UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

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

Study Title: A couples-based approach to improving engagement in HIV care

This is a research study about primary relationships and HIV. Dr. Mallory Johnson, Ph.D., or his research staff from the UCSF Department of Medicine, Center for AIDS Prevention Studies, will explain this study to you.

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 asked to take part in this study because you are 18 years or older, involved in a primary romantic relationship with another person who is also 18 years or older, and one or both of you is HIV-positive. The research project is focused on couples that have not been traditionally well represented in research. Your responses to our screening indicate there are potential areas of improvement in your or your partner's HIV treatment adherence. Your primary romantic partner is also being asked to participate in the study and, to enroll as a couple, you must both participate.

Why is this study being done?

The purpose of this study is to test a program designed to help HIV-positive partners improve their HIV treatment adherence and overall engagement in their HIV treatment. The ultimate goal of this research is to develop programs that will assist HIV-positive people to live longer and healthier lives. The study is funded by the National Institutes of Health (NIH).

How many people will take part in this study?

About 300 people (150 couples) will take part in this study.

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

Study Location: All in-person study procedures will take place at our study offices. Bloodwork takes place at any convenient Bay Area Quest Diagnostic Service Center.

If you are eligible for the study and you choose to continue, you and your partner will meet with a research staff member who will explain the study to you and answer your questions. If you agree to participate, you will sign this consent form and the following procedures will occur:

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

Interviews

- You will be asked to complete four private, individual computer-assisted surveys (one baseline and three follow-ups) during your 12 months of study participation. Baseline visits usually take about 2 hours on average to complete, while follow-ups take around 1 hour each. If you are HIV-positive and taking antiretroviral medications, a research staff member will verify your medications and then show you how to complete the survey on the computer. You will be asked questions about yourself and your relationship with your partner, your communication, intimacy, conflict, social support, and the role of HIV medications in your relationship. You will also be asked about your medical history, and your history of drug and alcohol use. The data collected on the computer screen will have no identifying data and will be coded by a participant identification number. If you finish your survey before your partner, you will be asked to wait while your partner completes the survey separately. This part of the interview may be audio recorded. The recordings will be destroyed after their content is reviewed and studied by the researchers. Follow-up surveys take place online through an online link we sent to your email. You can access the follow-up survey on your own device at any Wi-Fi enabled convenient location. You may also come to our study office to complete follow-ups on a study tablet in a private room if you prefer. At your final interview survey, you may be asked for your thoughts, feelings, and opinions about the study's surveys or program sessions and your study participation in general.
- Blood draws and laboratory tests: If you are HIV-positive, an experienced phlebotomist at Quest Diagnostics will draw a blood sample prior to your four surveys. The amount of blood drawn each time will be approximately 30 ml (2 tablespoons). Your blood will be used to test your CD4 count and viral load. The CD4 test will be done at the first survey visit only, and the viral load test will be done prior to all four surveys. You will have the opportunity to receive your CD4 and viral load test results as they become available.

Randomization

- You will be randomized to one of two study conditions: Group A or Group B. The group you are randomized to depends on chance, something like the toss of a coin.
- Group A: This is a program for couples. You and your partner will meet together with a counselor for 6 weekly sessions. These sessions usually last about 60 minutes. During the sessions, you will discuss your health, your relationship with your partner, and steps for improving HIV treatment adherence. Sessions are scheduled with as much flexibility as possible and tailored to meet your needs. Sessions will be audio recorded to make sure they are done correctly, and the recordings will be destroyed at the end of the study.
- Group B: This is a program for HIV-positive individuals. You will meet individually with a counselor for 3 weekly sessions. These sessions usually last about 60 minutes. During the sessions, you will discuss your health and steps for improving HIV treatment adherence. Sessions are scheduled with as much flexibility as possible and tailored to meet your needs. Sessions will be audio recorded to make sure they are done correctly, and the recordings will be destroyed at the end of the study.

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

If both you and your partner are HIV-positive, one or both of you will attend these individual sessions, based on the responses you each provided in the study screening and interviews.

If you are HIV-negative, you will not attend the program sessions, but you will participate in the interviews as described above.

Other Procedures

- Contact Information: A research staff member will ask you for detailed information about how best to contact you (for example, you will receive confirmation phone calls and/or written reminders about your study visits) and how we could find you if you miss an appointment for a study visit. You will be asked to provide the names of people and agencies who know how to reach you. Any location information that you provide will be kept in secure password protected files, and you can ask to have these contact procedures stopped at any time.

- Monthly Check-ins: During the months between your study visits, a staff member will call you for a brief check-in and to ask you a few questions. You can also come to the study offices in person for these check-ins if you'd prefer.

How long will I be in the study?

Participation in the study will take a total of about 12 months.

If you are randomized to Group A, your total time in the study will be approximately 15 hours over the course of the year.

If you are randomized to Group B, your total time in the study will be approximately 12 hours over the course of the year.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff right away if you wish to stop being in the study.

Also, the study researchers may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Privacy and confidentiality: Participation in research may involve 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, and the records linking names with numbers will be kept in secure password protected files. Only the 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.

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

No one other than the research staff and transcriptionists will be permitted to listen to study audio recordings. The audio recordings will be labeled with your study identification number, not your name, and will be kept in secure password protected files and destroyed after their use in this research project is completed.

- Randomization: You will be assigned to a group by chance, to receive either a couples intervention or an individual intervention. One condition may prove to be less effective than the other condition or other available treatments in helping you make informed decisions about your healthcare. However, we won't know if either Group A or Group B is better than the other until after the study is completed and the data have been analyzed.
- Study topics: Some of the questions in the interviews or discussions with study staff might make you uncomfortable; talking about your own or your partner's HIV infection, your relationship, your sexual behaviors and your drug-using behaviors may make you feel embarrassed, angry, uneasy, or sad in some way.

  Among the areas of interest in this study are communication and conflict among couples. Discussing these topics may be uncomfortable or may result in tense or difficult interactions with your partner following your participation in the study. You are free to decline to answer any questions or to take part in any discussions at any time. You will be given a list of resources including agencies that provide couples counseling and domestic violence services, as well as up-to-date phone numbers for crisis centers, hotlines, and referral agencies.
- Blood draws: The risks of drawing blood include temporary discomfort from the needle stick and bruising. Very rarely an infection can occur at the injection site.
- Inconvenience: Being in the study may sometimes be inconvenient. The study staff will make every effort to schedule interviews and sessions at convenient times.

Are there benefits to taking part in the study?

There may be no direct benefit to you from participating in this study. However, you may learn new ways to take better care of your health, and the information that you provide may help researchers understand the role of HIV medications among individuals in primary relationships.

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, the research staff will offer you a resource list of agencies giving support and services for people with HIV.

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. 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.

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute of Nursing Research (at NIH). 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.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- UCSF Committee on Human Research, who protect your rights as a research participant;
- Representatives from the National Institutes of Health, who sponsor 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.

What are the costs of taking part in this study?

You will not be charged for any of the study procedures.

Will I be paid for taking part in this study?

Yes. In return for your time, effort and travel expenses, you will be paid as follows:

- Consent: You will be paid $30 in cash for today's consent visit.
- Interviews: You will be paid $40 on a reloadable debit card when you complete the baseline visit, and $20 on a reloadable debit card when you complete each follow-up survey.
- Program sessions: You will be paid $45 on a reloadable debit card when you complete each program session.
- Blood draws: If you are HIV-positive, you will be paid $50 on a reloadable debit card for each blood sample obtained from Quest Diagnostics. Payment will not be given for labs acquired from your medical provider through a Release of Information.
- Referral: You will be paid $20 per referral if you refer eligible participants to the study.

The reloadable debit cards, called ClinCard, can be used anywhere a Mastercard can be used, including an ATM. ClinCard requires that your legal name and date of birth be linked to the card.

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

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.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. The Principal Investigator is Dr. Johnson, who may be reached at Mallory.Johnson@ucsf.edu or the Project Director, Lara Coffin, who may be reached at (415) 502-5216 or Lara.Coffin@ucsf.edu.

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 call the Office of the Committee on Human Research at (415) 476-1814.

We are often asked about other studies. Would you like to be contacted if we have other studies for which you might be eligible?

☐ Yes ☐ No

CONSENT

You have been given a copy of this consent form to keep.

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 Person Obtaining Consent

UCSF University of California San Francisco
IRB NUMBER: 16-19267
IRB APPROVAL DATE: 12/17/2019
IRB EXPIRATION DATE: 12/16/2020

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.