Approved
19-Mar-2021
Expires
14-Dec-2021

San Diego State University
INFORMED CONSENT FORM
Consent form version date: March 17, 2021

PrEP iT!: A Pilot Test of a Mobile Peer Support Intervention to Optimize PrEP Adherence and Retention in PrEP Care

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY:

We are inviting you to join this research study. The purpose of the research is to understand ways in which technology can be used to support young adults who are taking pre-exposure prophylaxis (PrEP) to prevent HIV infection.

We are asking people who join this study to attend 3 study visits (in-person or online via a teleconferencing platform such as Zoom) over a period of about 6 months. The study involves attending a study visit today, and in 3 months, and 6 months. You may also receive access to online information, activities, and resources related to PrEP during your time in the study.

We do not know if these activities would be helpful for managing PrEP, and it is possible that they could make it worse.

You do not have to join this study. You can choose to not join the study and your participation will not affect your access to PrEP or your current healthcare for PrEP. The reasons you may want to participate in this study are: 1) you may experience positive feelings about participating in a study that could lead to new ways to help persons like you manage PrEP and 2) you may learn new strategies for managing PrEP. The reasons you may not want to participate in the study are: 1) it may lead to emotional discomfort; 2) there is a small risk that someone could find out that you have sex with other men or that you are on PrEP; 3) we will ask you to provide a small amount of blood through a finger prick which may be slightly painful.

We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices you have. We will also give you any other information that you need to make an informed decision about joining this study.

The following information is a more complete description of the study. Please read this description carefully. We want you to ask us any questions that will help you decide whether you want to join this study. If you join the study, we will give you a signed copy of this form to keep for reference in the future.

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WHO SHOULD I CONTACT IF I HAVE QUESTIONS or Concerns?

Principal Investigator: Keith J. Horvath
SDSU Department: Psychology
Address: 5500 Campanile Drive; San Diego, CA 92182
Phone: 619-594-3346
Email: khorvath@sdsu.edu

Principal Investigator: Jason V. Baker
Institution: Hennepin Healthcare Research Institute (at Hennepin Healthcare)
Address: 701 Park Avenue (mail code G5); Minneapolis, MN 55415
Phone: 612-873-7678 (research program)
Email: Jason.baker@hcmed.org

WE ARE INVITING YOU TO JOIN THIS RESEARCH STUDY.

We are inviting you to participate in this research study because you have told us that you are on PrEP and identify as gay, bisexual or a man who has sex with men.

Up to 80 participants will be included in this study.

Research is not the same as treatment, or other medical or psychological care or therapy. The purpose of research is to answer scientific questions.

WHY ARE WE DOING THIS STUDY?

We are doing this study to find out if it is possible to provide men like you with access to online information, activities, and resources related to PrEP and, for those who agree to join the study, what they think about the website. We also want to know if men who are on PrEP find the online information, activities, and resources helpful for managing PrEP.

In the study we want to compare a group of men who are on PrEP and are provided access to a website with a group of men who are on PrEP but who are not provided access to the website. Persons who join the study have a 50% chance of being assigned to the website group and a 50% chance of being assigned to the no website group.

WHAT IS THE TIME COMMITMENT IF I JOIN THIS RESEARCH STUDY?

Your participation will last approximately 6 months. You will either come to the research office or teleconference with research staff via Zoom for three (3) study visits about 3 months apart. Each visit will last about two hours. In addition, if you are randomly assigned to the website group, you will be asked to use the website during the 6 months. The amount you use the website is up to you.

The research scientist could stop your participation in the research study at any time even if you want to still be in the study. This would happen if:

- They think it is in your best interest to stop being in the study.
- You are not willing or able to do all the things needed in the study.
- The whole study stops.

If you stop being in the study, your information collected before you stopped being in the study will be included in the study unless you request that your data be removed. You may request in writing by email or calling the study Principal Investigator.

WHAT WILL I BE ASKED TO DO IN THIS RESEARCH STUDY?

If you choose to be in the study, you will be asked to sign this consent form before you begin the study. This initial visit will last about 120 minutes.

Study staff will collect information from your medical record chart beginning from the time you enroll in the study until the end of your study participation. We will ask you to sign a medical records release form to collect information from the clinic in which you receive your PrEP care. The study staff will collect information such as clinic visits, medical diagnoses, medication use, and laboratory results related to your PrEP care. This information will be protected in the same way the information from your medical record is protected. If you decide not to sign a medical records release form, you can still participate in this study.

After you have provided your consent, you will give the study staff a list of ways to contact you, such as your e-mail address and phone number, as well as the phone number of a relative or friend who knows how to get in contact with you. Study staff will not leave phone messages unless you give permission. The study staff will also not tell your relative or friend anything about this study, your participation in the study, or give any information about you unless you give permission. Your contact information will be used to remind you to come in for your study visits and to help you with transportation to your study visits, if needed. You also can choose not to give any information that you do not want to give. However, you will need to provide a working email in order to use the website resources, and provide a form of communication (for example, your telephone number) in order for us to communicate with you during the study.

The following is the schedule of study visits and what will be done at each visit:

Today: 1st study visit

1. You will be asked to answer questions on a computer or a tablet by yourself in an assessment room (if in person). The survey will take about 35-45 minutes and we will ask you questions about PrEP, your attitudes and feelings about PrEP, substance use, internet use, and general information about yourself (race, ethnicity, income, education).
2. If you are randomly assigned to use the website (meaning you have a 50/50 chance, like flipping a coin, of being in this group), a study staff member will give you a unique username and password for the website, and take you on a brief tour of the website. You will have the opportunity to ask any questions about the website. Please use as many of the website features as possible. You may use the website on a computer, smart phone, or both.
3. If your first visit is in person, we will do a finger prick to collect several drops of blood. If your first visit is virtual, we will be mailing a self-collection kit that will be mailed to your home where you collect blood by pricking your finger, and then mailing the blood sample to a lab in a pre-paid mailer. Four to five drops of your blood will then be stored on a paper card until the end of the study, when it will be used to measure levels of medications that are used as PrEP. This is like getting poked with a needle and may cause discomfort.
4. You may be asked to provide additional blood draw to be stored for future research studies. This is optional and, if you agree, may result in discomfort.

About three months from today: 2nd study visit

1. You will be asked to answer questions on a computer or a tablet by yourself in an assessment room (if in person). The survey will take about 35-45 minutes and we will ask you questions about PrEP, your attitudes and feelings about PrEP, substance use, internet use, and general information about yourself (race, ethnicity, income, education).
2. If your visit is in person, we will do a finger prick to collect several drops of blood. If your visit is virtual, we will be mailing a self-collection kit that will be mailed to your home where you collect blood by pricking your finger, and then mailing the blood sample to a lab in a pre-paid mailer. Four to five drops of your blood will then be stored on a paper card until the end of the study, when it will be used to measure levels of medications that are used as PrEP. This is like getting poked with a needle and may cause discomfort.

About six months from today: 3rd study visit

1. You will be asked to answer questions on a computer or a tablet by yourself in an assessment room. The survey will take about 35-45 minutes and we will ask you questions about PrEP, your attitudes and feelings about PrEP, substance use, internet use, and general information about yourself (race, ethnicity, income, education).
2. If your visit is in person, we will do a finger prick to collect several drops of blood. If your visit is virtual, we will be mailing a self-collection kit that will be mailed to your home where you collect blood by pricking your finger, and then mailing the blood sample to a lab in a pre-paid mailer. Four to five drops of your blood will then be stored on a paper card until the end of the study, when it will be used to measure levels of medications that are used as PrEP. This is like getting poked with a needle and may cause discomfort.
3. You may be offered the opportunity to participate in a short optional interview with clinic study staff about your experience in the study for additional compensation. This interview may be recorded so the content discussed can be captured in detail for the study. The recording will be destroyed within one month of the interview.
4. You may be asked to provide additional blood draw to be stored for future research studies. This is optional and, if you agree, may result in discomfort.

You may be asked to complete a blood self-collection kit at some of the study visit time points (enrollment, 3 and 6 months), particularly for online study visits. You will receive $25 each time you return the kit (up to 3 times).

Some of your blood taken with the optional blood draw at the 1st and 3rd study visits may be stored. Your stored samples and the information collected about you during the study may be used by the study sponsor, its research partners or companies for additional testing of Tenofovir and metabolites. At the end of this study, these samples may be held in storage by Hennepin Healthcare Research Institute for up to 20 years. After 20 years, the samples will be destroyed. You can request that your samples be destroyed at any time by writing to the study doctor at the address listed on the first page of this form.

Additional Blood Specimen Collection Consent

1) Collect, store and use blood samples and data collected from the study for future research. I agree to allow my blood to be used for future research.

☐ Yes _____ *(initial)* ☐ No _____ *(initial)*

Signature of Participant Date

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WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

You may feel uncomfortable or embarrassed by providing information about yourself, including your PrEP use, drug use, or other information while answering surveys or speaking with research staff. You are free to provide as little or as much information as you like during the survey. If any of the topics on the survey make you uncomfortable or if you find something upsetting, you can stop at any time, and we can refer you to a counselor who may be able to help you.

The collection of a small amount of blood through a blood draw or finger prick may cause discomfort, bruising, or bleeding. Rarely people faint as a result of this procedure.

Potential risks of loss of confidentiality. There is some potential risk of disclosure of being on PrEP or other personal behaviors if someone sees the website on your phone, tablet, or computer. You will have a unique password-protected login to access the website and the connection will time out after a period of inactivity. The default text message is a generic text message that will serve as a weekly reminder, but will not contain any text about “medications,” “dose,” or “PrEP.”

There is a chance that some users could engage in hostile communication in comments on the website. We will post general rules for using the website. The website will be monitored daily by research staff. Comments that are considered hostile may be removed by study staff. Additionally, if participants continue to engage in hostile communication, they may be removed from the study.

We will make every effort to protect your confidentiality, but there is a small possibility that your name, PrEP use, or sexual orientation identity could become known to others.

We may discover new information during this research study. This new information my affect whether or not you want to still be in the study. We will tell you so that you can decide if you still want to be in the research.

ARE THERE ANY BENEFITS TO PARTICIPATION?

If you join the study, you may experience positive feelings about participating in a study that could lead to new ways to help persons like you manage PrEP. You may learn new strategies for managing PrEP. However, we cannot be certain that you will receive any benefits by being in this study.

AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION

Your privacy is important to us, and we want to protect it as much as possible. By signing this form, you authorize your Study Doctors, nurses and other research assistants at Hennepin Healthcare and San Diego State University to use and disclose information created or collected in the course of your participation in this research protocol. This information might be in different places, including your original medical record, but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

This information may be given to other researchers in this study, or to private entities such as academic research institutions, academic associated start-ups, and nonprofit companies. This information may also be given to state and/or federal government parties, or to regulatory authorities in the USA and other countries responsible for overseeing this research. These may include the Office for Human Research Protections, or

other offices within the Department of Health and Human Services, and the Office of Human Subject Research Committee at Hennepin Healthcare.

Any information that could be used to identify you will be treated in strict confidence to the extent allowed by law. Nevertheless, some uses and disclosures of your information are necessary to conduct the study. If you agree to be part of this study, you will also be allowing the uses and disclosures of your private health information as needed for the purposes of this study as described in this consent.

"Private health information" means information that identifies you and is collected:
- during this study;
- from your past and current medical records maintained by your regular health care providers (including, if applicable, HCMC), to the extent the information is relevant to this study or to your eligibility for this study; or
- from any payment records relating to items or services furnished to you during this study.

By signing this consent, you are agreeing that your private health information may be disclosed to and used by:
- the doctors and other health care providers involved in this study;
- their staff;
- the research center (Hennepin Healthcare Research Institute);
- members of the San Diego State University Human Subjects Research Committee/Institutional Review Board;
- research staff at San Diego State University;
- the sponsor of this study and its agents; and
- representatives from the United States Government and/or Food and Drug Administration (FDA).

The findings of this study may be used for scientific meetings, written reports, and publications, but no information that could be used to identify you will be disclosed for these purposes.

Private health identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from you

Once your private health information has been disclosed to a third party, federal privacy laws may no longer protect it from re-disclosure. However, anyone obtaining access to your private health information under this consent must agree to protect your information as required by this consent.

This consent to use your private health information as described above expires on December 31, 2023. However, if you later change your mind, you can revoke this consent by writing to Jason Baker, MD, MS saying that you no longer wish to allow your private health information to be used for this study. If you revoke your consent, you will no longer be able to participate in the study. Moreover, we cannot undo uses or disclosures of your private health information that have already taken place in reliance on your prior consent.

☐ **I authorize the release of HIV test results**

ARE THERE ANY ALTERNATIVES TO JOINING THIS RESEARCH STUDY?

There all no alternatives to joining this research study. However, you may choose not to participate in the research.

WILL MY INFORMATION BE PRIVATE?

Your participation in this study will be kept confidential and private as permitted by law. This includes information you provide on the survey, the audio recording of the interview, and anything you enter on the website.

Every effort will be taken to protect your identity as a participant in this study. You will not be identified by name in any study database, report or publication of this study or its results. Instead, you will be known only through a study ID number. Any data linking your name to your study ID number will be kept in a locked cabinet in a locked room at the study site, but separate from where your study records are stored. Staff members involved in this study are required to sign a form stating that they will protect and keep private all information on every person in the study.

We will keep your information private. No subjects will be identified in any report or publication about this study. However, there are things that the law does not allow us to keep private. If we think that a child or older person is being harmed, we are required to report any suspected harm to authorities. In some cases, your information in this research study could be reviewed by representatives of Hennepin Health Research Institute, San Diego State University, research sponsors, or government agencies for purposes such as quality control or safety.

At the end of the study, the electronic information from the study will be coded and stored on secure servers at the participating sites: San Diego State University, San Diego, CA and the Hennepin Healthcare Research Institute, Minneapolis MN. None of this study database information will identify you by name.

A description of this study will be available on http://clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can access this website at any time.

To help further protect your privacy, we have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). It adds special protection for research information that identifies you. It says that we do not have to identify you, even under a court order or subpoena. 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. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. This Certificate does not mean the government approves or disapproves of our project. You should understand that 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 assent/consent to receive research information, then the researchers may not use the Certificate to withhold that information.

In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and San Diego State University may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This means that they

will not tell others information about you or that you are in the study. De-identified information will be shared with the sponsoring agency at the NIH without obtaining additional informed consent. By signing this form, you are allowing such access.

Any paper research records will be stored in a locked office in a locked file cabinet and will only be accessible to research staff listed on the first page of this consent form. All electronic data will be encrypted and stored on a password-protected computer behind a firewall to ensure access is provided only to those involved directly in data collection or analysis.

At the end of the study, the identifying information (participants' names and contact information) is destroyed. The original data records will be archived for 7 years, and three copies of the de-identified dataset will be maintained (one working copy and two archived at different sites).

Data on what features of the website that participants in this study use will be collected and housed on physical servers residing in a secure facility that is audited to SOC3 SSAE-16 standards. The website databases and application will reside in a single tenant "private cloud" under the exclusive control of our partner, Radiant Digital. The website databases and application will be logically segmented in virtual private servers, ensuring that data may not be accessed by applications outside this project. To promote confidentiality of participant data, each participant will be assigned a study PIN login to the program during the evaluation. Users will access the system via this study PIN and an associated user-selected password. All communication between the app and server-side systems will be conducted using secure methods (e.g., SSL). All server-side systems will utilize a database-level encryption scheme to store data. No data will be collected or stored on any individual participant devices.

Your private information and bio-specimen(s) collected as part of this research study will not be used or distributed for future research studies or used for commercial profit.

The exit interview may be recorded so the content discussed can be captured in detail for the study. The recording will be destroyed within one month after the interview once the information is collected. You will only be identified on written information from the interview with a unique study ID number. The information from the recordings will not be used for any other purposes outside of this research study.

We will use the information we learn to for published articles or for presentations to other scientists. We will keep your information private. Others will not be able to identify you in those papers or presentations.

WHAT WILL HAPPEN IF I AM HURT OR INJURED WHILE I AM IN THE STUDY?

If any injury arises as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization because of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. San Diego State University, San Diego State University Research Foundation, and Hennepin Health will not pay for any care, lost wages, or provide other financial compensation. However, if you feel you have a claim that you wish to file against the State or the Foundation, please contact Graduate and Research Affairs - Division of Research Administration at (619) 594-6622 to obtain the appropriate claim forms.

DO I HAVE TO JOIN THIS STUDY?

No, you do not have to join this research study. Even if you agree to join, you can decide later that you do not want to be in the research. If you choose not to join or later decide that you do not want to be in the study, there is no penalty or loss of benefits to which you are otherwise entitled.

WILL I BE TOLD ABOUT THE RESEARCH RESULTS?

If you choose to be informed, we will contact you with results of this study after the study is completed.

WILL IT COST ME ANYTHING If I Join the Research?

There are no costs if you choose to join the research study.

WILL I BE PAID IF I JOIN THE RESEARCH?

You will be compensated the following for each study activity to help cover the cost of your time:

- Enrollment visit: $50 gift card
- 3-month visit: $50 gift card
- 5-month visit: $50 gift card

If you complete all of the study activities listed above, you will receive a total of $150 in gift cards.

If you are asked to complete a blood spot self-collection kit at study time points (enrollment, 3, and 6 months), you will receive $25 each time you return the kit (up to 3 times). This would be in addition to the study visit compensation amounts listed above for a total of up to $225 for completing all study activities and blood spots.

If you are asked to participate in an online interview during the 6-month visit and choose to do so, you will receive an additional $25 gift card incentive.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions now, please ask. If you have questions later about the research, you may contact Dr. Keith Horvath at 619-595-3346. If you have any questions about your rights as a research participant, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@sdsu.edu). At any time during the research, you can contact the IRB for questions about research rights, to discuss problems, concerns, give suggestions, or to offer input.

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CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The IRB must review the consent form yearly. The IRB approval expires on the date indicated by the stamp in the upper right-hand corner of this document.

Your signature below indicates that the study team has explained the study to you and you have read the information in this form. You have had a chance to ask any questions you have about the research. By signing this form, you are agreeing to join the study. You have been told that you can change your mind and stop participating in the research at any time. The researcher or a member of his/her research team has provided you with a copy of this consent form. This form includes contact information about who to contact if you have questions.

The researcher or member or his/her research team has provided you with a copy of this consent form and the Authorization to Disclose Protected Health Information.

Name of Participant (please print) Date

Signature of Participant Date

Signature of Research Study Staff Date