UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: It Takes Two (T2): A couples-based approach to HIV prevention for transgender women and their partners

Principal Investigators:	Mallory Johnson, PhD. University of California San Francisco; Professor of Medicine 550-16th Street, Suite 300 San Francisco, CA. 94158 Phone: (415) 476-2163; Email: Mallory.Johnson@ucsf.edu Kristi Gamarel, PhD., Ed.M. University of Michigan; Associate Professor 3826 School of Public Health I 1415 Washington Heights, Ann Arbor, MI. 48109 Phone: (734) 647-3178; Email: kgamarel@umich.edu

Introduction

This is a one-year long research study for transgender women and their primary partners. The study will test the impact of a four-session couples counseling program to reduce HIV risk by improving communication and increasing knowledge of HIV prevention issues.

Mallory Johnson PhD. from UCSF; Kristi Gamarel PhD., Ed.M. from University of Michigan; and Jae Sevelius PhD. from Columbia University, Research Foundation for Mental Hygiene along with their research colleagues and staff, are conducting the study. The National Institute of Mental Health (NIMH) sponsors the study, which pays some of researchers' salary. Besides this salary, the researchers have no financial interest in this study or its results.

You are being asked to take part in this couple's study because you are in a relationship in which one or both of you is a trans woman, and you were found to be eligible at a recent screening visit.

Participation in research is voluntary. Research studies only include people who choose to take part. It is your choice whether or not you want to be in this study. Please take time to make a decision about participating. You can discuss the decision with your family, friends and partner.

The first part of this consent form gives you a summary of the study and more details about the study are later in the form. The study team will also explain the study to you and answer any questions you have.

Study Summary: It Takes Two (T2) is a one-year research study for transgender women and their primary partners. The study is testing the impact of a four-session couples counseling program to reduce HIV risk by improving communication and increasing knowledge of HIV prevention. Couples in the study are randomly assigned – by chance – to either a four-session

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

couples counseling program, or to watch a short HIV prevention video. All couples attend quarterly research follow-up visits every three months thereafter, for one year.

If at any time during the study we cannot see you in-person because of COVID-19 restrictions, we will conduct visits remotely (including the enrollment and follow-up visits). We would do this on Zoom, Facebook Messenger video chat, Google G Suite Hangouts video or Skype for business. Use of these platforms may present some security risks and therefore additional risk to your privacy and the confidentiality of your information.

Why is this study being done?
The purpose of the T2 study is to test a couples counseling program for trans women and their partners to improve their HIV prevention strategies and relationship communication.

How many people will take part in this study?
About 100 couples (200 individual partners) will take part in this study.

What will happen if I take part in this research study?
If you agree to participate, you will sign this consent form and attend study visits at the offices of the UCSF Alliance Health Project (AHP) at 1930 Market Street (between Laguna and Buchanan Streets) in San Francisco.

When you arrive for each study visit, we will ask you some COVID-19 health screening questions through the closed door before you enter, for everyone's safety, and will provide you with a hospital mask. The number of people who can be at AHP at any one time is limited for safety reasons. Everyone at AHP must wear masks at all times, and observe social distance of at least 6 feet. The only exception is during blood draws where strict social distancing is not possible. However, the phlebotomist will wear a mask and face shield and will limit the amount of time they are close to you to less than 15 minutes. Participation in the one-year study involves:

1. You will complete an Enrollment visit that takes 2 to 2-1/2 hours. *If the visit must be remote, we will do this on Zoom or another video-conferencing platform*
2. We will collect information on how to contact you by phone, text, or in writing to remind you before study visits or contact you if you miss a visit. We will also ask for names of people and/or agencies who know how to reach you. We will ask about medications you may take to prevent or treat HIV, and ask you to sign a Release of Information so that if needed, we can get lab test results from your doctor or medical record. *If the visit is remote, you will sign this consent form and the Release of Information Form on DocuSign or using surface mail.*
3. You will complete a survey that takes about one hour. *For remote visits, we will do this on the phone or using Zoom or another video-conference platform.*
4. If you do not have HIV and take Pre-Exposure Prophylaxis (PrEP) medication, a phlebotomist will collect three-five (3-5) drops of blood from your finger to test for PrEP medication levels. *If we cannot see you in-person because of COVID-19 restrictions, we will mail you a PrEP Kit with instructions and a return envelope, and ask you to cut a small sample of hair from your head (40-50 strands) that we can analyze.*
5. If you have HIV, a phlebotomist will draw 20mL (4 teaspoons) of blood from a vein in your arm to test your viral load. *If we cannot see you in-person because of COVID-19 restrictions, we will*

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

ask you to go to a nearby lab to have your blood drawn. If you prefer not to do this, you can send us an HIV viral load result from within the last 30 days, or using a Release of Information, we can request a lab result from the last 30 days from your medical provider.

6. You and your partner will be assigned at random to one of two groups. The group you are assigned to depends completely on chance - like the toss of a coin – and there is a 50:50 chance that you will be assigned to either group.
   - Group A (Control Arm): If you are assigned to Group A, you and your partner will watch a 10-minute health education video.
   - Group B (Intervention Arm): If you are assigned to Group B, you and your partner will complete four weekly counseling sessions together as a couple. The four sessions take from 20-60 minutes each and are led by a trained counselor. Sessions are audio-recorded for training and quality control. If you do not want to be audio-recorded, you can 'opt-out' at the end of this Consent Form.

   If at any point we are unable to see you in-person because of COVID-19 restrictions, these activities will take place on Zoom or another video-conference platform. We would email you and your partner the video set if you are assigned to Group A control group. If you are assigned to Group B for the couples counseling intervention, sessions would take place on zoom or another video-conference platform.
7. After these visits, we will offer you a Resource List, condoms, and lubricant *(for remote visits we will mail these to you).*
8. You and your partner will come to Quarterly Follow-up Visits at 3, 6, 9, and 12 months after you enroll. At each follow-up visits:

   - We will update your Contact Information.
   - You will complete a survey that takes about one hour.
   - If you do not have HIV and are taking Pre-Exposure Prophylaxis (PrEP) medication, a phlebotomist will do a finger-stick procedure to collect three-five (3-5) drops of blood to test PrEP medication levels. *If at any point we are unable to see you in-person because of COVID-19 restrictions, we would ask you to cut a small hair sample and send to us in the mail for analysis.*
   - If you are living with HIV, a phlebotomist will draw 20mL (4 teaspoons) of blood from a vein in your arm for HIV viral load testing. *If at any point we are unable to see you in-person because of COVID-19 restrictions, we would ask you to go to a lab near you to have your blood drawn.*
   - At the end of each follow-up visit we will offer you a Resource List, condoms, and lubricant *(for remote visits we will mail these to you).*

How long will I be in the study?

The entire study takes a little more than one year (12 months). The time you will spend doing study activities will be about 480 minutes (8 hours) to 755 minutes (12.5 hours) depending if you are assigned to the intervention or to the control group, and which lab tests need to be conducted.

Can I stop being in the study?

Yes. Participation in this study is voluntary and you can decide to stop at any time. Just tell a Research Assistant or staff person right away if you wish to stop being in the study. Also, it is possible that the study investigators will end your participation if they believe it is in your best

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

interest, if you do not follow the study rules, or if the study is stopped. If you withdraw your consent, the researcher may request to continue to use information already collected.

What if my partner and I break up during the study?

If you and your partner break up after enrolling in the study, you will still be followed separately.

- If you are assigned to Group A (Control Arm) but later break up, both you and your former partner will come in separately to complete the quarterly Follow-up Visits at 3, 6, 9, and/or 12-months. If you are assigned to Group B (Intervention Arm) but break up before counseling sessions 2, 3, and/or 4, the rest of those sessions will be cancelled. You and your former partner will come in separately to complete the quarterly Follow-up Visits at 3, 6, 9, and/or 12-months.
- Once you have enrolled in the study as part of a couple, you cannot re-enroll with a new partner.

What risks can I expect from being in the study?

There are risks to taking part in research. Some of the risks of participating in this study are:

1. **Risk to confidentiality:** Participation in research involves a risk to your privacy. Your identity and research records will be handled as confidentially as possible. The information that you give will be coded with a number to help protect your privacy. The link listing names with numbers will be kept in locked files and only study staff will have access to the study files. At no time will any public reports about the study mention your name or the names of other participants. No one other than research staff are permitted to listen to audio recordings of the counseling sessions. The recordings will be labeled with your study identification number, not your name, and will only be used for training and quality assurance (internal) purposes. The recordings are saved on a fire-wall protected server and destroyed after this research project is completed.

   COVID-19 related issues: *If there is ever a time that we cannot see you in-person because of COVID-19 restrictions, we will conduct visits remotely on Zoom or another video-conference platform. Use of these virtual platforms may present some security risks and therefore may present additional risk to your privacy and the confidentiality of your information. You can choose not to complete remote visits, but that may affect our ability to keep you in the study.*

2. **Randomization risk:** You will be assigned to either a four-session couple's counseling program, or to watch a short HIV prevention video by chance. One condition may prove to be less effective than the other. We will not know which one is more effective until the study has been completed, and the data has been analyzed.

3. **Study topic risks:** Some of the questions in the survey might make you uncomfortable. Talking about your relationship, sexual behaviors, and HIV prevention may make you feel embarrassed, angry, uneasy, or sad in some way. You can decline to answer any questions or to take part in any of the discussions at any time.

4. **Blood drawing risks:** Drawing blood can cause temporary discomfort from the needle stick,

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

bruising, infection, and fainting. Very rarely an infection can occur at the injection site.

5. **Inconvenience:** Being in the study may sometimes be inconvenient, but staff will make every effort to schedule appointments at times that are convenient for you.

6. **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor (National Institute of Mental Health) depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Are there benefits to taking part in the study?
Although there may be no direct benefits, you may gain new knowledge about health and wellness or improve communication with your partner. The information you provide will help us develop and implement better HIV intervention services for trans women and their partners.

How will my specimens and information be used?
Although we are collecting specimens for lab testing as a part of the study, we will only give out lab results upon request.

Researchers will use your specimens (saliva and/or blood) and information to conduct this study. Once the study is done using your specimens and information, we may share the information with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

There may be times when researchers using your specimens and information may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

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. We will not share any of the information that you provide with your partner. However, we cannot guarantee total privacy. 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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality form the National Institute of Mental Health (NIMH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

- UCSF Committee on Human Research, who protect your rights as a research participant;
- Representatives from the National Institutes of Health, who sponsor this study;
- Representatives of University of California;
- Researchers at the University of Michigan who are helping to lead this study.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about incidents such as child abuse, elder abuse, and intent to hurt yourself or others. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects.

Because this study is a clinical trial, a description of the study will be available on **http://www.ClinicalTrials.gov**, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs of taking part in this study?
You will not be charged anything for any of the study procedures.

Will I be paid for taking part in this study?
Yes, you will be paid in cash after each study visit. This chart shows how much you receive for each visit, and how long each visit will take. *For remote visits, we can email you a code to redeem the visit incentive on Amazon or send to you on CashApp.*

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

Visit Type	Visit Incentive Amount	Visit Length
Enrollment Visit + Group A Control Videos or Group B Intervention Session 1	$100/person ($200/couple) * *For remote Enrollment Visits: (1) participants with HIV receive an additional $40 for completing VL testing at a Quest Service Center AND (2) if HIV-negative and on PrEP an additional $20 is given for collecting and providing a hair sample for adherence analysis.*	2 to 2-1/2 hours
IF you are assigned to Group B Counseling Intervention, Sessions 2, 3 & 4	$20/person ($40/couple) for each session	45-60 minutes
3-Month Follow Up Visit	$50/person ($100/couple) * *For remote Follow-up Visits: (1) participants with HIV receive an additional $40 for completing VL testing at a Quest Service Center AND (2) if HIV-negative and on PrEP an additional $20 is given for collecting and providing a hair sample for adherence analysis.*	1-1/2 hours
6-Month Follow Up Visit	$50/person ($100/couple) * *For remote Follow-up Visits: (1) participants with HIV receive an additional $40 for completing VL testing at a Quest Service Center AND (2) if HIV-negative and on PrEP an additional $20 is given for collecting and providing a hair sample for adherence analysis.*	1-1/2 hours
9-Month Follow Up Visit	$50/person ($100/couple) * *For remote Follow-up Visits: (1) participants with HIV receive an additional $40 for completing VL testing at a Quest Service Center AND (2) if HIV-negative and on PrEP an additional $20 is given for collecting and providing a hair sample for adherence analysis.*	1-1/2 hours
12-Month Follow Up Visit	$50/person ($100/couple) * *For remote Follow-up Visits: (1) participants with HIV receive an additional $40 for completing VL testing at a Quest Service Center AND (2) if HIV-negative and on PrEP an additional $20 is given for collecting and providing a hair sample for adherence analysis.*	1-1/2 hours
If you come to all visits you can receive at least:	**Group A: Control group ($300/person or $600/couple)** **Group B: Intervention ($360/person or $720/couple)**	

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

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. If you decide to take part, you can leave at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?
You can ask the research study staff any questions you have and discuss any concerns. You can also contact Dr. Mallory Johnson at Mallory.Johnson@ucsf.edu (415) 476-2163.

If you want to talk to someone other than the researchers or ask questions about your rights as a research participant, or you have a problem or concern about the study, please call the Institutional Review Board at (415) 476-1814.

****

CONSENT
You have been given copies of this consent form and the UCSF Experimental Subject's Bill of Rights to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. You can choose not to be in this study if you do not want to. You can also withdraw from the study at any time.

If you wish to participate in this study, you give your consent to participate by signing below.

_____ _____
Date Signature of Participant

_____ _____
Date Signature of Person Obtaining Consent

<u>Audio Recordings of Counseling Sessions:</u>
By checking yes and writing your initials below, you permit the researchers to record your sessions and use it for their research. If you choose not to have your sessions recorded you may still take part in the study.

_____ NA

_____ No, I opt out of

_____ Yes, I give my permission _____Initials

UCSF University of California San Francisco
IRB NUMBER: 19-28624
IRB APPROVAL DATE: 09/12/2022
IRB EXPIRATION DATE: 09/11/2023

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told of the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,

9) To receive a copy of the signed and dated consent form,

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.