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**

NCT: Pending

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INFORMED CONSENT FORM
"Gwan Enjoy Life Intervention": Peer Mental Health Mentor Program

Study 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"

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Introduction and Purpose of Study:
The above titled research study is being conducted with sexual minority men living with HIV in order to address things that contribute to the experience of violence and poor mental health and how those things can affect our engagement in HIV care. The *Gwan Enjoy Life* program is a multi-session intervention delivered by trained peer community health workers (peers) who are also living with HIV. The program is designed to strengthen coping skills, improve mental health, increase treatment adherence behaviors, and facilitate skills building in order to sustain engagement in care.

This consent form describes the intervention and what you may expect if you decide to participate. You are encouraged to read this informed consent form carefully and ask us any questions that you may have before you decide whether or not to participate.

Description of Study Procedures
The intervention is being conducted in partnership with Jamaica AIDS Support for Life (JASL), a community-based HIV service organization. A total of sixty persons will be randomized to either participate in the intervention or continue to receive ususal care (control group). A control group consist of persons not taking part in the intervention but will still have access to all the services available at JASL.

The Gwan Enjoy Life intervention is a 6-session choice-based program that will be delivered over a period of 5 months. To complete all 6 sessions, your participation involves 3 in-person group visits over a 5 month period with other the PMHM. You will receive the first two sessions at month 1, the third and forth session at month 3, and the final two sessions (5 and 6) at month 5. You are free to 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. You can self-select out of the group if you do not want that option or if you want to engage with the peer mental health mentor on a 1-1 basis if you missed any group sessions. If you decide to participate in the group PMHM sessions, you will more than likely be in a group with at least 5-10 other individual. We anticipate that each in-person sessions (month 1, 3 and 5) will last at least 2.5 to 3hrs each. After completing all in-person sessions, we will reach back out to you to complete survey interviews at month 6 and again at month 12.

You will be asked to complete a survey at baseline, 24 weeks, and 12 months using structured surveys. With your permission, the Data Manager at JASL will also extract several information from your medical records. The Data Manger is responsible for all medical data management and evaluation at JASL. The Data Manager will review your patient Master Card to extract information such as the date of your antiretroviral (ART) medication initiation, World Health Organization stage at ART initiation, the name of the HIV medication that you are correctly taking, and your appointment history (i.e., missed appointments and treatment interruptions), viral load data, and CD4 count. To ensure confidentiality, the medical chart (Master Card) reviews will be conducted only by the data manager. The data manager does not have a medical background and will not be interfacing with you or your care directly. Drs. Harris and Sewell, the PMHM, or any other member of the research staff will not have access to your private medical records. The only information the team will have access to is the de-identified numeric values documented on your Master Card. No information can be traced back to you after it has been de-identified. De-identificated information only applies to research data and not your participation in the intervention itself.

Those participants who were randomized to the control group will still have access to the services available at JASL. For example, if in the control group, you 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 your access to any of these services. Likewise, if you were assigned to the intervention group, you will still have access to these services as well while still in the intervention and if needed the PMHM can make referrals to any of the additional psychosocial support services available within JASL.

To determine your eligibility, we will ask you the following questions: (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 you have been deemed eligible, we will review the consent form with

you by going over each section of the form. Before signing the informed consent form, you will be asked to repeat back what you have read to ensure that you have comprehend what you have read. You will also be asked if you have any additional questions before you engage with any study activity.

Confidentiality in Group PMHM Sessions:
We will ask you and the other people in the group PMHM to use first names or a puesodonym during the group sessions. We will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researcher team cannot guarantee that everyone will keep the discussions private.

Confidentiality in Individual 1-1 PMHM Sessions:
What you say in the 1-1 PMHM sessions will stay confidential between you and the PMHM. However, confidentiality might be impacted if you reveal that you are a danger to yourself or others.

Risks of Participation
There are moderate risks associated with you participating in this study. Some participants may feel uncomfortable with some of the content or the questions being asked, while others may not feel uncomfortable. In addition, though unlikely, there is a small risk that your participation may increase the likelihood that your sexual activities will become known to others. These risks will be managed as described below in the confidentiality of records section below.

If you express, or we observe, any distress or feelings of an uncomfortable nature with the questions being asked or the content, we will ensure that a trained clinical professional (i.e., JASL's clinical psychologist) unconnected to the study is available either within the building during the sessions or via phone who can determine whether to discontinue your involvement in the session, assess if you are able to continue the session, or if additional support is needed. For situations where additional support is required, you are encouraged to contact your medical provider at your expense, or you may contact Jamaica AIDS Support for Life (JASL) at (876) 978-2345. The services provided at JASL are free and should not be of any financial burden to you. The research team is required by Jamacian law to report disclosures of current child abuse or concerns about the welfare of a minors. This means that if you tell the researcher that a child is being neglected or abused or that you have plans to hurt yourself or someone else, the researcher is required by law to report such situations to the appropriate authorities.

Benefits of Participation
There is some potential benefits to participating in the study. For example, the information you will learn and the skills that you will be able to build could be helpful in facilitating your continued engagement in your care. The information could also help with building strong coping skills that can be used to improve your mental health

Rights to withdraw or refuse to participate

Taking part in this program is your choice. You may choose either to take part or not to take part in the program. If you decide to take part in this program, you may leave the program at any time. No matter what decision you make, there will be no penalty to you in any way. In the event that you do withdraw from the program, the information you have already provided will be destroyed. Your medical care at JASL will not be impacted if you choose to leave the program or not take part in it any longer.

Sponsor Support

This study is sponsored by a grant from the United States' National Institutes of Health, National Institute on Mental Health. Although the NIH is providing the funds to conduct the study, they will not have access to the information collected during this study.

Costs

There is no cost to you for participating in the program.

Confidentiality of Records

Your name will appear only on this Informed Consent Form and on the receipt for your honorarium. These documents will be stored separately and apart from the other research documents. This will ensure that your name will not be associated with the data. A code number will be assigned to the information you give to protect your privacy. All research records will be kept in a locked cabinet and only the principal investigator will have access to them. All surveys collected will have a number assigned to them instead of your name. The surveys will not be tracable back to you as an individual.

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Other people such as the principal investigators and the co-investigators may need to see the information in order to ensure that your confidentiality is protected. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will only use your de-identified survey data that was analyzed to write peer-reviewed articles for publication.

The principal investigators are required to keep copies of all the data derived from this study including this informed consent form for review by the Ethics Committees at The University of The West Indies, Mona and representatives from the University of California. Please keep in mind that a review by the Ethics Committee is only a possibility—which might not occur. Authorized representatives from the U.S. National Institutes of Health and the U.S. Office of Human Research Protections may also look at your research data for the purpose of monitoring the conduct of this study.

This research is covered by a Certificate of Confidentiality from the United States (U.S.) National Institutes of Health. It prevents U.S. State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal identifiable information (by

subpoena or otherwise) about research participants that is stored in the United States. The Certificate DOES NOT:

- stop reporting of certain types of information that is legally required to be reported in the U.S.
- stop a sponsoring U.S. federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the U.S. federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by U.S. federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research.
- from having access to your own information that is stored in the U.S.

Contact Persons (Principal Investigators)
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Orlando Harris on WhatsApp at (917) 945-3883 or Orlando.Harris@ucsf.edu or our local collaborators Dr. Clayton Sewell at (876) 927-1660-9 or clayton.sewell@uwi.edu; or Mrs. Kandasi Walton-Levermore at Phone: 876.925.0021 or klevermore@jasforlife.org.

Rights as a Research Participant:
For independent advice on your rights as a research participant contact Dr. Wharfe, Chair-Mona Campus Research Ethics Committee, University of the West Indies, Mona, Kgn 7 (Tel: 876-970-4892, e-mail: medsci@uwimona.edu.jm). Also, if you wish to ask questions about the study or if you wish to voice any problems or concerns you may have about the study, please call Dr. Wharfe.

Payments

In return for your time, participation in the Gwan Enjoy Life program, and expenses related to your travel to the JASL clinic, you will receive an honorarium totaling up to a maximum of $5,000JMD for each session. If you are able to complete all three sessions, you will receive an honorarium totaling up to a maximum of $15,000JMD. You will be asked to sign a receipt to confirm that you received these funds. The signed receipts will be kept in a private office in a locked cabinet and only be accessible by the data manager.

Statement of DECLARATION:

1. I have read the informed consent form and understand its contents. I have been given a copy of this consent form to keep and have been encouraged to ask questions. My signature below indicates willingness to participate in the present study.

2. I have been provided time for me to consider my involvement in the study. I also understand that PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which I am otherwise entitled.

If you wish to participate in this study, you should sign below.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a **signed** copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the participant adequate opportunity to read the consent before signing.

Name and Title (Print)

_____

Signature of Person Obtaining Consent Date

_____ _____

Signature of Independent Witness Date

_____ _____