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 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 is to explain 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) adherence 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 family member to a patient living with SMI and HIV, who is taking part in the study. This patient has given us permission to talk to you.

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 your family member receives at the hospital will continue and nothing will change. Your family member will still have their normal doctor's appointment and care.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?

We will be comparing a group of family members to patients with SMI and HIV+ who complete a new type of education and counselling programme (called the intervention group), to a group of family members who will complete standard counselling without the new programme (standard counselling 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 counselling 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 3-session, group intervention will occur for 60-70 minutes per session. Family members will meet in groups of 4 to 10. 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. Sessions will include standard counselling and with the new programme. ***Standard counselling group procedures:*** Participants of these groups will receive standard counselling sessions of the same number and duration, but without the new programme.

Virtual format: You will have the option to participate virtually (via voice call using WhatsApp) if you are unable to attend any of the 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.

Participants will be asked to fill out questionnaires (asking for information on: various aspects of family members' experience of stigma in relation to the care of their patient, views on community norms, selected health information, and demographic information). The questionnaires will be completed at the beginning of intervention and at the end. If it is not possible to complete the questionnaire in person, a member of the study team may assist you to complete the questionnaire.

The study team will make an audio recording of each session, for the purpose of verifying the quality and completeness of each session. Audio recordings will be handled securely (see below).

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

All consenting participants will be asked to participate in group sessions that will occur over a 2-3 week period, and complete questionnaires (1) before the first session; (2) after the final session; and (3) about 4 months after the final session. At all three timepoints, participants will be asked to provide information on opinions about families, stigma, and gender. Family participants will be asked to provide socio-demographic information at the start of the intervention. The first questionnaires will be completed at Sbrana Psychiatric Hospital, however later ones will be completed 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. Participants in the standard treatment group will be evaluated at the same time-points. In total, participants should expect to participate for about 4.5 months

ARE THERE ANY RISKS TO ME AND FAMILY MEMBER?

This study presents no more than low risk to you and your family member. However, 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 personal information), (2) disclosure of information regarding your experience as a family member to a patient may cause some discomfort, and (3) for sessions that include virtual participants, confidentiality and privacy cannot be fully guaranteed in non-private settings. This should be reported to study staff who will conduct an in-person counselling and referral for further help should it be necessary.

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 encourage 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 their 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 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 from 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. 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. 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. Information not containing identifiers, however, may be used in future research, shared with other researchers, or placed in a data repository without your additional consent.

Audio files of intervention sessions will be transferred from recording devices and stored on secured computers only in Botswana for the purposes of rating fidelity. Audio files will not be shared with any other collaborating institution. Any data transmitted across the internet between evaluators will be deidentified and encrypted with passwords. Audio recordings will be destroyed no later than one year following completion of the study.

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

1. **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 Dr Dimpho Ralefala at the University of Botswana Office of Research and Development (ORD): 355 2900/2911.

CAN I CHANGE MY MIND ABOUT PARTICIPATING?
Yes. You may change your mind at any time without any effect on your family member's care or services that you are entitled to. Ms Onkabetse Matlhaba, Dr Philip Opondo, or 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 REVIEW ING 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 three sessions of a group intervention chosen for me, and participate in interviews before the intervention, after the intervention, and again four months later. A family member of mine who is a patient living with SMI and HIV 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: _____