Informed Consent for:

Mhealth for Pre-exposure Prophylaxis Adherence by Young Adult Men, Phase 2

NCT04633200

Informed Consent Form
Randomized Controlled Trial

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Funding Agency: National Institutes of Health

Study Title: Mhealth for Pre-exposure Prophylaxis Adherence by Young Adult Men, Phase II

Summary: The main purpose of this study is to develop and evaluate a mobile phone app (called DOT) to support adherence to PrEP medication by men, ages 18-35. If taken daily, the Pre-exposure prophylaxis pill—PrEP/Truvada/Descovy—can prevent HIV infection by 92-99 percent. If you agree to be part of this study, you will be randomly assigned to either an intervention group or a control group. Participants in the intervention group will download and use the DOT mobile app which provides daily pill reminders and other supportive information about PrEP. Participants in the control group will be emailed a PrEP patient education document. Participants in both groups will complete online questionnaires at the beginning and end of the 12-week study. Participants in both groups will receive a $175 Amazon gift card for their participation.

Risks: You should be exposed to minimal risk in this study. For intervention group participants, the potential risks involve someone seeing your text messages and possibly realizing that you are taking PrEP. For control group participants, the potential risks involve someone seeing the emailed PrEP education document (for control group participants). Other risks include possible discomfort or embarrassment from participating, and a potential loss of privacy.

If you are randomly assigned to the intervention group, it is important to note that the DOT mobile app may malfunction during the study. Therefore you should *not* rely on the mobile app alone to remember to take your pills. Also, if you are concerned about someone seeing the text messages you receive from the study, you should log into the mobile app when you are alone and delete the texts after reading them or save them in a password-protected file. If you are randomly assigned to the intervention group, you will have the option of participating in an online community. In order to participate, you will have to agree to our online community rules of conduct. The online community will also be monitored by DOT staff for inflammatory or objectionable content. However, it is still possible that content may appear in the online community that you personally find objectionable. If you have any concerns about being exposed to such content, you

should not participate in the community.

If you are randomly assigned to the control group that receives the PrEP education document and you have concerns that someone might see the document, you should place it in a password-protected computer file or delete it after reading.

For participants in both groups, if you think you might want to recover any study-related emails or texts that you deleted, we recommend that you check with your email provider, computer software or mobile phone manufacturer to learn how to do so.

At the end of the study, the DOT mobile app will be removed from participant phones.

Participants: You will participate in this study with approximately 109 other men.

Benefits: You will receive support for adhering to PrEP.

Findings: We do not expect to have significant findings during the course of the study. However, if significant findings are found during the study, we will contact you immediately. None of your data will be used in future studies, nor will we sell any data collected for this study. If we report study findings in publications, we will not use individual names or other information that would allow readers to identify specific individuals.

Costs: There are no anticipated costs to you for participating in this research.

Alternatives: Your alternative is not to participate.

Termination: You may be terminated from the study if we cannot recruit enough participants. You may also be terminated from the study if, in our judgment, you have enrolled in the study more than once or misrepresented your eligibility for participating. If you are terminated from the study, you will receive no further compensation in Amazon gift cards.

Withdrawal: You may choose to withdraw from the study at any time.

Confidentiality and Authorization to Use and Disclose Personal Health Information: All information collected in this study will be kept strictly confidential, and all data collected will have identifying information removed. Data will be stored on secure servers and transmitted with appropriate protections. A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA) describes how your personal healthy information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the sponsor (NIH) personnel associated with this study, regulatory

agencies, such as the Food and Drug Administration (FDA), and the Pearl Institutional Review Board (IRB), a committee that has reviewed this study to help ensure that your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner. Because of the number of individuals who may want to see your records, absolute confidentiality cannot be guaranteed. If any of your health information is likely compromised, the sponsor or other organization must notify government authorities.

Personal information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other records, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, your records may not be available until the study has been completed.

You may, by written notice to the study doctor, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization has no expiration date.

In accordance with the Massachusetts state law, all data collected in this study will be stored for 7 years from the date of the last participant's completion of study questionnaires. All electronic data from use of the DOT mobile app will be stored, fully encrypted, with our tech partner on both the mobile device and the remote database hosted by our HIPAA-compliant business affiliate Amazon Web Services (the cloud). The data will only be accessible by authorized study staff and the 52 Inc software developers. The tech partner software developers will only have access to de-identified data (i.e. no participant full names) as needed to provide software support. Participants who use the DOT mobile app will have access to their own mobile app-based data on their mobile device. Following the study, the data will be moved to a long-term storage database with Amazon Web Services and will only be accessible by EHG staff.

Online questionnaires and other study data collected using the Qualtrics online platform

(which is HIPAA compliant) will be removed from Qualtrics by study staff at study conclusion, and stored in two encrypted folders on an Environment & Health Group Macintosh computer, with the entire drive encrypted using FileVault. We will create two disk images from each folder—one for participant name & demographic data, and one for their questionnaire data. Both of the disk images will be encrypted with a 256-bit key. Both of the disk images will be protected by a secret key or password that enables study staff to decrypt it every time staff opens the file. Furthermore, the passwords to access each disk image will be stored in Last Pass, which uses strong encryption algorithms and uses AES-256 bit encryption with PBKDF2SHA-256 and salted hashes to ensure security in the cloud, as well as local-only encryption and multi-factor authentication that adds extra security and requires a second login setup before authorizing access to your vault.

There is a privacy loss risk when any study data is in transit. All data in transit between the DOT mobile app and the tech partner server will be secured using HIPAA-compliant security protections to help keep data safe.

Despite the precautions and protections outlined above, there remains a risk of privacy loss for study participants. If you are uncomfortable with that risk, you should not participate in the study.

Any significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

This study is registered with Clinicaltrials.gov: #NCT04633200.

Termination of Participation: Your participation is completely voluntary. You can excuse yourself from the study at any time with no negative repercussions.

Compensation: You will receive a $20 Amazon gift card for completing questionnaires at the beginning of the study. At study completion (12 weeks), you will receive a $155 Amazon gift card after re-taking the questionnaires.

Questions: If you have questions about the study you would like to ask before signing this form, you may call Dr. Patricia Weitzman at 617-455-5976 or email her at pat.weitzman@gmail.com.

By signing the form, you confirm that you are comfortable with study procedures and would like to participate. If you have questions about the study after signing the consent form, you may call Dr. Patricia Weitzman, Investigator, at 617-455-5976.

If you have any questions concerning your rights as a research subject, any related concerns or complaints, you may contact Pearl IRB at 29 East McCarty Street, Suite 100 Indianapolis, IN 46225 or via phone at (317) 899-9341. An Institutional Review Board is a committee that has reviewed this study to help ensure that your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner.

Voluntary Consent: I am free to withdraw or refuse consent, or to discontinue my participation in this study at any time without penalty or consequence. I voluntarily give my consent to participate in this research study. I will be emailed a signed copy of this consent form.

Signatures:

Participant's Name	Date
Participant's Signature	Date
Patricia Weitzman	11/2/2021
Investigator's Name	Date
	11/2/2021
Investigator's Signature	Date