

Official title: GamePlan for PrEP: A Pilot Trial of a Web-based Intervention to Help High-risk Men on PrEP Adhere to Their Medication, Reduce Alcohol Use, and Encourage Safe Sex

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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

GamePlan for PrEP
Version 2, 11/30/2021

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** The study involves testing whether a website/ videos that might help PrEP patients do well on this medication. You are being asked to be in this study because you are currently prescribed and taking PrEP.
- **PROCEDURES:** You will be asked to complete 4 online surveys, provide about 5 drops of blood three times, and view a website that provides health information.
- **TIME INVOLVED:** You will be enrolled in the study for up to 6 months. Each survey should take about 30 minutes of your time.
- **COMPENSATION:** You will receive up to \$320 for your time.

RISKS: Some of the topics and questions in this study might make you uncomfortable or embarrassed. You can skip any questions you choose not to answer. Additionally, your participation in this study, as well as any information you provide us during the study, is confidential. However, there is a risk that a data breach during the study may result in the loss of confidentiality. To minimize this risk, the systems we use to collect data throughout the study meet very high standards for security and are routinely checked for flaws. We also do not store any information that could identify you in the programs we use to collect data from you online.

- **BENEFITS:** You may not directly benefit from being in this research study. However, you will be contributing to a study that may help people in the future.
- **ALTERNATIVES TO PARTICIPATION:** There are no alternatives to participation. If you have any questions about your PrEP, it is recommended that you consult your health care provider.

1. Researcher(s):

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2. What is this study about?

The study involves using a website/watching videos that might help improve outcomes in those who are on PrEP. Specifically, we are interested in ways that we might be able to improve adherence outcomes. You are being asked to be in this study because you are currently prescribed and taking PrEP.

3. What will I be asked to do?

You will be asked to:

- Complete an online survey when you join the study, and 1, 3, and 6 months from now. We will send you instructions and links via email to help you complete this each time it is due. If you cannot complete it or are busy on the day it is due, we will remind you again via email if you have not finished the questionnaire after 2 days. This survey should take about 30 minutes to complete, and asks about your mood, stress, quality of life, medication adherence, alcohol/drug use, and sexual behavior. You can choose not to answer or “skip” any question you do not want to answer.
- Take a sample of about 5 drops of blood three times: When you start the study and 3 and 6 months from now. This process is similar to the process that people who have diabetes use to check their blood sugar. We will send a kit to an address you provide to us that will provide all of the materials you need to provide the sample each time. Written and video instructions will walk you through how to provide the sample. You will use provided lancets to prick your finger, and squeeze five drops of blood onto a card we provide you. Let it dry for at least 4 hours, and then place it inside a plastic bag we provide and then a postage paid envelope to send back to us.
- This study will have 2 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin.
- Use a website or watch videos we send to you. The website/videos take about 30 minutes to use, and you can skip any portions you do not want to use.
- You will be enrolled in the study for up to 6 months. Each of the 4 surveys should take about 30 minutes of your time. Collecting dried blood spots may take up to 30 minutes of your time as well.
- We will also ask your permission to access your medical records from your PrEP doctor. This might include information about your prescription, when you started, etc.

4. Will I be paid?

You can earn up to \$320 for participating in this study. You will be paid \$20 for viewing the website or videos, \$75 for each time you complete the online survey and provide



drops of blood (at baseline, 3-months, and 6-months) and \$25 for completing a survey at 1-month, plus a bonus of \$50 for completing all study procedures.

Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card.

We mail you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that uses ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card within 72 hours of completing your online survey and returning your blood spot sample at each timepoint. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn \$600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

5. What are the risks?

During this study, some of the questions we will ask you are about sex, alcohol and drug use, and other sensitive behaviors. These questions might make you uncomfortable or embarrassed. You are free to skip any questions that you do not feel comfortable answering.

Your participation in this study, as well as any information you provide us during the study, is confidential. To safeguard your confidentiality, we store all data you provide us in secure locations and in password-protected and encrypted files, and after the study is over, we destroy any information that could identify who you are (e.g., your name,



phone, email). However, there is a risk that a data breach during the study may result in the loss of confidentiality. To minimize this risk, the systems we use to collect data throughout the study meet very high standards for security and are routinely checked for flaws. We also do not store any information that could identify you in the programs we use to collect data from you online.

You may experience discomfort associated with the collection of dried blood spots, such as pain, bleeding, or discomfort. The stick site could become infected. If this is the case, please seek care with your health care provider.

You may experience problems as a result of taking PrEP or while undergoing any medical procedure done as part of the typical course of monitoring your use of PrEP (e.g., HIV/STD testing/treatment). However, you may experience these even if you chose not to join the study, since these are a result of taking PrEP and not the study procedures themselves. It is recommended that you address any concerns regarding PrEP with your prescriber or health care provider.

6. What are the benefits?

You may not directly benefit from being in this research study. However, you will be contributing to a study that may help people in the future.

7. How will my information be protected?

All data we collect from you is stored on servers that are protected by two-step (password and device push) verification. Only authorized study personnel will have access to this data. While we will collect limited information about you in order to contact you in the future, we will only collect your name, phone number, and email address. We will destroy this information as soon as your participation in the study is complete (either the 2 year maximum period has passed or you asked us not to contact you in the future). This identifying information will also be collected and stored in a separate survey at the end, and linked to your survey responses with a unique code number. Your identifying information will never appear alongside your survey responses.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

Biospecimens collected as part of this study will not be used for commercial profit.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.



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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.

8. Are there any alternatives to this study?

There are no alternatives to this study. If you choose not to be in this study, you can continue receiving PrEP care from your prescriber.

9. What if I want to stop?

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, your current or future relationship with Brown University or your PrEP care clinic will not be affected.

10. 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 study staff at (401) 863-6633 or email gameplan@brown.edu.

11. 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.

12. Consent to Participate

Clicking the link below confirms that you have read and understood the information in this document, are over 18 years old, and that you agree to volunteer as a research participant for this study.

You can print a copy of this form.
<include URL for pdf consent here>