Making it last: A randomized, controlled trial of a home care system to promote persistence in PrEP care

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Making it last: A randomized, controlled trial of a home care system to promote persistence in PrEP care (PrEP@Home)

Principal Investigators: [redacted], PhD and [redacted], MD

Sponsor: National Institute of Health (NIH), National Institute of Mental Health

Sites: Emory University (Atlanta, GA), Fenway Health (Boston, MA), Washington University St. Louis (St. Louis, MO), and University of Mississippi Medical Center (Jackson, MS)

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can request a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

A description of this clinical trial 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 is the purpose of this study?

The purpose of this study is to understand the acceptability of maintaining pre-exposure prophylaxis (PrEP) care for HIV prevention through a home care system for PrEP, PrEP@Home. This involves having all the medical specimen collections and doctor visits for PrEP follow-up care to be done in your home rather than at a doctor's office.

What will I be asked to do?

Participant procedures:
You will be asked to participate in a randomized control trial and download the PrEP@Home application to your smartphone. Randomization means that you will randomly be placed into one of two groups. One group will continue with the standard of care and the other group will have a home-based specimen collection kit and telemedicine visits with a study clinician. The duration of the study is 6 or 12 months.

Initial Procedures: Study staff will contact you to review the consent and confirm eligibility. You will then have an initial visit with study clinician either in-person at the study clinic or via telehealth over Zoom. Specimen samples will be collected to verify that you are eligible to take PrEP. This specimen collection can be done either in-person at the clinic or laboratory or through self-collected home test kit. In-person or telehealth visits will be determined based on current public health guidance as well as participant preference. If after the initial visit you are still interested and eligible to receive a PrEP prescription, you will be contacted by study staff regarding your lab results and PrEP prescription. Through the app, you will upload an image of your prescription once you have picked it up from your pharmacy.

Once you send a confirmation that you picked up your prescription you will be enrolled in the study. You will then be randomly placed by a computer program into one of two groups. One group will continue to have quarterly visits with their provider and fill out electronic surveys. The second group will collect home specimens, fill out electronic surveys, and will have a "virtual" doctor's visit, using video-chat to talk with a study doctor.

Follow-up Procedures: The group that is randomized to the home specimen collection and telemedicine visits will do the following procedures every 3 months for either 6 months or one year. If you were enrolled prior to May 2022 you will have one year of follow-up and if you were enrolled after May 2022 you will have 6 months of follow-up). Using the home specimen kit will include collecting a rectal swab sample, a throat swab sample, a urine sample, and finger prick blood samples. Rectal swab collection will involve inserting the tip of a swab about one and a half inches to collect a sample. Throat swab collection will involve using a swab to reach the rear area of your throat, collecting a sample with the swab tip. Urine sample collection will involve urinating in a cup and transferring urine with a pipette from the cup to the sample tube. You will receive detailed printed instructions regarding how to collect each of these samples.

Home Specimen Collection: You will also receive printed and video instructions in self-administered finger prick blood draw methods. You will conduct 1-2 self-administered finger pricks, similar to the practice someone with diabetes might follow on a regular basis. Although this is a smaller needle than used for a traditional blood draw, you may experience more or less pain from it. The finger prick device is spring-loaded and encased in a plastic shell, so you will not see or manipulate the needle. Following the finger pricks, you will collect blood by blotting your finger on collection paper and by using a collection tube. This will be a small amount of blood, about 6 drops total. If the sight of blood makes you feel light-headed, or if at any point you feel uncomfortable or wish to stop participating, please immediately notify study staff. You will be provided with a 24/7 call-in line to receive help with any unexpected problems. Collecting the specimens will take you at most one hour. If you have a positive test for HIV or an STI, state law requires us to report that positive test to the state health department for purposes of statistics and service planning. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

After collecting the samples, you will mail them to a certified laboratory in a prepaid mailer included in the kit. Your samples will be used to conduct tests conducted in a typical PrEP visit: STI testing for gonorrhea, chlamydia, syphilis, and HIV, and creatinine to test kidney function. We will share these results with the study doctor to inform your "virtual" visit. We will not sell your samples. Your test results will be returned by study staff or the study doctor. If you agree, your samples and health information will be stored and available to help answer research questions, such as research to understand certain diseases, or to develop new scientific methods.

Our syphilis test is performed with a standard syphilis test and determines a preliminary positive result. It does not provide detailed results like a similar test from a doctor's office or health department. Therefore, if you test preliminary positive for syphilis, we will recommend that you seek additional testing from either your doctor or health department.

You will also be asked to complete an electronic survey with questions similar to those doctors usually ask of PrEP patients. Your answers to these questions will be shared with the study doctor. There will be a section of the survey that includes questions about your experience using ePrEP and other research.

Since PrEP is recommended in combination with safer sex practices, you will also be encouraged to practice condom-protected sex throughout the duration of your participation in the study and at all times that you are on PrEP.

For participants that are randomized into the group that will continue with the PrEP standard of care, study staff will link you to a local PrEP provider. You will still have to download the study app to complete electronic surveys at 3, 6, (and 9, and 12 for those enrolled prior to May 2022) months after picking up your PrEP prescription. The surveys will take you approximately 45 minutes to complete. Your local provider visits and labs will be in-person and not through the study. However, staff will link you to care that is at low or no cost. At 6 months (and 12 months for those enrolled prior to May 2022) you will be asked to complete a Dried Blood Spot card, which will be mailed to you. You will complete the specimen collection and send it back to the lab in a prepaid return mailed that will be included in the specimen collection kit. You will incur no costs. Filling it out the DBS card will take you approximately 15 minutes, however, it needs to dry 4 hours before being sent back to the lab.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy of your choice. If you have questions about PrEP, you should ask the principal investigator, study doctor or study staff. You may also call the pharmacy if you have questions about the medicine.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. If you withdraw from the study and would like your data not to be used and your samples to be destroyed, inform the study staff.

What are the possible risks and discomforts?
There are minor risks associated with this study. You may experience physical discomfort from the self-administered specimen collection, including the finger prick, rectal swab, and throat swab. You may also experience bruising around the site of the finger prick. You may find out that you are infected with HIV or another STI. This might upset you. If you are infected with HIV or another STI, we will help you find a doctor. For HIV, we will also provide you with additional lab tests to help you get into care.

Some of the questions in the surveys are personal and may make you uncomfortable. We hope you will answer all questions to the best of your ability. You can choose not to answer any question that makes you uncomfortable. We will keep information about your HIV and STI testing, and your responses to the survey questions. Although we will take steps to reduce the chance, there is a small chance that someone other than study staff might see your study information. More information about how we will protect your confidentiality is below.

There are risks associated with taking PrEP that would be the same if you took PrEP outside of the study. The study provider will discuss with you about the most common risks and discomforts associated with PrEP are: nausea, headache, and flatulence. These side effects are uncommon and usually resolved within the first month of taking PrEP. The less common risks and discomforts associated with PrEP are: decrease in bone mineral density, moderately decreased renal function. Rare but possible risks include: acute renal injury. We will monitor your creatinine levels to decrease any potential risks related to renal function.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

You will be tested for HIV and STIs and be linked to treatment if necessary. You will have a lower chance of acquiring HIV if you take PrEP as directed. The study results may be used to help others in the future, if the information we learn helps improve HIV and STI prevention services.

Will I be compensated for my time and effort?

You will receive a $125 incentive for completing all initial procedures ($25 for the initial visit/survey, $75 for completing labs, and $25 for prescription image upload). You will receive $10 for completing a month 1 survey, $25 for quarterly survey completion, and $75 for DBS collection. If you complete all study visits, you will receive an additional $50 at the end of study. If you were enrolled after May 2022 and you complete all study activities, you will also receive an additional $125. If you do not finish the study, we will compensate you only for the visits, kits and surveys you have completed.

You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, there are HIV testing, STI testing, and PrEP available to you outside of this research study. The study staff will discuss the other options with you. You do not have to be in this study to receive HIV testing, STI testing or PrEP. Taking part in this study, however, may make you unable to participate in some other research studies if they exclude people who currently taking PrEP. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Any information about you obtained from this research will be kept as confidential as possible.
Your personal information may be disclosed if required by law. Any publication of this study's results will not use your name or identify you personally in any way. The study staff may use your personal information to verify that you are not in any other research studies. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. Your records may be reviewed by:

- Study monitors
- Study staff
- Emory University employees
- The Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care. If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs. If you believe you have become ill or injured from this research, you should contact Dr. [redacted] at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

Participation: There will be no costs to you for participating in this study, other than basic expenses like transportation to the post office for mailing specimens. You will not be charged for any of the research activities, including the postage costs of mailing the specimens you provide.

PrEP medication: If you have health insurance, we will assist you in accessing PrEP coverage through your insurance and also accessing copayment assistance programs. If you do not have health insurance, we will help you enroll in drug access assistance programs. However, the study does not pay for medication costs that are not covered by insurance or assistance programs. We will work with you to refer you to services that are at low or no cost and make sure you are aware of any out-of-pocket costs before accessing PrEP.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to go off PrEP. If you leave the study before the final planned study visit, the researchers may follow up with you on completing final study procedures. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you, including your medical history and present/past medications
- Results of exams, procedures and tests you have before and during the study
- Laboratory test results
- Behavioral survey results

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.

- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration; Veterans Administration].
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Rollins School of Public Health, Emory University, [redacted], [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [redacted] at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Future Storage

I voluntarily agree that my blood and information can be stored. I understand it may be used in future research to learn about, prevent, or treat health problems.
In addition, I have made the optional choice marked below. I know that I can take still take part in the study, even if I answer 'no' to this option.

☐ Yes, I give permission to have my samples stored for future use.

☐ No, I do NOT give permission to have my samples stored for future use.

Consent and Authorization

Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the survey at any time.

If you agree to the above information and would like to be in the study, please sign your name using mouse or touch pad, and then type in your name below. *

I understand that checking this box constitutes a legal signature confirming that I have read the consent form, and agree to participate in the PrEP@Home study. *

○ Legally sign document

○ Do NOT legally sign document