Title:
RCT of an Intersectional Stigma Intervention to Sustain Viral Suppression Among Women Living With Serious Mental Illness and HIV in Botswana

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INFORMED CONSENT FORM

RANDOMIZED CONTROLLED TRIAL RCT OF AN INTERSECTIONAL STIGMA INTERVENTION TO SUSTAIN VIRAL SUPPRESSION AMONG WOMEN LIVING WITH SERIOUS MENTAL ILLNESS AND HIV IN BOTSWANA

You are invited to take part in a research study being conducted at Sbrana Psychiatric Hospital and selected community centres. This research is being done in collaboration with the University of Botswana, the University of Pennsylvania, and New York University. This form explains to you what we are going to do and why we need to ask for your consent.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to reduce serious mental illness (SMI) and HIV stigma and improve anti-retroviral treatment (ART) compliance in Botswana. We are studying ART adherence among women with SMI and HIV because there is a chance that they may stop their medications after they've ended their hospital stay. We also want to study family-level SMI and HIV stigma since family members can also play an important role in helping women to stay on treatment.

WHY AM I BEING ASKED TO BE IN THIS STUDY?
You have been asked because you are a woman aged 18 to 65, who have Botswana citizenship, speak either English or Setswana, and who are diagnosed with both SMI and HIV in Botswana. In addition, you have identified a nuclear or extended family member who consents to participate in a family member-only programme while you participate in this one.

HOW MANY PEOPLE WILL BE ASKED TO BE IN THIS STUDY?
A total of about 180 participants will be enrolled in Botswana.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?
You do not have to participate in this study and if you choose not to participate all the services you receive at the hospital will continue and nothing will change. You will still have your normal doctor's appointment and care.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
We will be comparing a group of women with SMI and HIV+ who complete a new type of education and counselling programme (called the intervention group), with a group of women who complete standard treatment without the new programme (standard treatment group). If you agree to participate in the study, research staff will randomly assign you to be part of the intervention group or the standard treatment group. This is like flipping a coin to choose one of two actions, which means you can choose to withdraw from the study at any time, but you will not be able to choose which group you are in. ***Intervention group procedures****:* Our 8-session group intervention will last 60-70 minutes. Women will meet in groups of 4 to 10. The first five (5) sessions will be carried out during your admission in Sbrana while the remaining three (3) will be carried out after your discharge.

Virtual format: You will have the option to participate virtually (via voice call using WhatsApp) under the following circumstances: 1) If you are discharged before completing the five inpatient sessions and are unable to attend in person 2) If you are unable to attend any of the last three outpatient sessions in person. To protect your confidentiality, virtual participation will be conducted through audio-only (no video) communication. We recommend that you participate in a private setting to help maintain confidentiality during virtual sessions.

A peer (a woman with both a SMI and HIV) who has been trained will be helping the leading clinician to guide the group intervention sessions. Certificates will be awarded to participants who complete the intervention. ***Attention control group procedures:*** Participants in the attention control group will also receive an 8-session group intervention. Both intervention and attention control groups will receive standard treatment, including their usual ART and mental health care.

Participants will be asked to fill out in-person questionnaires at three timepoints: 1) at the start of the intervention, 2) right after the intervention, and 3) 4-months after the intervention. At all three timepoints, participants will be asked to provide information on care compliance, stigma, quality of life, psychosocial wellbeing, social functioning, social support, sexual behaviour, and substance use. Socio-demographic information and clinical characteristics (such as a brief history of psychiatric and HIV treatment) will only be collected at the start of the intervention.

The first questionnaires will be completed at Sbrana Psychiatric Hospital. The later questionnaires will be completed after you've returned home from the hospital, at the centre at which you will have your final sessions. If it is not possible to complete the questionnaire in person, a member of the study team may contact you to complete the questionnaire by telephone. Questionnaires will be completed at the following times-points: (1) before the start of the intervention; (2) at the completion of the intervention; and (3) 4-months after the completion of the intervention. Participants in the standard treatment group will be evaluated at the same time-points.

Blood draw. If you decide to take part, we will also have a trained study staff collect a small sample of blood from your arm – about 1 tablespoon or less. These samples will be tested for HIV viral load and other features of the blood that will help us to understand how HIV and mental illness has affected your health. To protect your confidentiality, no one outside of the research team will review your study records.

Other information about your health and your patient care (including information about your HIV and mental health status, your medical care, and related illnesses) will be collected from your hospital and clinic medical records. We also request your permission to contact a family member who you identify as your primary caregiver (that is, the relative 'most involved in your care').

We will not link any potential incidental findings with identifiable data. Therefore, there will be no conditions under which clinically relevant individual results will be disclosed. Information about your family member (socio-demographic information, opinions about families, and stigma) will be collected through separate interviews with them at the start and 4-months after completion of the intervention. Hospital records will provide information about your HIV history including date of diagnosis, HIV treatment as well as CD4 and Viral Load amongst others. Information on your mental health history such as your psychiatric diagnosis and treatments will also be collected. Please note that no identifiable health information will be shared with outside institutions.

FOR HOW LONG SHOULD I EXPECT TO PARTICIPATE IN THIS STUDY?

All consenting participants will be asked to complete questionnaires during your hospitalisation. Participants assigned to the Intervention Group will also meet multiple times per week and be asked to complete a questionnaire before the beginning of the five inpatient sessions prior to discharge, at the end of the intervention, and 4-months after the intervention. Participants should expect to participate for about 4 months beyond the end of the intervention.

ARE THERE ANY RISKS TO ME AND MY FAMILY MEMBER?
We will draw a small amount of blood from you. The blood draw will be done for research purposes only, will take place in a private space (typically consultation room), and done by trained phlebotomist research personnel at the time of the baseline interview and 4-months after the intervention. The blood draw has only very minimal risk to you but there may be some discomfort from the needle stick. Sometimes swelling can occur at the site where blood is drawn, however this often disappears after a few minutes. The research assistant will also ask whether the participant has allergies, phobias or has ever fainted during previous injections or blood draws. If the participant is anxious or afraid, reassurances will be given, and efforts made to make the participant comfortable.

Otherwise, this study presents no more than low risk to you and your family member. There are some limits to our ability to protect your confidentiality. These limitations include: (1) because of the group-format of the intervention - there is a chance that participants might tell others about what happened in the intervention group (including sharing another person's HIV or Mental Illness diagnosis), (2) disclosure of violence within the home is required to be reported to study staff who will conduct an in-person clinical evaluation with you and will either directly connect you to a treating clinician at Sbrana Psychiatric Hospital or your local district health authority (DHMT) or will refer you to psychiatric counselling and other services such as domestic violence support groups, and (3) for sessions that include virtual participants, confidentiality and privacy cannot be fully guaranteed in non-private settings.

To reduce the likelihood of breaching confidentiality, intervention groups will be consistently reminded that information shared during the group intervention is confidential and should not be shared with others. We will also require the use of first or preferred names only for all participants (for both in-person and virtual participants). To further protect your confidentiality, we will abide by strict guidelines for maintaining confidentiality and securing data. Each research participant is assigned a unique study number that will be used to identify her data. All identifying information (name, address, telephone number) will be kept in a separate file apart from the research data. At no time will research data be linked with names, addresses, or telephone numbers, nor will any participants be identified in the presentation of results.

ARE THERE ANY BENEFITS TO ME AND MY FAMILY MEMBER?
There may be no direct benefit to you or your family member by being in this study. The information from this study may help inform doctors in the future to promote better ART-adherence among this population.

WILL I BE COMPENSATED FOR PARTICIPATING?
Yes. For each group session or questionnaire interview/blood draw appointment that you travel to attend, you will be reimbursed a total of P50 to cover the travel-costs related to participate in that session or appointment. Should the session be virtual, the P50 would contribute to the data cost of participating in that session in lieu of the travel cost. No additional compensation will be provided. If you choose to withdraw early in the study, you will be compensated in full for the sessions/appointments you travelled to, however you will not receive compensation for the sessions you did not travel to participate in.

WILL THERE BE ANY COSTS TO MY FAMILY MEMBER OR ME?
No.

WILL INFORMATION FROM THIS STUDY BE KEPT CONFIDENTIAL?
Yes. While the study team cannot guarantee total confidentiality, as information may be disclosed by other study participants, intervention groups will be consistently reminded that information shared during the group intervention is confidential and should not be shared with others.

Audio recording and data management: Intervention sessions will be audiotaped with participants' permission for research purposes only (to rate fidelity of the interventions only). Audio files of intervention sessions will be transferred from recording devices and stored on secured computers only in Botswana. Audio files will be stored on secured computers at our facility and will not be distributed; they will not be shared with any other collaborating institution. Audio recordings will be destroyed no later than one year following completion of the study.

Strict guidelines for maintaining confidentiality and securing data are in place for this study. Each research participant is assigned a unique study number that will be used to identify her data. All identifying information (name, address, telephone number) will be kept in a separate file apart from the research data. All computer databases are password protected, and hard copies of all data and records will be stored in locked filing cabinets. At no time will research data be linked with names, addresses, or telephone numbers, nor will any participants be identified in the presentation of results. Any data transmitted across the internet between evaluators will be deidentified and encrypted with passwords. Information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent.

WHOM MAY I CONTACT FOR MORE INFORMATION?
If you have more questions, please contact the Study Coordinator, Ms Onkabetse Matlhaba (Email: Matlhabao@ub.ac.bw; Telephone: +267 7323 1031).

You can also call any of the investigators listed here to tell him/her about a concern or complaint about this research study. The investigators can be reached as follows:

1. **Dr Philip Opondo**
   Email: opondopr@ub.ac.bw
   Telephone: +267 355 5613 / +267 71853285

2. **Mr. Ari Ho-Foster**
   Email: hofostera@ub.ac.bw
   Telephone: +267 355 4553 / +267 72515786

If you want to talk with someone other than those working on the study, you may contact the Ministry of Health's Health Research Development Committee (HRDC) with any question, concerns or complaints at: 391 4467. You may also contact Ms Dimpho Ralefala at the University of Botswana Office of Research and Development (ORD): 355 2900/2902.

CAN I CHANGE MY MIND ABOUT PARTICIPATING?
Yes. You may change your mind at any time without any effect on your care. Ms Onkabetse Matlhaba, Dr Philip Opondo, or Mr Ari Ho-Foster should be notified of your decision to withdrawal from the study (refer to the contact information listed above). This can be done either by phone or email.

STATEMENT OF CONSENT

The procedures, risks, and benefits of this study have been told to me and I agree to be in this study and sign this form. My questions have been answered. I may ask more questions whenever I want. I do not give up any of my legal rights by signing this form. A copy of this signed consent form will be given to me.

_____
Subject's Name

_____ _____
Subject's Signature Date

_____ _____
Signature of Interviewer Date

_____ _____
Signature of Witness (if illiterate) Date

INTERVIEWER: ASK THESE QUESTIONS OF ALL PARTICIPANTS AFTER REVIEWING THE INFORMED CONSENT FORM BUT PRIOR TO SIGNING IT.

Now I'm going to ask you a few questions about the consent form to make sure that everything I described was clear.

1. The purpose of this study is to:
a. Learn from you about the way people think about and understand HIV/AIDS and Mental Illness stigma in Botswana.
b. Get your opinion about medications for HIV.
c. See how people get along with their family members.

2. If I agree to participate, I am agreeing to:
a. Participate in a group intervention chosen for me, and ten research interviews.
b. Participate in eight session of a group intervention chosen for me, and participate in interviews before the intervention, after the intervention, and again four months later. Have a small amount of my blood drawn and access to my medical records before the intervention and again after four months. An immediate family member of mine will also need to, on their own, agree to participate.
c. Participate in one research interview group.

3. I can refuse to answer any questions that make me feel uncomfortable.
a. True
b. False

4. By consenting to participate, my interviewer and other members of the research team agree to keep my responses confidential.
a. True
b. False

5. The interview will last up to:
a. 10 minutes
b. 45 minutes
c. 1.5 hours

6. Scoring:

Question Number	Correct Initially? (Y/N)	Number of times Re-explained? (0-2) **	Competent? (Y/N) **
1			
2			
3			
4			
5			

** Interviewer: If on any question the content is re-explained two (2) times and the respondent still does not answer correctly then the respondent is incompetent to proceed and should not be interviewed at this time.

NIH Data Sharing Consent Addendum

If you agree, your data from this study will be submitted to the National Institutes of Health (NIH) database. This large database is where deidentified study data from many NIH studies is stored and managed. If you participate in more than one NIH study, then your data from each of these studies may be combined. To do so, the researchers need to collect certain identifiable information about you (see bottom of page). However, the researchers will submit only deidentified data to the database. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the database. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with database. The study data provided to the database may help researchers around the world learn more about health. You will not be contacted directly about the study data contributed to the database.

It is your choice whether your data is added to the database. You may decide now or later that you do not want your study data to be added to the database. *You can still participate in this research study even if you decide that you do not want your data to be added to the database.* If you decide any time after today that you do not want your data to be added to the database, contact the study staff, and they will tell the database to stop sharing your study data. Once your data is part of the database, the study researchers cannot take back the study data that was shared with other researchers before they were notified that you changed your mind.

Select one:

___ Yes, I agree to have my deidentified data added to the NIH database. (Sign and complete bottom).

___ No, I do not agree to have my deidentified data added to the NIH database. (Do not sign or complete bottom. You can still participate in the research study).

You have received a copy of this document to keep.

_____
Subject's Signature & Date

Provide information as it appears on your birth certificate

First name: _____ Middle name: _____ Last name: _____

Date of birth (mm/dd/yyyy): _____ Sex: _____ City/municipality of birth: _____