UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SANTA CASA SCHOOL OF MEDICAL SCIENCES, SÃO PAULO

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Reducing Intersectional Stigma among Women in Brazil to Promote Uptake of HIV Testing and PrEP (Project Manas por Manas)

Principal Investigators at UCSF: Drs. Sheri Lippman and Jae Sevelius
Principal Investigator at Santa Casa: Dr. Maria Amelia Veras
Contact Number: +55 (11) 3367-7781

This is a research study about using peer support to improve engagement in HIV prevention in Brazil by addressing the stigma that trans women face. In this study, participants will be assigned to receive study interventions either immediately, or after a 12-month waiting period. The intervention includes about six group sessions facilitated by two peer navigators over about two months followed by six months of individualized peer health navigation. The group and individual sessions are designed to support participants in staying healthy.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being invited to take part in this study because you are HIV-negative; identify as a trans woman, *travesti*, and/or identify as a woman but were assigned male sex at birth; and reside in or around the city of São Paulo.

Why is this study being done?

The purpose of this study is to find out if the combination of group-based and individualized peer health navigation can enhance gender pride, empower trans women to combat stigma they face in their lives, and increase uptake of HIV prevention services, including HIV testing and pre exposure prophylaxis, or PrEP, which is a pill you can take to help prevent HIV.

Who pays for this study?

The National Institutes of Health in the United States is paying for this study.

How many people will take part in this study?

We expect about 400 people to take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

Researcher's initials: _____
Participant's initials: _____

- A study representative will meet with you in a private space and ask you to respond to some questions about your health, your living arrangements, the health services you use, support you have from friends and family, and things that you do or don't do that can affect your health.
- We will randomly assign you to one of two study groups. One group will begin to receive the study intervention immediately. The other group will receive the same study interventions after a twelve-month waiting period. The group assignment is made at random by a computer, not the study staff.
- You will be asked to provide a mobile phone number that can be used to call you or send you text messages so we can follow-up with you. If you do not have a mobile number, you can provide a landline, such as for a social service office, where we can reach you.
- To learn about the HIV prevention services you receive, we will request your authorization to check your medical record at the clinic where you seek HIV-related services. We will record information from your clinic file in our study database, but the data will appear with your subject ID number only, not with your name. Your name will be kept private. Only our research team will have access to your medical record data.
- Every three months for two years, while you are in the study, we will ask you to return to take a survey. At three, nine, fifteen, and twenty-one months, the surveys will be brief, about your healthcare and your experiences in the study. At enrollment, six, twelve, eighteen, and twenty-four months, the surveys will be more comprehensive, with questions about your health, and things that you do which can affect your health. There will be a total of eight follow-up surveys.

During the time that you are in the peer navigation intervention – either immediately after enrollment or after a waiting period of 12 months – the following procedures will also occur:

- You will be introduced to peer navigator who will lead your group sessions and later work with you individually to develop a personalized HIV prevention plan.
- You will be asked to attend about six peer navigator-facilitated group sessions over about 2 months before your individual sessions begin. During the individual peer navigation, you will also be asked to return to attend one more "reunion" group session.
- During these group sessions, you will be offered the opportunity to use a HIV self-test kit, or to take one home to use later, and will be shown how to use this kit. You are not required to use it if you are not comfortable doing so. You will also be given information about where you can go to get an HIV test with a counselor.
- During these group sessions, you will also learn more about PrEP, a daily pill which can prevent HIV. You are not required to take PrEP to be in the study, but you can talk to your peer navigator to see if it might be a good strategy for you, and also get help with setting up and attending a medical appointment to start PrEP if you decide you want to use it.
- After the group sessions, your peer navigator will check in with you by SMS, What's App, or by phone over a period of six months. Your navigator may remind you about health appointments, remind you to use health services, or provide other information about health and health behaviors. During this time, you may also meet with your peer navigator in person to discuss your health needs and health behaviors.

If you decide to take PrEP as part of your personal HIV prevention plan, the following procedures will also occur:

- You will be referred to a provider at the CRT or SAE Campos Elíseos, who will explain the risks/benefits, the tests the clinic will need to do to determine if you are a good candidate for PrEP, as well as monitor your ongoing health while on PrEP.
- If you start PrEP, we will ask you at that time to provide consent to have a few drops of blood taken and placed on a card to test for PrEP medications in your body. These blood spots will be used for PrEP adherence monitoring and nothing else. The samples will be sent to Colorado Antiviral Pharmacology Laboratory, part of Skaggs School of Pharmacy and Pharmaceutical Sciences, located at 12850 E Montview Blvd. Aurora, CO 80045, USA. These samples will be under the responsibility of Dr. Peter Anderson and will be kept in the laboratory only until the tests are performed. Upon completion of the study, all samples will be destroyed.

Study Location

The interviews and group sessions will occur at either the health facilities (CRT or SAE Campos Elíseos) or the NUDHES research group's community office in central São Paulo, depending on which is most convenient for you.

How long will I be in the study?

Participation in the study will last about two years. Your first survey will happen immediately after you agree to participate and will take about 30-45 minutes. The longer surveys that occur every six months will also take about 30 minutes to complete. The brief surveys that occur on the three-month intervals are designed to last about 15 minutes. During the time that you are in the peer navigation group sessions, there will be about six sessions over about two months, which will each last about two hours; the reunion group session will also last about two hours. While you are in the individual peer navigation phase, your check-in meetings with the peer navigator will last anywhere from 10 minutes over the phone to an hour in-person, depending on your needs.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study staff person right away if you wish to stop being in the study. Also, if study staff believe that you are not comfortable participating in the study or that the study is raising difficult issues for you, she/he will talk to you about whether being in this study is causing you any discomfort. Based on that conversation, he/she could suggest that you leave the study and stop your participation. If you do not continue to participate, this will have no impact on your treatment or other services you receive at the CRT or SAE Campos Elíseos.

If for some reason the study is interrupted, the principal investigator in Brazil will notify the participant, the Committee for Ethics in Research (CEP), and the National Commission for Research Ethics (CONEP).

What risks can I expect from being in the study?

Because some activities take place at the clinics and because you may take home an HIV self-testing kit or PrEP pills as part of your study activities, it is possible that people could think you have HIV or some other health condition. Also if someone sees an SMS/WhatsApp message from your navigator reminding you to go to the clinic for a test or to take your pills, someone might ask about it.

If you choose to use an HIV self-testing kit, you could experience discomfort if you have a positive HIV self-test result, which can be frightening or distressing. It is not necessary to use the HIV self-test to participate in the study, but peer navigators are trained to help participants who use them, including confirming a new diagnosis with additional testing. Each self-test kit includes detailed instructions and a 24-hour national hotline for support and counseling.

Some of the survey or interview questions may make you uncomfortable, such as about sexual practices or substance use, or upset by bringing up challenges experienced by the transgender or travesti community. You are free to decline to answer any questions you do not wish to answer or to stop your participation at any time.

If you decide to take PrEP, the provider prescribing the medication will explain the risks and benefits of PrEP. We will also ask those choosing PrEP to consent to participate in a few more research procedures, including collection of blood for monitoring PrEP drug levels, which could cause some discomfort.

We will ensure that all possible precautions are taken to protect study records so that information you provide stays confidential and does not get back to anyone outside of the study. We ask that you talk to your navigator about the best way to communicate to ensure your privacy.

If you suffer any harms resulting from your participation in this research, you have the right to seek assistance. By signing this consent form, you will not be waiving your rights as a Brazilian citizen, including compensation.

For more information about risks, ask one of the researchers.

Are there benefits to taking part in the study?

There is no direct benefit to you from participating in this study. However, learning your HIV status in a timely manner and private setting as a result of using the HIV self-testing kit or connecting to prevention services or care through the support of a peer navigator could be beneficial to your long-term health. Additionally, the information that you provide may help us improve future health services for transgender women in Brazil.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care and services the way you usually do.

How will my information be used?

Researchers will collect information about you to conduct this study. Once the study is over, the investigators can share the data collected with other researchers if requested. We will not share your name or any other personal information that would reveal who you are. We would only share data identified by a study ID that is not connected to your name.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private even after the study has ended. Your name and any other form of personal identification will be coded with a confidential study number. All study materials will be labeled only with this confidential study identification number. The study staff, including your peer navigator, will have access to your study number and contact information so we can contact you if necessary. If information from this study is published or presented at scientific meetings, no names or personal information will be used.

The researchers cannot release or use information, documents, or samples that would identify you unless you say it is okay. However, access to your research records from the study will be available to authorized organizations in accordance with the Brazilian regulations to protect research participants. Research records can be reviewed by the study team, by authorized individuals from the Comitê de Ética em Pesquisa (CEP) of the Santa Casa de São Paulo, the research sponsor the National Institutes of Health (NIH) in the United States, and the UCSF Institutional Review Board (IRB), as well as other regulatory authorities, according to Brazilian legislation.

In exceptional situations, we may need to talk with the medical staff attending to your health services at this clinic: (1) if we have trouble reaching you and need the clinic's assistance in helping to find you or (2) if you indicate that you might harm yourself or need urgent help.

This study was submitted to the Human Research Ethics Committee of the Santa Casa de Misericórdia de São Paulo, in São Paulo; the National Commission for Research Ethics (CONEP) in Brazil; and approved by the Ethics Committee (IRB) of the University of California, San Francisco, United States.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study. You will receive a small reimbursement for your expenses incurred (transportation and food) during your time completing the surveys in the

study (R$ 50), as well as for the group and individual sessions (R$ 40). This money should ensure that you do not spend any money in order to participate in this research. Expenses related to travel for medical appointments or routine exams and other health and social services you receive that are not part of the research will not be covered by the study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. Your access to care and services will not be affected by choosing not to participate.

Who can answer my questions about the study?

You can talk to Dr. Maria Amelia Veras about any questions, concerns, or complaints you have about this study, from Monday through Friday during business hours, from 9 am to 6 pm. This can be done by telephone or by email using the following information:

Rua Dr. Cesário Mota Jr. 61 - 6° andar – São Paulo/SP
Telephone: (11) 3367-7781
Email: maria.veras@gmail.com

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact the Comitê de Ética em Pesquisa (CEP) of the Santa Casa de São Paulo, from Monday to Friday 7 am to 4 pm, by telephone (11) 2176-7689 or by email at: cepsc@santacasasp.org.br . Their office is located on R. Marquês de Itu, 381 – 4th floor, Vila Buarque, São Paulo – SP. Additionally, the field supervisor for the project will be accessible for 24-hour communication for questions related to the project by telephone at (11) 95745-7566.

Alternatively, you can contact the National Commission for Ethics in Research (CONEP), by phone (61) 3315-5877, from Monday to Friday, 8 am to 6 pm. The National Commission for Ethics in Research is located at thr following address: SRTV 701, Via W 5 Norte, lote D - Edifício PO 700, 3º andar – Asa Norte CEP: 70719-040, Brasília/DF.

The Committee on Ethics in Research (CEP) and the National Commission for Ethics in Research (CONEP) are responsible for monitoring this study and can help you if you have any questions or suffer harm resulting from your participation.

CONSENT

Please read the sentence below and think about your choice. After reading, put your initials in the "Yes" or "No" box. No matter what you decide to do, it will not affect your care.

I am willing to allow the research teams to contact me in the future about other research studies for which I may be eligible.

YES	*NO*

If I decide to use PrEP during the study, I agree to provide a sample of dried blood for adherence testing.

YES	*NO*

You have been given a copy of this consent form to keep. The other copy will remain with the research team. If you decide to participate in the research, you should initial the two copies of this consent form, signing the last page (below). The responsible researcher must do the same.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You 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 you are otherwise entitled.

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

_____ _____
Date Participant's Signature for Consent

_____ _____
Date Signature of responsible researcher obtaining Consent