Official Title: eTest: Real-time, Remote Monitoring System for Home-based HIV Testing Among High-risk Men Who Have Sex With Men

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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

eTEST Study
Version 4, 08/04/2021

KEY INFORMATION:
You are invited to take part in a research study. Your participation is voluntary.

- PURPOSE: The study explores different ways of helping people test for HIV.
- PROCEDURES: You will be randomly assigned, like the roll of a die, to one of three groups. Depending on which group you are in, you will be asked to either receive text messages reminding you to get tested, HIV tests you can do at home, or you may receive HIV tests you can do at home, be asked to download a study app on your smartphone, and receive calls from a counselor. You will be asked to complete online surveys about every 3 months. In these surveys, you will be asked about any testing you may have had done recently and given the option to upload testing results. At the end of the study you will be asked to come to a specific clinic in your area to get a free HIV test.
- TIME INVOLVED: You will be involved in this study for 12 months.
- COMPENSATION: You will receive up to $250 for your time.
- RISKS: If you test for HIV at home, you may feel uncomfortable while waiting for your results and/or if your results are "reactive." While very rare, you may also receive a "false positive" result, or a "reactive" result when you do not have HIV. There is a chance that this data, which includes personal health information, could be disclosed to unauthorized people. Some of the clinics we refer you to may ask you to show a government-issued ID when you check in. In many of these clinics, you can still get care if you do not show your ID. You are also free to choose a different clinic yourself or to not receive these services. If you go to a clinic and you are an undocumented resident of the United States, you should know your rights. The following webpage provides information about your rights in health care facilities: https://www.brown.edu/research/immigration-enforcement.
- BENEFITS: You will not receive any direct benefits for participating in this research study.

1. Researcher(s):

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Site Principal Investigator(s): Jeffrey Klausner, M.D. (Los Angeles, California); Lori Ward, PhD (Jackson, Mississippi)
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2. What is this study about?
The purpose of this research is to explore different ways of helping people test for HIV. In this study, we will either send you an HIV test you can do at home or text messages reminding you to get tested in a clinic every three months for a year. If you are chosen to receive home tests, you

may receive test kits that have a small sensor in them that detects when you use the test. If you are in this group, a counselor will call you within 24 hours of when you use the test to answer any questions and provide you with any information you ask for. Whether you receive home tests (with or without the sensor) or text messages will be decided using a process that is like rolling a die. No matter what you receive, it is your choice to test for HIV or not.

3. What will I be asked to do?

During this year-long study, we will either send you HIV tests you can do at home or send you text messages reminding you to get tested. If you are chosen to receive home tests, you may receive test kits that have a small sensor in them that detects when you use the test. If you are picked to receive these kits, a counselor will call you within 24 hours of when you use the test to answer any questions and provide you with any information you ask for. You may be asked to send a picture of your at-home test results to eTest study staff. No matter what you receive, it is your choice to test for HIV, talk to a counselor, or send a picture of your results.

You may be asked to download a study app and keep it on your smartphone throughout the time you are involved in the year-long study. About every three months during this time, you will be asked to complete an online survey (for a total of five). Each of these takes about 45 minutes to do. We will send you an email each time this survey is due with a link that you can click in order to complete it. If you forget to do it, we will send you reminder emails each day for five days. If you do not do the survey within five days, a staff member will call you to encourage you to do it. In these surveys you will be asked about any recent testing you have had, and given the opportunity to upload a photo or screenshot of any testing results you may have received. You will also be asked about co-enrollment in other research studies. If you report enrollment in another study, you may be contacted for more information and/or withdrawn from the eTest study if it seems that the other study is in conflict with the outcomes of the eTest study. At the end the study, you will also be asked to come to a specific clinic in your area to get a free HIV test. A staff member will call you about two weeks before the study is over to schedule an appointment for you.

This study will have 3 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like rolling a die. You will not know which group you are in. The researchers *will* know. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. However, we can give this information out if you have a medical emergency.
Follow-up phone calls and closing interviews may be recorded.

4. Will I be paid?

You will receive $25 for the baseline survey and each of the five online surveys that you complete, with a $50 bonus for completing all within 5 days of being due. You will also receive $50 for completing the in-person HIV test after the study is finished, for a possible total of $250. You will be paid via a reloadable debit card that you will receive in the mail after you join the study. If you leave the study early, or if we have to take you out of the study, you will only be paid for the surveys you completed.

5. What are the risks?

If you are picked to receive home HIV tests in the mail, we will send you test kits that have been approved by the United States' Food and Drug Administration for over-the-counter sale to anyone in the US (OraSure's OraQuick® Rapid In-Home HIV Test). This test uses a mouth swab and gives you results in about 20 minutes. The test kit provides detailed instructions about how to use the test, as well as a free 1-800 number you can call with questions.

Although FDA approval of the test suggests it is safe for most people to use, it is possible that you may feel uncomfortable while waiting for your results and/or if your results are "reactive". "Reactive" results mean that that test has found antibodies to the HIV virus in your saliva. While the test is also very accurate, there is a chance you may get a "false positive" result, or a "reactive" (preliminary positive) result when you do not actually have HIV**. For this reason, if your home test results are "reactive," you should not consider it positive for HIV until you have another test at a clinic to confirm it, but it is important to get this test as soon as possible. This confirmatory test is does not have a cost associated. If you get a "reactive" result from a home test, or think you may be in crisis, call the eTEST study counselors 24-hours a day (at 401-863-9424) or OraSure's 24-hour helpline (at 1-800-436-6527). The staff at these numbers will help you make an appointment for another free test at a clinic in your area and/or connect you with any other resources you might need.** Information cards included in each test kit also have a section entitled, "What should I do if my OraQuick® test result is "reactive?" that provides the above instructions and contact information, if you need it later.

As part of this study, we will encourage you to receive various sexual health services (for example, HIV testing, testing for STDs) from local clinics. Most clinics listed as referrals offer free services, but some may charge for service use. Some of these clinics may also ask you to show a government-issued ID when you check in. In many of these clinics, you can still get care if you do not show your ID, but you are also free to choose the clinic yourself or to not receive these services. If you are an undocumented resident of the United States, it is against the law for anyone at these clinics to release information about you to immigration officials. If you go to a clinic and you are an undocumented resident of the United States, you should know your rights. The following webpage provides information about your rights in health care facilities: https://www.brown.edu/research/immigration-enforcement.

Finally, while we take many steps to keep the data we collect from you confidential and safe (see *7. How will my information be protected?*), there is always a risk that this information could be seen by others who are not supposed to see it. To make sure your information is safe, fill out the online surveys in a private place where others cannot see your answers, and make sure you close your internet browser when you are done. If you are picked to get home HIV tests, make sure to do the tests somewhere private and throw the test strip away in the privacy bag provided in your kit.

6. What are the benefits?

You may not benefit from being in this study yourself. However, we hope that the results of this study will help us find better ways to make sure people get regularly tested for HIV in the future. This study is not designed to treat any illness or to improve your health.

7. How will my information be protected?
The information you provide us while you are in this study, including your personal health information, will be confidential, meaning that only study staff and others you authorize will be able to see it. To help keep your information confidential, all of the information we collect from you will be stored in secure files and protected with passwords that only important study staff members know. A study ID number will be paired with your answers to survey questions during the study, and information we collect that could identify you (for example, your name, phone number, email address, mailing address) will be stored in a different place. This way, it is more difficult to connect your answers to data that can identify who you are. Once the study is complete, your personal information will be deleted. It is recommended that participants delete any pictures of test results from their phone after it is sent to the study team and have confirmation that the team received the photo.

If anyone outside of the study asks for the information you provide to us during this study, like a court, lawyer, or other administrator, we will also refuse to release it, unless you give us written permission to, or the study's funders (the National Institutes of Health) request it to perform an audit or evaluation. However, these steps cannot protect information you choose to tell others yourself, so be careful who you tell about your participation in this study and your responses to the questions we ask.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

8. What if I want to stop?
Taking part in research is voluntary. You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, it will not affect your future relationship with Brown University, the Miriam Hospital, the University of California, Los Angeles, or the University of Mississippi Medical Center.

9. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Erik at 401-863-6684 or smashlabs@brown.edu.

10. Who can I talk to if I have questions about my rights as a participant?
If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at irb@brown.edu.

11. Consent to Participate
Clicking the radio button below and going on to the next sections indicates that you have read and understood the information in this document, and that you agree to volunteer as a research participant in this study. You can print a copy of this form or email a copy to yourself by clicking the buttons in the upper right-hand corner of this page.

○ I understand this information and agree to participate
○ I do not wish to participate at this time