Official Title: P3-T: Novel mHealth Technologies to Enhance PrEP Adherence among Thai YMSM, Collaborative Adaptation and Evaluation

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Consent Form- Full Study

P3-T Randomized Controlled Trial Consent

Chulalongkorn University & Thai Red Cross AIDS Research Centre (TRC-ARC)
Consent to Participate in a Research Study
Participants ages 16-24 years old

Duke IRB Study # 2020-0099

Consent Form Version Date: Version 1.0 dated 04-29-2020

Title of Study: P3-T: Novel mHealth Technologies to Enhance PrEP Adherence among Thai YMSM, Collaborative Adaptation and Evaluation

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Key Study Information

- The purpose of this study is to gain your perspective as a young man who has sex with men on a mobile phone app called P3-T. The purpose of P3-T is to help young men who have sex with men take PrEP, a medicine that helps prevent HIV.
- You are being asked to take part in a research study. You do not have to join. You can quit the study at any time, for any reason, and nothing bad will happen as a result.
- This form contains details about the study that will help you make a choice about participating.
- We are asking about 60 people to take part in the study.
- Participants in the study will be randomly sorted into two groups. One group will get the P3-T app and one group will not get the P3-T app. Research staff have no control over what group you are sorted into and no one can change what group you are in.
- All participants will be in the study for 6 months.
- The study involves three clinic visits:
    - At the enrollment visit you will meet with research study staff who will guide you through the visit.
        - You will complete a survey to collect information about your demographics, factors related to PrEP adherence, sexual risk, among other items, and review the intervention materials.

    - At the 3- and 6-month visits, a research study staff will guide you through the visit.
        - You will complete a survey similar to the enrollment survey.
        - A trained phlebotomist will draw a small amount of blood (2mL) from a vein in your arm or your hand.
        - At the 3-month visit, some participants will have an opportunity to complete an interview with a study staff member about their experience using the app.
- The study will include daily use of the intervention materials (about 5-10 minutes) for the first three months of the study period.
- While you may not personally benefit from participating in the study, your feedback about the intervention and your experience in the study may help other young men who have sex with men by adding to the resources available to help them protect their health.
- <u>There are potential risks or discomforts involved with being in this study including:</u>
    - While completing the survey, you may find some of the questions a little embarrassing or difficult to answer.
    - Study staff will make every effort to keep your information confidential, but there is a small possibility that your name and information that you share during this research study could become known to others. The efforts we will take to prevent this from happening are described in detail below.
    - For the blood draws, you may experience discomfort or bruising at site where the blood is drawn. There is a small risk of fainting and a rare risk of infection.
- Study staff will make every effort to keep your information confidential. The efforts we will take to protect your confidentiality are described in detail below.
- For participating in this study, you will receive $20 at each of the three visits (total $60). Depending on what group you are randomly sorted into, you may have the opportunity to earn additional money, up to $15 for app use and $20 for the qualitative interview (total $95).
- There are no costs to you for participating in this study.

<u>What are some general things you should know about research studies?</u>
You are being asked to take part in a research study. You do not have to join. You can quit the study at any time, for any reason, and nothing bad will happen as a result.

We are doing this research to learn information that could help young people like you, in the future. All research has risks and benefits. We will talk about these risks and benefits with you before you decide if you want to join the study.

This form contains details about the study that will help you make a choice about participating. You will be given a copy of this form to keep. You can ask any questions you want of the study staff, or the researchers listed at the top of this form.

<u>What is the purpose of this study?</u>
The purpose of this study is to gain your perspective as a young man who has sex with men on a mobile phone app called P3-T. The purpose of P3-T is to help young men who have sex with men take PrEP, a medicine that helps prevent HIV. This study will help us see if the app helps young men who have sex with men who are starting PrEP take it regularly. HIV rates are high among young men who have sex with men. If people at risk of HIV take an HIV treatment medicine on a regular basis, they are much less likely to get infected with HIV.

The idea of taking a medicine to prevent HIV is called pre-exposure prophylaxis, or “PrEP” for short. Some people have trouble taking PrEP, so we developed P3-T to help them be active in

their own health care and remember to take their PrEP. The P3-T app includes features such as a medication tracker and reminders, daily activities including a social wall where you can anonymously connect with other PrEP users, access to an adherence counselor, and resources about PrEP and sexual health. We don't know if the app will work, and that is why we are testing it out.

How many people will take part in this study?
We are asking about 60 people to take part in the study.

How long will your part in this study last?
Your participation in the study will last 6 months.

What will happen if you take part in the study?
Participants in the study will be randomly sorted into two groups. One group will get the P3-T app and one group will not get the P3-T app. Research staff have no control over what group you are sorted into and no one can change what group you are in.

All participants will be in the study for 6 months. This study involves three clinic visits as well as daily use of the intervention materials (about 5-10 minutes) for the first three months of the study period.

At the enrollment visit you will meet with research study staff who will guide you through the visit. You will complete a survey to collect information about your demographics, factors related to PrEP adherence, sexual risk, among other items, and review the intervention materials.

You will then have the intervention materials for 3 three months to use. During those months, we ask that you use them a little bit every day (about 5-10 minutes of use).

After 3 months, you will come back in for a follow up visit. At the 3-month follow up visit you will meet again with a research study staff member. You will complete a survey similar to the one completed at enrollment and a trained phlebotomist will draw a small amount of blood (2mL) from a vein in your arm or your hand and several drops of the collected blood will be used to fill in a dried blood spot (DBS) card.

Some participants will have an opportunity to complete an interview with a study staff member about your experience using the app. If you are chosen and are available to participate, audio from the interview will be recorded to make sure we have an accurate record of the information you give us.

After this period, if you were in the group that got the P3-T app, you will still have access, but you will not be required to use it daily. You will not have access to some features, including the adherence counselor and the virtual bank account.

After 6 months, you will come back in for the final follow-up visit. At the follow up visit you will meet again with a research study staff member to guide you through your visit. You will complete a survey similar to those completed at prior visits and a trained phlebotomist will draw a small amount of blood (2mL) from a vein in your arm or your hand and several drops of the collected blood will be used to fill in a dried blood spot (DBS) card.

At the end of the study, the DBS cards collected at 3- and 6-months will be sent to the Program for HIV Prevention and Treatment (PHPT) Research Unit at Chiang Mai University to be

analyzed by Dr. Tim Cressey for the levels of PrEP in your blood. To protect your privacy, your name will not be recorded on any of the samples shipped to PHPT.

We will not be able to provide you with the results of your blood test because samples will not be analyzed until all participants have completed the study.

What are the possible benefits from being in this study?
You may not benefit personally from being in this research study. However, your feedback about the intervention and your experience in the study may help other young men who have sex with men by adding to the resources available to help them protect their health.

What are the possible risks or discomforts involved with being in this study?
While completing the survey, you may find some of the questions a little embarrassing or difficult to answer. Your participation is entirely voluntary. You may choose to not answer any question or leave the study at any time. If you are upset by anything we discuss, please let a research staff member know.

You will have 2mL of blood drawn from a vein in your arm or hand at the follow up visits at 3 and 6 months. The total amount of blood taken for the whole study will be 4mL. You may experience discomfort or bruising at site where the blood is drawn. There is a small risk of fainting and a rare risk of infection. Even though we are confident these risks are unlikely if you have any questions or concerns please let the research team know. If you have experienced discomfort, bruising, fainting, or infections from previous blood draws, please let us know.

You will be informed if the study staff learns of any new risks associated with PrEP use or any study activities.

What if you want to stop before your part in the study is complete?
You can leave the study at any time you want. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped.

How will your confidentiality be protected?
To protect you, all of the information collected about you during the study will be identified by a study ID number, not your name. A file that links your name to your study ID number will be kept in a secure folder on a secure server at Duke University separate from the secure folders where your study records are stored. This file will only be accessible to key study staff using a strong password only known to them.

If you participate in an interview with a study staff member at your 3-month visit, your name will not be audio recorded during the interview and the recording will only be used by research team members. The audio recording will be kept confidential, meaning it will only be identified by your study ID number. It will be stored in a secure folder on a secure server at Duke University only accessible to select study staff. All audio recordings will be permanently destroyed within six months of study completion.

DBS cards sent to PHPT and sample results will only be identified by their study ID number, therefore, the lab at PHPT will not be able to link DBS cards or sample results to participant names. DBS cards will be stored in locked storage at PHPT. The results of the PrEP drug level testing will be sent in a password protected spreadsheet via secure email to the P3-T Principal

Investigator in Thailand. The Principal Investigator will store the sample results in a secure folder on a secure server at Duke University only accessible to select study staff.

Your original blood samples, identified only by your study ID number, will be stored securely at Chulalongkorn University. Your DBS card, identified only by your study ID number, will be stored securely at PHPT Research Unit at Chiang Mai University. These samples will be destroyed 3 years after the completion of the study.

All data collected from you after you enroll in the study, including survey, interview, app use, and blood sample data will be linked by your study ID number only.

The project's industry partner, Ayogo, may use de-identified app data from the study for quality improvement of their digital healthcare platform in commercial products such as health apps.

A description of this study will be available on http://clinicaltrials.gov, as required by United States Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can access this website at any time.

To help further protect your privacy, we have obtained a Certificate of Confidentiality for the study from the United States Department of Health and Human Services (DHHS). It adds special protection for research information that identifies you. It says that we do not have to identify you, even under a court order or subpoena. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any United States federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and the Duke University and Chulalongkorn University IRBs may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This means that they will not tell others information about you or that you are in the study. By signing this form, you are allowing such access.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

While every effort will be made to keep your participation in the study and any personal information about you private and confidential, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member may be required by law to take steps to keep you and others safe. This means that study staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, such as

telling study staff that you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

Will you receive anything for being in this study?
You will receive $20 at each of the three visits (total $60). Depending on what group you are randomly sorted into, you may have the opportunity to earn additional money, up to $15 for app use and $20 for the qualitative interview (total $95).

Are there any costs to you for taking part in this study?
You will not be charged for anything that is done for this study.

Who is sponsoring this study?
This research is being sponsored by Duke University and is funded by the National Institutes of Health (NIH). This means that the sponsor, Duke University, is providing money from the NIH to Chulalongkorn University and TRC-ARC to help conduct this study. The researchers do not, however, have a direct financial interest with the sponsor or funding source or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research at any time before, during, or after your participation. The Chulalongkorn University investigator in charge of this study is Dr. Wipaporn Natalie Songtaweesin. If you ever have questions, or concerns about this study, you may call or email Dr. Songtaweesin: +66 (662) 256-4930 or wipaporn@doctors.org.uk

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Duke University IRB at +1 (919) 684-3030 or campusirb@duke.edu

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent