MyPEEPS (Male Youth Pursuing Empowerment, Education, and Prevention Around Sexuality) Mobile for Young Transgender Men

Version 07/24/2023

NCT05424718

Consent Form (Aims 2 & 3)

Please complete the survey below.

Thank you!

Columbia University Consent Form

Protocol Information Attached to Protocol: IRB-AAAT8624
Principal Investigator: Rebecca Schnall PhD, MPH, RN-BC, FAAN (rb897)
IRB Protocol Title: Development and Pilot Testing of the MyPEEPS Mobile Application for Young Transmasculine Youth

General Information Participation Duration: 6 months
Anticipated Number of Subjects: 80
Research Purpose: This is a research study to assess the use of a mobile app for HIV prevention. We will use findings from this multi-site study to assess the effectiveness of MyPEEPS in improving HIV prevention behaviors.

Contacts

Contact Title Contact Information
Rebecca Schnall Principal Investigator Phone: 212-342-6886

Email: rb897@cumc.columbia.edu

Detailed Information on Research You are being asked to participate in this research study about HIV prevention. The purpose of this form is to give you information to help you decide if you want to take part in a research study. This assent form includes information about:

-why the study is being done;

-the things you will be asked to do if you are in the study;

-any known risks involved;

-any potential benefit;

-options, other than taking part in this study, that you have; and

-the way your health information will be used and shared for research purposes.

A member of the study team will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research and its procedures are described below in the 'What is Involved in This Study?' section of this assent form. This assent form is written to address a research subject.

What is Involved in this Study?

We are conducting a study to assess the use of a mobile app for HIV prevention. First, we determine if the study is a good fit for you through the online screener, and if it is then:

-A baseline visit will be conducted virtually involving a behavioral assessment and will last approximately 1.5-2.5 hours.

-You will be asked to be part of a mobile app study and will use a login and password to access information about HIV prevention.

-Subjects will be randomized (randomly assigned, like flipping a coin) to one of two arms: Intervention Arm or Control

Arm. You will have a 50/50 chance of being assigned to either the control or intervention group. All participants will be given access to the MyPEEPS application.

-If you are assigned to the intervention arm, you will receive access to the MyPEEPS app at the baseline visit.

-If you are assigned to the control arm will receive access to the MyPEEPS app at the 3 month follow up visit.

-You will be asked to complete 4 modules (25 activities) over 3 months. You will complete the modules through the app on your mobile phone at your own pace. Each module contains educational information and activities to increase knowledge about HIV prevention.

-You will be asked to complete 3 surveys that ask about you, your attitudes, practices, and experiences.

1.One survey will be completed at the baseline visit.

2.One survey will be completed at the end of the 3-month period you are given to complete the module activities.

3.A follow up survey will be completed 6 months after you complete the first survey as well.

After completion of the intervention, you may be selected for a 45-60 minute in depth interview.

When you arrive to begin the study, we ask you to confirm that this study is a good fit for you; if the study is not a good fit for you, we will thank you for your time, and there will be no other obligations; if the study is a good fit for you, we will invite you to participate in the study following completion of a written informed assent/consent form, which we will give you a copy of for your records.

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1) Permission for Future Contact The researchers may want to contact you in the future for other studies. We would contact you only once to solicit you participation in any research associated with the current study.

Please indicate whether or not you give permission for future contact.

◯ I give permission to be contacted in the future for research purposes.
◯ I do NOT give permission to be contacted in the future for research purposes.

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2) Permission to Access Medical Records

We would also like to use information from your medical records, for example HIV and STI test results. We will look at this information from the time you enroll in the study onward. If we require medical records from outside institutions, we will ask you to sign a separate authorization form to obtain them. Please indicate whether or not you give permission to use your medical records.

◯ I give permission for my medical records to be accessed for research purposes.
◯ I do NOT give permission to for my medical records to be accessed for research purposes.

Risks General risks

Others may observe your use of the MyPEEPS application. Therefore it is important that you access this application in a private location if you are concerned about other people seeing your use of MyPEEPS. You may become tired while listening and completing the online information. You are free to stop completing the surveys at any time or skip any questions that may make you feel uncomfortable.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of confidentiality or privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the 'Confidentiality' section of this consent form. A potential risk is a breach of confidentiality regarding your decision to complete or not complete the study.

Benefits There are no direct benefits to study participants. Your participation will assist the study team in improving HIV prevention in adolescents.

Alternative Procedures You have the option to not participate in this research. At any point during the session, you may ask the researcher to stop the session.

Confidentiality Columbia University is conducting this study. The study is funded by the National Institutes of Health.

To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research. If an insurer, employer, or other person gets your written consent to receive research information, then we cannot use the Certificate to withhold that information. The Certificate cannot be used to resist a demand for information from representatives of the United States Government that is used for auditing or evaluation of projects they are responsible for overseeing. You should also know that this Certificate does not protect you from our responsibility to report to appropriate state or local authorities any information obtained in the research of suspected child abuse, or intent to hurt self or others.

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your computer and survey responses will be assigned a unique identification number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a secure environment certified by the Columbia University and only the investigator and study staff will have access to the file.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. This will include information about HIV test results, sexual habits, substance use, and mental health.

Any research information that is shared with people outside of Columbia University Medical Center and its affiliated institutions will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

-The Investigators, Columbia University Irving Medical Center study staff and other medical professionals who may be evaluating the study
-Authorities from Columbia University including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- Our sponsor, the National Institute of Mental Health/National Institute of Health ('NIMH'/'NIH')

Your authorization to use and share your health information will expire when the research is completed.

Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Rebecca Schnall, at 212-342-6886.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

Identifiers, or pieces of information that might identify you, will be removed from the data that is collected and analyzed and, after such removal, the information could be used for future research studies without additional consent.

Compensation There are no costs to you for participating in this study.

You will be compensated for your time.

- $25 survey completion at baseline
- $30 survey completion after 3 months
- $35 survey completion after 6 months
- $100 for completing the MyPEEPS activities ($20 x 4 modules + $20 bonus for completing all components) In total over the 6 months of the study, you may receive up to $220 (if randomly selected to complete an in depth interview (+ $30) after 6 months).

All compensation will be administered via Amazon gift codes.

Voluntary Participation Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. Your refusal to participate, or your early withdrawal, will not affect any benefits to which you are otherwise entitled nor will it affect the care provided by the members of your care team.

Additional Information Technical Difficulties If you have questions about the study or technical difficulties using the app, please contact our study staff: Dorcas Adedoja at (mypeeps@cumc.columbia.edu) 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.

If you have any questions or concerns about the study, you may contact:

Dr. Rebecca Schnall at (212) 342-6886 or rb897@cumc.columbia.edu

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact:

Human Research Protection Office, Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 2nd Floor
New York, NY 10032
Telephone: (212) 305-5883 Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent and HIPAA Authorization I have read the consent form and HIPPA authorization, and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher.

Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

3) Signatures
Study Participant's Full Name:

_____

4) Study Participant's Signature:

_____

5) Date:

_____

Research Staff Signatures

Person Obtaining Consent: [redacted]

6) Date:

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