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

Study Title: Intervention for Virologic Suppression in Youth (iVY)

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This is a research study about using technology to address barriers to HIV care engagement. The Principal Investigator, who is the person in charge of the study, or another member of the study team from the UCSF Division of Prevention Science 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 18-29 years of age, have access to a smartphone, and have had a detectable viral load at some point in the past year.

Why is this study being done?

The purpose of this study is to try out a technology-based intervention to address barriers to HIV care engagement. The intervention includes receiving counseling via video-chat along with using a mobile health app designed specifically for young people living with HIV.

This study is funded by the National Institutes of Health.

How many people will take part in this study?

About 200 people will take part in this study. 100 people will be randomly selected to receive the intervention, and 100 people will receive care as they normally would.

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

The whole study will take 48 weeks (about 12 months). If you agree, the following procedures will occur:

<u>Enrollment, Baseline Survey, and Randomization</u>

- After we receive your consent, we will ask you for various ways of contacting you in case we have a hard time reaching you by phone. This will include the names of people

who may know how to find you; however, you may ask us at any time to no longer contact these people.
- We will ask for your permission to request your medical records from your primary HIV medical clinic.
- We will ask you to take a baseline survey to learn more about you, your background, current health, HIV medical care, and substance use. This survey will last about 30 minutes.
- We will also ask you to mail in a home-collected HIV viral load test (see details below).
- We will randomly assign you to one of the below study groups: Group A (the intervention group) or Group B (the standard of care group).

Group A: Video-Counseling+App
- You will meet with a counselor weekly over video-chat for 12 sessions (over a 16-week period) each taking about 30 minutes. A series of 3 to 6 fixed introductory sessions will be completed by all Group A participants covering topics such as engagement in HIV care, mental health, and substance use. During the remaining sessions, you will choose from a menu of topics to discuss other concerns affecting your life.
- We will text you every week to send session reminders, follow up on any questions or resources that came up, and periodically check on your contact information.
- You will also be given access to the WYZ app. This app includes features to help you remember to take your meds, find community resources, and connect anonymously with other young people living with HIV.
- After completion of 12 sessions or the passage of 16 weeks (whichever comes first), we will ask you to take a 30 minute survey and complete a home-collected HIV test kit.
- At this time, based on your viral load results:
    - You will receive an additional 12 sessions (over a 16-week period) with the counselor over video-chat, along with use of the WYZ app.
    - OR you will continue with just using the WYZ app. We will check in with you monthly to answer any questions about the app and make sure your contact information is up-to-date.
- We may ask you to participate in an interview so that we can get your feedback on your experience with the intervention.

Group B: Standard of Care
- If you are randomly selected to be in this group, you will receive care from your primary HIV clinic as you normally would. You will still complete the 30min surveys and home-collected HIV tests described below. Based on your survey responses, we may refer you back to your clinic for medical, psychological, or substance use services.
- We will also check in with you monthly to make sure we have your updated contact and clinic information.

Surveys and Home-Collected HIV Test Kits
- Every 16 weeks (about 4 months), we will ask you to complete a 30min survey about your mental health, use of substances, HIV-related health, and overall well-being. This means you will complete 4 surveys (at baseline, 16, 32, and 48 weeks).
- We will also mail you a home test kit and ask you to mail it back for HIV viral load testing. The test kit will ask you to prick your finger and place about 2 drops of blood on a small device, let it dry for 1 minute, then mail it back in the envelope we provide. We

will review this kit with you extensively and provide instructional videos to help you. We will not share the results with you, and they will only be used for study purposes.

Study location: All study procedures will be done in your home or at a private location of your choosing.

How long will I be in the study?

Participation in the study will last 48 weeks (about 12 months). Depending on which group you are randomly assigned to, study activities will take between 5.5 to 18.5 hours over the total study.

Can I stop being in the study?

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

If you withdraw from the study, any data or specimens we have already collected from you will remain part of the study records. After you withdraw, the researchers may still get information from your medical records if it is relevant to the study (e.g., laboratory results, treatment courses, health outcomes). You must tell the study team you do not want this information to be collected when you withdraw, otherwise, it will be collected.

Also, the study researcher 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?

- Loss of confidentiality is the main potential risk associated with participation in this study, however, we will do our best to make sure your information is kept private. Security and privacy are our top priorities. The survey tool, video-chat, and mobile health app are all HIPAA-compliant. Text messages are not HIPAA-compliant, but we will show you how to set up your privacy settings on your phone. Our text messages and the home test kit packaging will not mention anything about HIV or the study. The lab processing your HIV test will only know your participant ID number and not your name.
- Emotional distress: It is possible you may experience emotional distress during the study, but you do not have to answer any questions you do not wish to answer, and you may end a counseling session or withdraw from the study at any time. If it is necessary, we will refer you to your healthcare provider or to other medical, psychological, or substance use services as needed.
- Minor pain: You may experience some minor physical discomfort or pain doing the finger prick of the HIV test. To help ensure you understand how to properly collect your sample, we will explain the process to you and send you instructions.
- For more information about risks and side effects, you may call or text us anytime.

Are there benefits to taking part in the study?

You may or may not benefit from participating in this study.

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 from our institution the way you usually do.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. We will not share the results of the home-collected testing with you, and they will only be used for study purposes.

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.

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

- Representatives of AIDS Healthcare Foundation (AHF Patients only)
- Representatives of Research Triangle Institute (RTI)
- Representatives of the National Institutes of Health
- Representatives of the University of California

This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the Federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research.
- from having access to your own medical record information.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time and effort, you will be paid between $470 and $530 for completion of all study activities. This amount depends on which group you are randomly assigned to. Please refer to the complete breakdown of payments below:

Surveys:

- Baseline: $40
- 16 weeks: $50
- 32 weeks: $50
- 48 weeks: $40
- Total = $180

Home-Collected HIV Test Kits:

- Baseline, 16, 32, and 48 weeks: $40 x 4 = $160
- Tests mailed before their due date will get a $10 'Early Bird' bonus: $10 x 4 = $40
- Total = $200

Group A: Video-Counseling+App

Participants in Group A will receive 12 video-chat sessions and based on your HIV test, you may receive 12 more sessions OR continue with just using the WYZ app:

- Video-chat+app followed by Video-chat+app:
  - Weekly sessions for 24 weeks: $5/session x 24 = $120
  - Surveys (see breakdown above): $180
  - Home test kits (see breakdown above): $200
  - Monthly check-ins for weeks 36, 40, and 44 (3 x $10 each): $30
  - Total = $530
- Videochat+app followed by app alone:
  - Weekly sessions for 12 weeks: $5/session x 12 = $60
  - Surveys (see breakdown above): $180
  - Home test kits (see breakdown above): $200
  - Monthly check-ins for weeks 20, 24, 28, 36, 40, and 44 (6 x $10 each): $60
  - Total = $500
- Exit interview for participants who are selected: $50

Group B: Standard of Care (SOC)

Participants in Group B will just complete study surveys, home test kits, and monthly check-ins:

- Surveys (see breakdown above): $180
- Home test kits (see breakdown above): $200
- Monthly check-ins for weeks 4, 8, 12, 20, 24, 28, 36, 40, and 44 (9 x $10 each): $90
- Total = $470

Will I be reimbursed if I pay expenses related to my participation in this study?

You will not be reimbursed for expenses if you take part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Parya Saberi if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at 415-735-1507.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide the 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, depending on a number of factors. The University does 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.

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 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. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Who can answer my questions about the study?

You can contact the study team with any questions, concerns, or complaints you have about this study at 415-735-1507.

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 Institutional Review Board at 415-476-1814.

A description of this clinical trial is available at https://clinicaltrials.gov/study/NCT05877729, 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.

The National Clinical Trial (NCT) number for this study is NCT05877729 .

CONSENT

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

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

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