Optimizing PrEP Adherence for YMSM through the Exploration of Facilitators and Barriers and by the Provision of a Culturally-Tailored Peer Navigation Program

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INTRODUCTION

We are doing this research study to learn more about the barriers that young men who have sex with men (YMSM) face when accessing and adhering to pre-exposure prophylaxis (PrEP). We also want to learn about things that make adhering to PrEP easier for YMSM. New HIV infections occur at a disproportionately high rate among YMSM. HIV incidence rates among YMSM are among the highest of any subpopulation in the United States. Oral pre-exposure prophylaxis (PrEP) can reduce HIV acquisition among MSM when patients take their PrEP medication and increasing the effective use of PrEP among YMSM is an important goal in HIV prevention.

We know from previous PrEP studies that YMSM may have unique needs when it comes to deciding to start PrEP, accessing PrEP after it has been prescribed. We also know that YMSM need help using it correctly to ensure the maximum level of protection against HIV. We are interested in whether or not the use of peer health system navigators can help with these unique needs. Navigators are healthcare workers who are trained to support adherence and retention in care for individuals.

To learn more about how helpful a peer navigator might be, we will ask participants of this study to work with a peer navigator and come into the clinic for three visits.

We are asking you to participate because you have identified as being YMSM, you are between the ages of 15 and 24 years old, and you started to take Truvada as PrEP within the past week. We plan to enroll 20 people in this study.

This study is being funded by the National Institutes of Health and the Harvard Center for AIDS Research.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY

You are being asked to participate in a research study. It is important that you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or anytime during the study.
- If you join the study, you can change your mind later and quit the study at any time.
- If you decide to quit the study, it will not affect the care you receive at Fenway Health.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study.
- How the study may help you or others.
- Any risks you may face while participating in this study.
- What is expected of you during the study.

Once you understand the study, and if you decide to take part, you will be asked to sign this consent form, and you will be given a copy of it to keep. This process is called informed consent.

This consent form gives you information you will need to help you decide if you want to be in the study. It will tell you the purpose of the study, what you will be asked to do in this study, the possible risks and benefits, and your rights as a volunteer. We want you to ask any questions you may have about this study. When all of your questions are answered, you can decide if you want to be in the study. This process is called "informed consent." Once you understand the study and have all your questions answered, you

will be asked to sign this consent form if you want to be in the study. You will be given a copy of the signed consent form to keep.

DO I HAVE TO JOIN THIS STUDY?

Your participation in this study is completely voluntary. You get to decide if you want to be in this study or not. Your decision will not change your usual health care or your relationship with any staff at Fenway Health. If you join the study, you can decide to stop at any time.

WHAT IS THIS STUDY ABOUT?

People who join this study will work with a peer navigator from Fenway Health and will come into the clinic for two or three study visits, depending on when you join the study.

The information given in the interviews will be used to better understand:

- Do YMSM on PrEP find working with a navigator to be helpful?
- What makes it difficult for YMSM to obtain and adhere to PrEP?
- What types of barriers to adherence can a navigator help a young person overcome?

HOW LONG WILL THE STUDY LAST?

This study lasts 3-6 months. Depending on the date you join, you will be in the study either 3 months or 6 months. This means that you will either have 2 or 3 study visits.

WHAT WILL I HAVE TO DO IN THE STUDY?

Baseline Visit (2-2.5 hours):

- We will ask for your address and contact information so that the study staff will be able to get in touch with you. This information will be stored under double locks, separate from all other study records and only the study staff will have access to it.
- You will complete an interview on a computer in private which will take about 45 minutes to complete. You will enter your answer right into the computer. When the interview is complete, the computer "locks in" your information and no one at the clinic will look at your answers in real-time. The interview will ask you to give some information about your thoughts and feelings, health status, substance use, sexual activity, and relationships. You will also be asked about PrEP to find out how much you know about it and your feelings about it. You will not be asked your name, phone number, birth date, address, social security number or any other information that could identify you. Some of the questions may be very personal, such as questions about sexual activity, substance use, and about if you have a history of sexual or physical trauma. You do not have to answer any question that you do not want to, and you can end the interview at any time if you do not want to continue. However, we hope that you will answer all the questions because we can learn much more about young men like yourself if all the questions are completed.
- You will complete an assessment with the peer navigator to talk about any PrEP adherence-related needs that you have.

Follow-Up Visits (3 months and in some cases, 6 months) (about 2 hours)

- You will complete another computer interview. The interview is similar to the one you completed at the Baseline visit except there will be additional questions asking about how your behaviors and beliefs may have changed since you started the study. The interview will include questions on beliefs related to HIV risk, sexual behaviors, STIs, drug and alcohol use, and reasons for missed medications. It will also ask questions on how well you like the peer navigator program.

- Blood (less than ¼ teaspoon) will be drawn to test the medication levels in your body to check on how often you are taking the PrEP drug. This test will not be performed in "real-time" and study staff will not know the result until after the study is done.

- You will complete a 30 minute interview with a study staff member (not the navigator). This interview will be audio recorded. We hope to learn about how you feel about the navigator program and if you find it helpful. We also want to know what would make it more helpful.

At the end of your time in the study, we plan to collect information about your healthcare from your medical record. Study staff will gather information about appointments, medical tests and treatments, vaccinations, and laboratory tests related to PrEP that you may have had while in the study.

WHAT ARE SOME POSSIBLE RISKS?

The blood draws needed for the lab tests may cause discomfort, bleeding, or bruising where the needle enters the body. A small clot may form and there may be some swelling where the needle enters the vein. There is a small risk of minor infection occurring at the blood draw site. In rare cases, lightheadedness and fainting may occur.

There is some risk that answering questions about some of the topics may be uncomfortable or upsetting. If it is, there are counselors at Fenway Health with whom you can talk. You do not have to answer any questions that you do not want to answer. You may stop at any point if you do not wish to continue with the interview.
We will make every effort to protect your confidentiality, but there is a small possibility that your name and test results could become known to others. You may experience stigma or discrimination as a result of being involved in an HIV prevention study. People may make assumptions about your sexual behavior.

If you are injured as a result of being in this research study, the cost of treatment will be charged to your insurance company. In such a situation it is possible that your parents or legal guardian may find out about your participation in this study.

The study staff members are trained to counsel you on these issues and can provide you with support. The study staff can put you in contact with many different types of services which may help you. If you decide you want to tell your friends and family about the study, we can help you figure out the best way to talk about it. We will talk to you about how to protect your confidentiality at every visit.

WHAT ARE THE BENEFITS TO ME?

There are no direct benefits from being in the study. However, we hope that the information from this study will help the research team to develop programs that will help make accessing PrEP easier for YMSM. We also hope that what we learn will help develop peer-navigator programs that make YMSM remember to take their PrEP correctly for optimal protection against HIV.

ARE THERE ANY COSTS TO ME FOR TAKING PART IN THIS STUDY?

You will not be charged for anything that is done for the study. You or your insurance company will pay for any medical care that is not part of this study. We can't promise that the risks we told you about or other unknown problems will not happen. There will be counselors for you to talk to if you get upset during the interview. However, this study will not pay for the cost of these services. Any other care or treatment after the study is over will be charged to you or your health insurance company as would be done for your regular health care.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY (WHAT OTHER CHOICES DO I HAVE)?

You may choose not to join this study or if you do join, stop participating at any time.

CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- If you received care at Fenway Health you will continue to receive your regular medical care at Fenway Health if you leave the study early.
- If you leave the study early, The Fenway Institute may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

WHAT IF NEW FINDINGS DEVELOP DURING THE COURSE OF THE STUDY?

If we learn anything during the study that might change your mind about being in it, we will tell you as soon as possible.

ARE THERE ANY REASONS WHY I MAY BE ASKED TO STOP TAKING PART IN THE STUDY?

- The staff sees that you are drunk or high when it is time to do the computer interview or the face-to-face interview. If this occurs, they may ask you to return another day when you are not drunk or high; or
- You seem to become very upset or angry while doing the face-to-face interview. If this occurs, you may be able to return at a later date to complete the interviews if the study staff member feels it is safe for you to do so. You may be asked if you want to talk to a counselor.
- The study is stopped by the Harvard Center for AIDS Research (CFAR) the government agency sponsoring this study, or by the Institutional Review Board (IRB) at The Fenway Institute. An IRB is a committee that watches over the safety and rights of research subjects.

- The study has to be stopped for other administrative reasons.

WHAT WILL I GET FOR TAKING PART IN THIS STUDY?

You will be given a $50.00 gift card for completing each study visit. You will not be compensated for meeting with your navigator in-between study visits.

HOW WILL MY PRIVACY BE PROTECTED?

Your participation in this study will be kept confidential (private) as permitted by law. This includes the information collected from the face-to-face interview, and the questions we asked before you are enrolled in the study. You will be assigned a unique code number that will be used for the face-to-face interview and all study forms. The list that links your name with your code number will be kept in a password protected document on the server separate from research files at the research site. Staff members involved in conducting this study are required to sign a form stating that they will protect participant information.

Information about the study may be published in a scientific magazine or presented at a scientific meeting or used by other researchers, but names or other personal information will never be used.

Every effort will be made to keep your participation and the personal information of your research record private and confidential, but absolute confidentiality cannot be guaranteed. For example, if the study staff learn something that would immediately put you or others in danger, the researchers are required by law to take steps to keep you and others safe. This means that they will have to report to the authorities (hospital, police, or social services) any information you provide that suggests that you might be in danger, such as if you tell us that you plan to hurt or kill yourself, hurt or kill someone else, or if you tell us that someone is abusing or neglecting you.

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Fenway Health involved in this study
- Medical staff at Fenway Health directly involved in your care that is related to the research or arises from it.
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital.
- People at Fenway Health who oversee and evaluate research and care. This includes the Fenway Health Institutional Review Board.
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities
- People or groups that are hired to provide services related to this research or research at Fenway Health, including services providers, such as laboratories, and others

- Your health insurer for portions of the research and related care that are considered billable.
- Public health and safety officials (for instance, if we learn information that could mean harm to you or others, we may need to report this, as required by law.

The main reasons why we may share this information include:

- To conduct the study as described to you in this informed consent.
- To make sure the study meets all legal and organizational requirements.
- To monitor the safety of participants in the study.

We will use and disclose your protected information only as described in this form; however, people outside Fenway Health who receive your information may not be covered by this promise. We will try to ensure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

A description of this clinical trial will be available on 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.

CERTIFICATE OF CONFIDENTIALITY

To help further protect your privacy, the Fenway Institute has applied for a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this Certificate in place, the investigators cannot be forced (for example by court subpoena) to turn over research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. But, as mentioned above, your record may be reviewed by the NIH to make sure that the study is being conducted the way it is supposed to.

You should understand that a Confidentiality Certificate does not prevent you from releasing information about your involvement in this research if you want to. This means that if someone (like an insurer or employer) finds out about your research specimens or research information, asks you for it and you say it is okay for them to have it, then the researchers here cannot use the Certificate to keep your information private. Your research information would have to be turned over. This means that you must also actively protect your own privacy. You have to be careful about who you permit to look at your research information.

WHAT HAPPENS IF I AM INJURED?

It is not expected that you will experience any physical injury by being in this research study. If you are injured as a result of being in this research study, you will receive immediate, short-term treatment for the injury. The cost of the treatment will be charged to you or your insurance company, as would normally be done for your medical care. You will then be told where you could receive additional treatment for

injuries. Your insurance carrier may or may not pay for treatments for injuries that are caused by taking part in this study. Fenway Health does not have a policy to offer monetary compensation (payment to you) or other forms of compensation for such injuries.

WHO DO I CONTACT IF I HAVE PROBLEMS OR QUESTIONS ABOUT THE STUDY?

The person in charge of this study at The Fenway Institute is Dr. Douglas Krakower. The Project Manager is Julian Dormitzer. If you ever have questions about this study, or you get a research-related injury, you may call Doug Krakower at 617-927-6440 and/or Julian Dormitzer at 617-927-6309. In addition, if you have any questions about your rights as a research participant, you may call Amy Ben-Arieh, Manager of Research Integrity and Compliance 617-927-6031.

STATEMENT OF CONSENT

The purpose of this research study, what you will be asked to do, and the risks and benefits of the study have been explained to you. You have been given the time to ask any questions you might have about this study. You have been told that participation in this study is voluntary. You may be a participant in it only if you wish, and you may refuse to participate or may stop participating at any time without affecting your future treatment at this hospital/clinic, or your future relations with the hospital or its employees.

By signing this consent document, you are agreeing to take part in the study described to you. You will be given a copy of this signed consent form to keep.

Subject's Name (print)	Subject's Signature	Date	Time

PI or Designee's statement:

I have reviewed this study and the consent form with the subject. To the best of my knowledge, he/she understands the purpose, procedures, risks, and benefits of the study.

PI or Designee's Name (print)	PI or Designee's Signature	Date	Time