statistical & Qualitative Analyses**

**5D4A: Analysis of Quantitative Data**

Descriptive analyses of feasibility, acceptability and fidelity variables; missing data; and workflow documentation and reproducibility considerations. Frequency tables for all variables and measures of central tendency and variability for continuous variables will characterize the sample and the intervention outcomes listed in Tables 3 and 4 to measure acceptability and feasibility of the intervention, the primary goal of this pilot study. I will learn how to address incomplete data via direct maximum likelihood estimation (MLE) or multiple imputation (MI)[1] which make the relatively mild assumption that incomplete data arise from a conditionally random (MAR) mechanism.[2] Auxiliary variables will be included to help meet the MAR assumption[3,4] and I will also learn how to perform sensitivity analyses with pattern-mixture models and pattern-based MI [5,6] to assess the robustness of the MAR assumption.[7] The proposed analyses will be conducted using validated algorithms in the general purpose statistical programs SAS and Stata, and in the specialized modeling program M*plus*. An important part of my training in quantitative analysis will be learning how to optimally document program code to enable future code review, transparency, and results reproducibility.

Inferential exploratory analyses to address Aim 1: Assessment of preliminary intervention effects on HIV care engagement. To meet the secondary goal of this pilot study, evaluation of preliminary effects of the intervention on HIV care engagement outcomes, proportions of HIV care engagement outcomes will be plotted by group over time to enable descriptive evaluation of overall patterns of change across time in the outcomes for the intervention and control groups. I also hypothesize that following the intervention men exposed to the intervention will exhibit higher odds of a) retention in care, b) self-reported adherence and c) undetectable viral load. For these three binary outcomes, I will test these hypotheses by using generalized linear mixed models (GLMM) with a binomial distribution and logit link. Repeated observations from each participant will be the unit of analysis. To maximize the rigor of these analyses, quasi-likelihood estimation methods will not be used because simulation studies show they can yield biased results for binary outcomes with few observations per cluster [8]. Instead, GLMMs will be estimated by maximum likelihood via adaptive Gaussian quadrature. To promote stable results, a minimum of 15 numerical integration points will be utilized to obtain final estimates. Since GLMMs estimated by maximum likelihood lack a residual correlation structure, clustering at the person level will be accounted for via a random intercept term in a 2-level multilevel model specification. A limited number of pre-selected additional baseline individual-level (e.g., age, education, income, history of sex work, and urban vs. rural clinic site) control variables will also be included to maximize statistical efficiency of the analysis and to give me experience in including multiple predictor variables in a GLMM. Linearity of the association of continuous covariates with the log-odds of the outcome will be assessed by creating *K* restricted cubic splines for continuous covariates and testing the significance of the non-linear splines 2 through *K*; continuous covariates with non-linear associations with an outcome will be represented in the analysis via the restricted cubic splines (the number of splines, *K*, will be chosen based on Harrell's optimality criteria) [9]. Diagnostics to examine model fit [10] and potentially high leverage or outlying data points will be performed [11]. If outliers are detected, results will be reported with and without outliers included. As a training exercise, each GLMM will be fitted in SAS, Stata, and M*plus* in order to compare how to specify a GLMM in each

program, understand differences in how the programs handle missing covariate data and convergence difficulties and their unique diagnostic features, and how they display results. Our team have experience fitting GLMMs in each program and interpreting their results and will guide me in this process. Alpha (α) will be set at .05 for effects estimated in these exploratory analyses, though hypothesis testing will be de-emphasized relative to descriptive measures of change across the intervention vs. control groups over time due to the statistical literature's demonstration of the instability of point estimates from small-scale pilot studies [12,13].

For continuous outcomes (e.g., CD4 counts, HCP stigma), I will fit additional exploratory models using the same overall modeling approach as above, except I will substitute linear mixed models (LMMs) for GLMMs. In addition to investigating whether mean CD4 counts increase and mean HCP stigma decreases following the intervention, these analyses will provide an important opportunity to apply linear mixed modeling techniques I will learn in my training to actual data using the same or similar measures to be administered in a subsequent larger scale trial. To maximize rigor, the assumptions of normality and constant variance of residuals for my continuous outcomes will be evaluated by examining LMMs' histograms of the residuals and scatter plots of predicted values-by-Cholesky-scaled residuals, respectively. Transformations of outcomes will be employed as needed to improve data conformance with LMM model assumptions (e.g., square root transformation of CD4 counts). Inferences for models whose residual statistics still do not fully meet assumptions following transformations will be generated via robust heteroskedastic-consistent Huber-White "sandwich" variance estimators [14]. All analyses will include outlier and influential case screening via computation of Cook's *D*, DFBetas, and likelihood displacement statistics. If outliers are found, results will be reported with and without outliers included [15].

Sex as a biological variable. Not applicable; all participants will be biological males.

Power analysis. Although the main purpose of the proposed study is to determine preliminary feasibility and acceptability and to visualize changes in outcomes and mechanisms of change over time rather than to perform formal hypothesis tests, I conducted several power analyses using NCSS PASS to supply additional information. For instance, for the measures collected to assess the study's primary goal of determining feasibility and acceptability, assuming power=.80, α=.05, and N=48 participants available at the follow-up measurement following 20% attrition, I used NCSS PASS 19[16] to compute confidence interval widths for a) proportions for binary variables and b) means for continuous variables. For example, for the enrollment proportion to assess feasibility, assuming α=.05, power=.80, and the 80% enrollment benchmark, the width of the confidence interval for single proportions is 24.2% (standardized distance to the limit: 0.32). For continuous standard normal variables, the distance from the mean to the confidence limit is 0.29.

For mixed models analyses proposed to assess preliminary efficacy, assuming power=.80, α=.05, and N=60 participants allocated to two study arms, two post-intervention measurements and assuming 20% attrition, I used the two-groups comparisons of repeated measures proportions module in NCSS PASS to compute the minimum detectable proportion increase in these outcomes due to intervention participation. Since the within-subject correlations among outcomes over time are unknown, I specified within-subject correlations of .20 to .80 for correlations among repeated measures from the same participant. The minimum detectable proportion increase ranged from 26.6% to 40.7%; corresponding conversion of these differences to Cohen's standardized effect size

metric *h* resulted in a range of .66 to .84 with odds ratios ranging from 4.06 to 6.97.

As a point of reference, benchmarks for standardized effects are .20, .50 and .80 for small, medium, and large effects, respectively. Therefore, taken collectively, the power analysis results suggest the pilot study is powered to detect small to medium distances to confidence limits for descriptive statistics to assess feasibility and acceptability (primary goal) and large effects for preliminary effectiveness effects (secondary goal), though, as noted above, formal hypothesis testing will not be the focus of this pilot study.

**5D4B: Analysis of Qualitative Data**

To assess acceptability, exit interviews will be audio-recorded and transcribed verbatim. Audio recordings will be stored using password-protected encryption software and only accessible to the research team. Codes, transcripts, and memos will not contain any identifying information. Exit interviews will be first be transcribed by a professional transcriptionist trained human subjects protection. Template analysis will be applied to coding and analysis using ATLAS.ti. software. In this approach, codes are developed during the review of interview transcripts and by comparing passages. We will apply the codes to text in an iterative process of reading and refining codes, during which new codes emerge. Interviews will be digitally recorded, transcribed verbatim, and entered into Atlas.ti qualitative data management software for data analysis. Qualitative data analysis will be conducted in a rigorous process by the investigative team under my direction. Qualitative description will be the primary method for data analysis.[83,126] Transcripts will be analyzed using template analysis, a standard qualitative technique for identifying and organizing themes through the development of a coding template.[127] This technique is useful for analysis when some *a priori* themes are defined based on theory and/or the research questions of interest. In this case, the *a priori* themes are based on our conceptual framework and our research aims. The use of *a priori* themes can expedite the initial coding phase of qualitative data analysis. Data that does not relate to the *a priori* themes will not be disregarded, however, as this material may suggest other useful ways of categorizing the themes and codes as they relate to the conceptual model.[127] Together with the research team, we will code the data for *a priori* themes such as: (1) positive/supportive reactions; (2) negative/unsupportive reactions; (3) needs and concerns; (4) intervention components, content, and delivery; (5) review and evaluation of existing interventions; and (6) cultural and contextual considerations.

**5D5: Data Handling & Record Keeping**

We have a number of procedures planned to handle the data and keeping of results**.** To participate in any of the aforementioned study activities, participants must be willing and able to participate and be able to sign or mark a consent form. To ensure confidentiality, all data must be coded by a unique participant ID to participants names and contact information and will NOT include any research data and it will be stored separately from any research data or research-related forms (e.g., informed consent forms). Only JASL clinic staff will know the identity of the participant or be able to trace those codes back to a particular participant. All data, research-related forms and key identifier will be kept in locked cabinets at the JASL research office. Data will also be backed up daily by a designated staff member and transferred via two-way encryption via the enCrypted Cloud program for the principal investigator to review for quality

control using an encrypted laptop stored in in a locked office. Research records will be kept confidential to the level allowed by the Data Protection Act of Jamacia. All research team members will adhere to the Data Protection Act of Jamacia. Both Dr. Sewell, Dr. Harris, and Ms. Kandasi Levermore-Walton will ensure compliance with the Act. Interviewers and support staff will be trained on procedures for maintaining privacy and will sign a pledge of confidentiality. All transcripts and computer records will be password-protected to prohibit illicit access. All personal identifiers will be removed from any paper study forms, which will be coded only by numerical identifiers. When these procedures are followed, it is highly unlikely that any information revealed by participants during the course of the interviews will be disclosed to anyone outside the research team.

Electronic data, including digital voice recordings and data collected via tablet will have several protections: 1) data will be stored on password-protected computers; 2) all files on project computers will be protected by encrypted Cloud software, which offers two-way encryption to ensure secure transfer of data between UCSF and Jamaica on a secure server; 3) all study staff will be trained in participant data confidentiality protocols and will be consistently monitored by the PI on data safety and confidentiality; 4) audio files generated from the qualitative interviews will be designated with a code to ensure name confidentiality and delivered securely to the transcribers who will establish a memorandum of understanding to ensure their compliance with confidentiality procedures.

All participants will be recruited from JASL clinics where they will be under the care of JASL staff and initiated on appropriate ART therapies. We will not interfere or make changes to participant's care instructions and will encourage them to speak to their healthcare provider if they have any questions or concerns about their medication or side effects of these medications. Any unexpected ethical issues that arise with our participants will be discussed immediately with Drs. Sewell and Harris. All identifiers from qualitative interviews will be replaced with participant ID numbers in the transcripts. To ensure data quality all recordings will be reviewed by the PIs within 72 hours of the interview by the research team. Additionally, after the data is transcribed, transcripts will be checked for accuracy against the audio files. All audio files will be destroyed immediately after they have been transcribed.

## 6. Ethical Consideration

**Participant Honorarium**:

Based on information available on the Jamaica Information Service website and the Ministry of Labor, the National Minimum Wage is $17,000JMD for a 40-hour work week. In addition, the hourly rate for the National Minimum Wage is $425JMD. The amount allocated for participant's time and participation was set in accordance with the principles of research ethics in the available literature (Bentley & Thacker, 2004; Grady, 2005) and is based on best practices. The goal of the honorarium was not to make the incentives too high that it surpasses the National Minimum Wage for an hourly work week that it potentially entices participants, which could be interpreted as coercive. Participation in this study might require participants to travel to one of the three JASL sites where they may have to commute by private taxis. Therefore, the amount set aside for the honorarium is appropriate; thus, not necessitating for the honoraria to be tailored according to distance travelled. The PIs and the

research team member will travel to all three JASL sites (i.e., Kingston, St. Ann's Bay, and Montego Bay) to ensure that potential participants do not have to travel far to get to the study site. These funds also serve as an opportunity for gender nonconforming individuals to find adequate modes of transportation as they are at increased risk for transphobic violence because they do not conform to traditional gender norms. Since they are at risk for homophobic violence, we anticipate that they will need to take chartered transportation which may be cost prohibitive. Therefore, to accommodate those persons that who will be traveling from long distances, our honorarium includes compensation for travel.

- Participants who complete each intervention engagement (n=3) will receive an honorarium of $5,000JMD for their time, travel to either one of the three JASL sites, and participation in the study. If participants complete all study engagement activities, they will receive an honorarium totaling up to a maximum of $15,000JMD.

**We have a number of procedures planned to protect human subjects.** To participate in any of the aforementioned study activities, participants must be willing and able to participate and be able to sign or mark a consent form. To ensure confidentiality, all data must be coded by a unique participant ID to participants names and contact information and will NOT include any research data and it will be stored separately from any research data or research-related forms (e.g., informed consent forms). Only JASL clinic staff will know the identity of the participant or be able to trace those codes back to a particular participant. All data, research-related forms and key identifier will be kept in locked cabinets at the JASL research office. Data will also be backed up daily by a designated staff member and transferred via two-way encryption via the enCrypted Cloud program for the principal investigator to review for quality control using an encrypted laptop stored in in a locked office. Research records will be kept confidential to the level allowed by the Data Protection Act of Jamacia. All research team members will adhere to the Data Protection Act of Jamacia. Both Dr. Harris, Dr. Sewell, Mr. Biggs, and Ms. Kandasi Levermore-Walton will ensure compliance with the Act. Interviewers and support staff will be trained on procedures for maintaining privacy and will sign a pledge of confidentiality. All transcripts and computer records will be password-protected to prohibit illicit access. All personal identifiers will be removed from any paper study forms, which will be coded only by numerical identifiers. When these procedures are followed, it is highly unlikely that any information revealed by participants during the course of the interviews will be disclosed to anyone outside the research team.

Electronic data, including digital voice recordings and data collected via tablet will have several protections: 1) data will be stored on password-protected computers; 2) all files on project computers will be protected by encrypted Cloud software, which offers two-way encryption to ensure secure transfer of data between UCSF and Jamaica on a secure server; 3) all study staff will be trained in participant data confidentiality protocols and will be consistently monitored by the PIs on data safety and confidentiality; 4) audio files generated from the qualitative interviews will be designated with a code to ensure name confidentiality and delivered securely to the transcribers who will establish a memorandum of understanding to ensure their compliance with confidentiality procedures.

All participants will be recruited from JASL clinics where they will be under the care of JASL staff and initiated on appropriate ART therapies. We will not interfere or make changes to participant's care

instructions and will encourage them to speak to their healthcare provider if they have any questions or concerns about their medication or side effects of these medications. Any unexpected ethical issues that arise with our participants will be discussed immediately with the PIs. All identifiers from qualitative interviews will be replaced with participant ID numbers in the transcripts. To ensure data quality all recordings will be reviewed by the PIs within 72 hours of the interview by the PIs. Additionally, after the data is transcribed, transcripts will be checked for accuracy against the audio files. All audio files will be destroyed immediately after they have been transcribed.

**Rationale for Involving Proposed Population**. This study involved only sexual minority men living with HIV in Jamaica. This is because our study focuses on how key determinants negatively impact SMM's ability to engage in HIV care. We will be collecting data from these 60 sexual minority men living with HIV. They will be recruited through all three JASL clinic sites. This information will provide vital information in understanding how experiences with intersectional stigma and violence affects mental health and impact HIV care engagement and test a pilot intervention to mitigate those factors.

**Collaborating Sites**. The research will be carried out in collaboration with JASL, which will comply with all pertinent U.S. federal regulations and policies. The PIs, Dr. Harris and Dr. Sewell, will supervise the implementation of this protocol, together with a trained study coordinator who will be available as the primary point of contact in Jamaica. This coordinator will represent the study to local regulatory and oversight agencies and JASL. Dr. Jarrett, as a co-investigator who is familiar with the Jamaican context and who is familiar with Ministry of Health procedures, will work closely with the PI to oversee the program's operations and ensure that all activities are within the JASL and Jamaica national policies. Although no data will be collected at UCSF, UCSF will support JASL with compliance on regulatory matters, including adhering to standard operating protocol, IRB applications and approvals, quality control and data analysis. Ethical approval will be sought from both UCSF and Jamaica IRB.

**Potential Risk**

**Potential Risk to Subjects:** The risks of taking part in the study are moderate. However, participating in this study may result in discomfort from answering questions related to sensitive topics and confidentiality breach, discussing sensitive topics such as their HIV status, mental health, history of violence may cause psychological distress. Study staff will be trained in counseling and will continually monitor the participant for signs of distress. If signs of distress are apparent, the interviewer will offer to pause the session until the participant feels comfortable to carry on. The participant will also be reminded that they may stop the session or de-enroll from the study at any time without penalty. If needed, referrals will be made to psychosocial support services available within JASL. To reduce risk of accidental disclosure of HIV status, all study activities (i.e., eligibility screening, interviews, assessments) will take place in a private room of the clinic where the study is based. Data collected will not contain the name of the participant and will instead be identified by their unique participant ID number. All data will be stored in locked file cabinets and encrypted computers. Although this study is focused on intersectional stigma, violence, mental health, and HIV care engagement, study staff will not be prescribing medications of any kind, nor will they be advising on dosing or scheduling of medications. If a participant discloses issues related to their medications such as confusion on the dose, schedule, side-effects, renewals, or duration of treatment, study staff will refer the participant back to their physician.

For the consent procedures, we will spend a significant amount of time discussing what topics will be covered on the surveys, particularly highlighting questions that may elicit discomfort such as those around HIV status, experience with violence and mental health to ensure that participants understand the risks of discomfort before giving consent. We will also emphasize that participants may pause the interview at any time or may de-enroll from the study at any time without penalty. Additionally, risks to confidentiality breach will be discussed and procedures taken to minimize this risk. All ethical issues requiring urgent attention will be reported to the PIs immediately. All unanticipated ethical issues that are not urgent will be discussed during the weekly team meeting.

**Alternative Treatments**. The purpose of this study is to understand the impact of intersectional stigma, violence, and mental health on HIV care engagement and to test an intervention to mitigate these factors. This knowledge will help inform the development of an intervention that aims to expand on standard of care for sexual minority men living with HIV in Jamaica. The standard of care includes some nurse-delivered counseling around the importance of ART adherence. However, content varies based on how busy the clinic is, how much time is allocated for the appointment, timing of HIV testing and diagnosis, and the individual nurse attitudes on the most important information to convey. This intervention is proposed to improve HIV care engagement and support overall health of sexual minority men as it pertains to their mental and physical health. In the proposed intervention development, all SGM enrolled will continue to receive standard of care.

### Informed Consent

**Informed Consent**. All informed consent procedures will follow protocol approved by UCSF IRB and Ministry of Health Ethics Review Board. The consent process will be conducted with a staff member who has been trained in research ethics and the specific consenting protocol for this study. The consent process will be conducted in the language of the participants choosing (Patwa or standard English). The informed consent process will highlight the specific risks associated with the study, including discomfort from in-depth discussions of HIV infection, experience with violence, history of depression or anxiety, and risks for breaches to confidentiality. The participants will be informed about the precautions put in place to minimize the risk of breaches in confidentiality. Interviews and focus group discussions, while we will ask focus group participants not to divulge other's statements outside the focus group, we cannot guarantee that they will not discuss such information to others which could harm the participant. This potential risk will be stated on the informed consent document and discussed during the informed consent process. In addition, we will emphasize that any question or discussion the participant does not feel comfortable providing input to is their choice and they are not obligated to answer every question. Research staff will discuss with participants enrolled in feasibility testing that they can decline answering or participating in any component and they can opt out of the study at any time. The participants will be informed about all procedures put in place to reduce the risk of breaches in confidentiality including: the use of a unique participant ID number on all research data and that their name will not be used in relation to their data and that all data will be kept in a safe, locked filing cabinet or password-protected computer in a locked office. It will also be noted that study staff are not practicing doctors, nurses or any type of healthcare provider and, thus, cannot diagnose, treat or prescribe medications of any kind. The participant will be allowed to ask questions, and the staff member will probe for complete understanding during key points of the consent form. The participant can take as much time as they need to make a decision, and they will be reminded that they can de-enroll in the study at any time and that participation is completely

voluntary and will not impact their regular clinic visits. All participants will be provided the contact numbers of the PIs Dr. Harris and Sewell, Dr. Jarrett and the Ministry of Health Ethics Review Board to answer any questions that the participant might have about the study or one's rights as a human subject. Completed, signed consent forms will be kept in a locked filing cabinet in our secured research office. The participant will be allowed to take a copy of the consent form home to have a reference but will be reminded that someone finding the form may result in a breach of confidentiality.

**Importance to be Gained**

This study will fill key gaps about the interplay of intersectional stigma and violence and its impact on mental health and engagement in care among sexual minority men living with HIV. Background literature suggests there is causal, additive impact between intersectional stigma (HIV-related stigma, poverty, and housing insecurity) on mental health, however, there isn't enough evidence that demonstrate any association between intersectional stigma and violence on mental health and HIV care engagement. Furthermore, both intersectional stigma and violence against sexual minority men are substantial social determinants/ health issues in their own right on sexual and gender minority health. Addressing them together and to aid in HIV care engagement will have the added benefit of improving overall health. Additionally, using different measures of adherence including self-report will contribute the most to better understanding the most effective way of measuring adherence in resource-limited settings such as Jamaica. Thus, the risks of the proposed study are reasonable and balanced by the potential contribution of longitudinal findings that can advance HIV treatment and prevention and overall health among sexual minority men living with HIV in the Caribbean.

**Data Risk and Monitoring**

Data-related risks: Data-related risks to participants could consist of circumstances where an insufficient amount of data was collected to answer the research questions. Data monitoring procedures. Overall recruitment goals will be monitored monthly, as will missing data and follow-up failures. The PIs will monitor study progress.

Data-related risk reporting and action plan: We will set up a clear communication structure to report adverse events from participants, sites and to the Principal Investigators. We will review any reports from participants during the study. The Jamaica Cares Study will have a clear way for participants to provide input, feedback, or report problems. The research assistants along with the Project Manager will be responsible for compiling numbers of participants recruited, completing required assessments, maintaining databases, and identifying missing data and missing follow-up assessments. The research assistant will prepare recruitment and missing data reports for weekly review by the PIs. The PIs will then review these materials with the study biostatistician. All data are de-identified and stored on a firewall-protected server. Upon recognition of unacceptable recruitment or follow-up rates, or of missing data, the PIs will intervene with strategies to remedy the shortcomings. Should we experience events related to study procedures, Drs. Harris and Sewell will lead the development of an action plan.

Data monitoring procedures. Overall recruitment goals will be monitored monthly, as will missing data and follow-up failures. The PI will monitor study progress. The Project Manager (who is also the monitoring and evaluations manager at JASL) will conduct initial training and quarterly quality assurance meetings with the Principal Investigators to ensure proper handling of the data.

Reporting Mechanisms of AEs/SAEs to UWI Mona Ethics Board, the UCS IRB, and the NIH**:** Adverse events will be tracked, and follow-through will be conducted via referrals and clinician follow-up. An adverse events form will detail the incident, actions taken, supervisor notes, and follow-up steps. The study team will meet periodically by conference call and in person. Agendas for the meeting will be developed by the PI with support from the Project Manager. The project manager will track and report directly to the PIs (Harris and Sewell) any perceived or actual adverse events from participants and site location with 24 hours of their occurrence. Drs. Harris and Sewell will carefully track potential serious adverse events that will be reviewed at each Research Advisory Committee meetings in-person or via conference call. After meeting with the Research Advisory Committee, the PIs (Drs. Harris and Sewell) will report all serious adverse events that are deemed to be related to the study procedures will be reported within 72 hours to the University of the West Indies Ethics Committee and the UCSF IRB. Other notable incidents that occur during recruitment, consent, or at the study visits, but are determined to be unrelated to the study procedures, will be reported in a detailed log on an annual basis. Should we experience events related to study procedures, Dr. Harris and Dr. Sewell will lead the development of an action plan.

**Participation of Vulnerable Populations**

The study population includes people living with HIV who are accessing care from all JASL clinic sites. There are moderate risks associated with you participating in this study. The research is moderate risk because of the survey questions that will be asked and the qualitative focused group discussions, and individual interviews. Some participants may feel uncomfortable with some of the questions being asked, while others may not feel uncomfortable. The research team (Drs. Sewell and Harris and JASL clinic staff) is experienced with ensuring procedures to maintain the confidentiality of clients' de-identified data.

**Description of the Potential Risks to Participants**

**Protection Against Risk**

**Planned Procedures to Protect Against or Minimizing Potential Risks.** Steps to minimize discomfort: We will minimize discomfort associated with potentially uncomfortable or distressing topics (e.g., victims of violence, discrimination, depression and anxiety, poverty, HIV infection, trauma, and treatment engagement) by acknowledging these types of topics during the informed consent process with eligible individuals. We will also remind participants that they can pause or stop the interview completely if they feel that they are becoming too uncomfortable with the topics discussed. If the participant appeared to be in distress, the interviewer will offer to pause the interview. Aim 1 will be conducted through individuals interviews via a computer assisted device. Aim 2 will be a mixed of focus group discussion with member of the target population and one-on-one individual interviews with key stakeholders to identify the intervention components and to assess the acceptability of the proposed intervention, participants can opt out of answering any questions during the focus group discussion. Similarly, participants enrolled in the Aim 3, the feasibility testing phase, can opt out of the study at any point. Detailed descriptions of the commitment, timeline and procedures will be discussed at enrollment to help mitigate confusion over study commitments. Research staff will be available to participants if they report any discomfort with the intervention,

which will be directly reported to the PI. Participants may be referred to a mental health provider at one of the JASL clinic should additional follow up be needed.

**Steps to protect privacy**: We will minimize breaches in confidentiality by using unique participant ID numbers on all data resulting from this project and will not use identifying information (i.e., participants names) in databases or forms that contain data. We will also let participants know that they may use a pseudonym in the interview or focus group discussion to keep their identity unknown on the recording. Regardless, all names and other identifying information will be expunged from the transcripts of the interviews. All data generated from this project will be kept in locked filing cabinet or password protected computer in a locked office. to minimize the risks of accidental HIV status disclosure, all study procedures will occur in a private room in one of the JASL clinics. Eligibility questions will be asked within a large set of questions to minimize ineligible participants from guessing that HIV positive status is an eligibility criterion for the study.

**Medical or Professional Intervention in the Event of Adverse Event**. Although we do not anticipate any events in need of medical intervention associated with our quantitative or qualitative interviews at the different time points identified, due to our population of sexual minority men living with HIV and in the context of stigma and violence we do recognize the need for some safeguards. All participants will be under the care of a physician as our study site is based at all three JASL clinics and prescription of ART is an eligibility criterion of our study. We will emphasize that research staff are not medically trained, and any medical concerns should be discussed with the participant's healthcare provider. If a medical event does arise during our research activities, with the participants permission, we will consult the medical staff in the clinic and transfer them to their care, if necessary. We will also screen for history of or ongoing violence. Persons who screened positive violence will be referred to either a mental or medical provider within one of the JASL facilities. Since JASL provides comprehensive AIDS education, counseling, and services, it will be possible for the interviewers to provide immediate referrals for research participants who are in emotional distress or exhibit any concerning physical signs or symptoms. As we will screen for depression, for participants who have suicidal thoughts, we will ask participants to speak with one of our study health providers who can further screen them for suicidal ideation. This may lead to some discomfort, but we hope will provide benefits for the participants if they are able to get access to appropriate mental health care. All adverse events will be immediately reported to the PIs. Serious adverse events will be reported to the UCSF IRB and the Ethics Review Board of the Ministry of Health by phone with a written report of notification to follow within 24 to 72 hours of the event. The PIs will also notify the NIH program officer and will report adverse events in writing to the NIH funding institute. The adverse event will also be reviewed with the research team to determine subsequent actions and if revisions to current protocols are needed.

### Benefits to Participants

**Potential Benefits of the Proposed Research to Human Subject and Others:** There may be little or no direct benefit to participants from this study. A possible benefit to participants may be a therapeutic effect from talking through lived experiences with a research team member both in a group setting or individually. Some additional possible benefits to the field may include a coherent intervention program explaining the complex links between substantial health issues among sexual minority men in Jamaica that can be applied to future research in the wider Caribbean region. In

addition, the development of an acceptable behavioral intervention to improve HIV care engagement among Jamaican sexual minority men living with HIV may provide important benefits to SMM health in low-resource settings. Intervention participants who take part of the feasibility testing may also incur benefits of improved skills to cope with the effects of intersectional stigma, violence, symptoms of depression and anxiety, and engagement in care. They may also experience a benefit from being followed and supported as they continue their care. All participants will be given information on HIV infection, importance of treatment adherence, general health considerations, as well as references to local health and social services. Referrals to more intensive resources available within JASL will be made as needed. The risks associated with this research are reasonable in relation to the potential benefits of advancing empirical knowledge about intersectional stigma, violence and mental health on HIV care engagement and an intervention approach to improve HIV care engagement for this high priority population and setting.

**Methods to Minimize Risks**

Participants risk will be minimized in the following ways:

1. No identifying information will be collected.
2. The dataset used for data management and analyses will not include patient names or other identifying information or the ability to link to other datasets.
3. Electronic data will be encrypted and stored on password-protected computers
4. Study investigators are trained in measures to keep data confidential and secure

**Steps to protect privacy**: We will minimize breaches in confidentiality by using unique participant ID numbers on all data resulting from this project and will not use identifying information (i.e., participants names) in databases or forms that contain data. We will also let participants know that they may use a pseudonym in the interview or focus group discussion to keep their identity unknown on the recording. Regardless, all names and other identifying information will be expunged from the transcripts of the interviews. All data generated from this project will be kept in locked filing cabinet or password protected computer in a locked office. To minimize the risks of accidental HIV status disclosure, all study procedures will occur in a private room in one of the JASL clinics. Eligibility questions will be asked within a large set of questions to minimize ineligible participants from guessing that HIV positive status is an eligibility criterion for the study.

**Medical or Professional Intervention in the Event of Adverse Event**. Although we do not anticipate any events in need of medical intervention associated with our quantitative or qualitative interviews at the different time points identified, due to our population of sexual minority men living with HIV and in the context of stigma and violence we do recognize the need for some safeguards. All participants will be under the care of a physician as our study site is based at all three JASL clinics and prescription of ART is an eligibility criterion of our study. We will emphasize that research assistants are not medically trained, and any medical concerns should be discussed with the participant's healthcare provider. If a medical event does arise during our research activities, with the participants permission, we will consult the medical staff in the clinic and transfer them to their care, if necessary. We will also screen for history of or ongoing violence. Persons who screened positive violence will be referred to either a mental or medical provider within one of the JASL facilities. Since JASL provides comprehensive AIDS education, counseling, and services, it will be possible for the interviewers to provide immediate referrals for research participants who are in emotional distress or

exhibit any concerning physical signs or symptoms. As we will screen for depression, for participants who have suicidal thoughts, we will ask participants to speak with one of our study health providers who can further screen them for suicidal ideation. This may lead to some discomfort, but we hope will provide benefits for the participants if they are able to get access to appropriate mental health care. All adverse events will be immediately reported to the PI. Serious adverse events will be reported to the UCSF IRB and the Ethics Review Board of the University of the West Indies by phone with a written report of notification to follow within 24 to 72 hours of the event. The PI will also notify the UWI Mona Ethics Committee as well as the NIH program officer and will report adverse events in writing to both UWI Ethics Committee and the NIH funding institute. The adverse event will also be reviewed with the research team to determine subsequent actions and if revisions to current protocols are needed.

**Provision for Protecting Privacy and Confidentiality**

All researchers involved in the collection and/or handling of data, and writing of reports, will acknowledge and agree that they will not disclose any personal information they observe while handling datasets. Patient confidentiality and privacy is strictly held in trust by the JASL. The study protocol, documentation and data set will not include or request access to any identifying information such as name, date of birth, home address, telephone number, or docket number, that might be available in clinic records. Investigators, co-investigators, and collaborators will not have access to patient clinical records. The medical chart reviews will only be conducted by JASL's clinic staff and the monitoring and evaluations manager.

Individual participants and their research data will be identified by a unique study identification number. The inclusion of demographic and clinical data will not make specific individuals identifiable (e.g., date of birth). Electronic data will be encrypted and stored on password-protected tablets, flash drives and computers. Hardcopy information will be placed in locked file cabinets at JASL. No information regarding the data will be released to any unauthorized party. The study will adhere to all local laws, including the Data Protection Act of Jamacia.

**We have a number of procedures planned to protect human subjects.** To participate in any of the aforementioned study activities, participants must be willing and able to participate and be able to sign or mark a consent form. To ensure confidentiality, all data must be coded by a unique participant ID to participants names and contact information and will NOT include any research data and it will be stored separately from any research data or research-related forms (e.g., informed consent forms). All data, research-related forms and key identifier will be kept in locked cabinets at the JASL research office. Data will also be backed up daily by a designated staff member and transferred via two-way encryption via the enCrypted Cloud program for the principal investigator to review for quality control using an encrypted laptop stored in in a locked office. Research records will be kept confidential to the level allowed by law. Interviewers and support staff will be trained on procedures for maintaining privacy and will sign a pledge of confidentiality. All transcripts and computer records will be password-protected to prohibit illicit access. All personal identifiers will be removed from any paper study forms, which will be coded only by numerical identifiers. When these procedures are followed, it is highly unlikely that any information revealed by participants during the course of the interviews will be disclosed to anyone outside the research team.

Electronic data, including digital voice recordings and data collected via tablet will have several protections: 1) data will be stored on password-protected computers; 2) all files on project computers will be protected by encrypted Cloud software, which offers two-way encryption to ensure secure transfer of data between UCSF and Jamaica on a secure server; and 3) all study staff will be trained in participant data confidentiality protocols and will be consistently monitored by the PI on data safety and confidentiality.

All participants will be recruited from JASL clinics where they will be under the care of JASL staff and initiated on appropriate ART therapies. We will not interfere or make changes to participant's care instructions and will encourage them to speak to their healthcare provider if they have any questions or concerns about their medication or side effects of these medications. Any unexpected ethical issues that arise with our participants will be discussed immediately with the PIs.

All identifiers from qualitative interviews will be replaced with participant ID numbers in the transcripts. To ensure data quality all recordings will be reviewed by the PI within 72 hours of the interview by the PI. Additionally, after the data is transcribed, transcripts will be checked for accuracy against the data files.

**Report of Changes to Protocol**

Report of Changes or Amendments to the Protocol: Any significant changes to the intervention or study data collection protocols of this project will be discussed with the NIMH program officer before the team implements them. The relevant IRBS will also review and approve any modifications to the study procedures prior to their implementation.

Conflict of Interest: There are no financial conflicts of interest to disclose in this propose trial.

Collection and Reporting of AEs and SAEs**:** The PIs will keep a detailed AE log and a detailed report for each AE will be submitted for review to the relevant IRBs within 10 working days the event. As per the IRB requirements, SAEs will be reported within 24 hours for this trial, and a final report will be provided within 72 hours. A SAE report will be generated by the PI and copies of the report will be shared with the Research Advisory Board. Examples of SAEs for this research project include: active suicidal/homicidal ideation; panic attacks requiring medical attention; or other debilitating mental health symptoms requiring immediate medical/psychiatric attention that may be exacerbated by study assessment or intervention procedures (e.g., symptoms of paranoia). Some might find the personal sessions triggering or discomforting.

**Expected Application of Results**

Dissemination, Notification, and Reporting of Results

After the completion of the study, we will disseminate study results to the community, JASL health care staff, Ministry of Health and Wellness partners, and the relevant Regional, Parish and Facility Health Management teams through both written and oral presentations (see **Appendix 10**). No study participant will be identified by name in any report or publication derived from information collected for

the study. Data will not be reported at the individual patient level. Drs. Sewell and Harris as well as JASL will disseminate the findings to other national stakeholders and implementing partners. We anticipate the data will be presented at scientific conferences and in peer-reviewed journals. Additional procedures for data storage and management are detailed elsewhere (see **Appendix 8**).

### Future Studies

Study results will provide baseline data for a future federal NIH R01 grant application for a full-scale efficacy trial. These data will also inform JASL, MOHW, and other stakeholders on the impact of intersectional stigma, violence, and poor mental health among sexual minority men living with HIV. The findings will also facilitate prioritization of limited resources to expand activities and provide baseline data for any future national evaluations of the HIV treatment program and/or other applications of operational research.

### Fair Selection of Subjects

All data will be collected from persons only because of the specific problem under investigation. Persons were not selected because of their easy availability, diminished autonomy or due to social bias.

### Declaration of Conformity with Guidelines

All principles stated in the Ethics Committee Guidelines for the conduct of research on human subjects has been complied with.

### Funding and Conflicts of Interest

The Jamaica CARES – GWAN Enjoy Life study is being supported by a grant from the National Institute of Mental Health at the National Institute of Health. The investigative team have no real or perceived financial and other conflicts of interest.

## 7. Limitations

**Limitations, Feasibility, Potential Pitfalls & Alternative Strategies.** We anticipate that gender identity may arise as a concern when recruiting participants to complete the survey instrument. We learned in our preliminary studies that some persons may identify as gender-fluid, which may pose challenges for recruiting people who may not identity as men.[35] Earlier we found that most persons identifying as gender-fluid reported a transgender identity upon further probing. To ensure maximum participation, I will make a significant effort to recruit those who identify as gender-fluid or nonconforming and using similar probing techniques from my prior work. Loss to follow-up may occur among vulnerable populations such as SMM. Identified reasons for loss to follow-up include housing and employment instability, and competing demands. We will collect multiple forms of contact information as well as two back-up contacts to minimize loss to follow-up. External validity may be limited given that the sample will consist of SMM LWH already engaged in some form of clinical care.

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