

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Adapting effective mHealth interventions to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in Thai Young Men who have Sex with Men (MSM): Aim 2

Sponsor: NIH/NIMH

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STUDY DETAILS

Why is this research being done?

This study is designed to develop and pilot a technology-based intervention to promote PrEP (an HIV prevention medication) initiation and adherence among young men who have sex with men (aged 16-29 years) in Thailand. If successful, this behavioral intervention will help more people access information about PrEP and use the medication correctly.

How many people will take part in this research?

Approximately 120 people will participate in this study.

How long will I be in this research?

6 months.

What happens if I say yes, I want to be in this research?

If you choose to participate, all participants will receive standard PrEP counseling.

Additionally, participants will need to complete the following tasks:

- 1) Complete a questionnaire at baseline, 1-, 3-, and 6-months: The questionnaire takes about 30 minutes to complete.
- 2) Give blood samples through venipuncture for HIV testing, syphilis testing and Tenofovir diphosphate measurements (to measure the amount of PrEP medication in your bloodstream) at baseline, 1-, 3-, and 6-month visits.
- 3) Urine, oral, and rectal swabs for gonorrhea and chlamydia testing at baseline and 6-month visits.

As a part of this study, you will also be randomly assigned to one of two treatment conditions: 1) standard PrEP counseling; or 2) a two-session behavioral intervention and motivational text messages.

If randomized to the group receiving the behavioral intervention, this will take place in the HIV clinic at the baseline and one-month visits. Each session will take approximately 30-45 minutes to complete. It will be self-administered on an iPad.

If randomized to the text messaging group, you will receive daily text messages for 30 days (Month 1). You will have the option to continue to receive these messages until the end of month 6, if desired.

What are the risks for being in the study?

You may feel embarrassed or discouraged answering personal questions about risk behaviors or talking about confidential information. Participants can refuse to answer any question at any time without impacting their enrollment in the study or compensation. If you experience feelings of personal distress (e.g., anxiety, depression, anger, panic), psychiatrists affiliated with the study site are available by phone and/or pager.

There may be physical risks associated with venipuncture. It can result in discomfort, bleeding, bruising and, rarely, infection of the puncture site. To reduce the discomfort from venipuncture, the procedure will be performed by experienced phlebotomists.

There is also a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, if other people learn about your HIV or STI results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining employment. We believe the chance these things will happen is very small, but we cannot make guarantees.

There are social and psychological risks associated with testing for HIV/STIs. Being tested for HIV/STIs can make you feel nervous about the test results. The researchers will keep your test results confidential and will not release them to anyone. [We will notify you if you test positive](#); you will be scheduled for confirmatory testing and counseling and will receive free treatment through either clinic. [In addition, you may be embarrassed or experience any physical discomfort when undergoing the urine, oral, and rectal swabs.](#)

If assigned to the mobile text messaging group, there is the risk of disclosure if someone else sees the text message. All participants have the right to request cancellation of text messages at any time. Messages will be sent and received by a secure password-protected computer at the Institute of HIV Research and Innovation (IHRI).

Will being in this research help me in any way?

You may gain better knowledge about PrEP and self-protection while taking part in the study. This study will help you use PrEP more effectively for HIV prevention.

What other choices do I have besides taking part in this research?

If you choose not to participate, you can still receive all medical services at participating HIV clinics.

Will it cost me any money to take part in this research?

No, there is no cost to you.

Will I be given any money or other compensation for being in this study?

If you participate in the clinical trial, you will receive up to \$85 compensation for participating in this study (\$25 for baseline, and \$20 for each subsequent visit at 1-, 3-, and 6-months).

What are my responsibilities if I take part in this research?

If you take part in this research, you will be asked to attend clinic visits at baseline, 1, 3, 6, 9, and 12 months. At clinic visits, you will complete study questionnaires and provide blood samples, urine samples, oral and rectal swabs. You have the potential to receive two iPad-delivered intervention sessions in clinic at baseline and 1-month and text messages on your mobile phone.

What happens if I say yes, but I change my mind later?

Even if you agree to participate, you may withdraw from the study at any time. Your decision to participate will not affect the medical service that you receive.

How will my information be stored and when will it be destroyed?

All information collected during the course of this study will be kept confidential. You will be identified by a code number. Only one master list will link the code number to your name. The master list will be kept in a locked cabinet in the Study Coordinator's office and will be destroyed after all data are collected and linked before data analysis.

Who has access to my information?

Researchers at the University of Massachusetts Medical School, Wayne State University, University of California San Francisco, and Institute of HIV Research and Innovation (IHRI), Thailand will have access to the de-identified data.

You will only be identified by a code number. There will be one master list of names and code numbers which will be kept in a locked cabinet in the Study Coordinator's office and will be destroyed after data are collected and the forms are linked, before any data is analyzed. No one other than the Study Coordinator will have access to this list. That is, no one else on the study team, including myself, will know what responses you have checked. Your information will not be used or distributed for future research studies even when identifiers are removed.

Will you share any results with me?

The cumulative and clinic results will be shared with the Institute of HIV Research and Innovation (IHRI), Thailand. We propose to conduct town hall meetings at IHRI, the clinics, and Non-government Organizations in Thailand. We will also present findings to community advisory groups within IHRI.

Who can I talk to?

Nittaya Phanuphak, M.D., Ph.D., the Executive Director at the Institute of HIV Research and Innovation; phone: +6681 825 3544); Bo Wang, PhD (Departments of Population and Quantitative Health Sciences, University of Massachusetts Medical School; phone: 1-774-455-4672).

Signature Block

Your signature documents your consent to take part in this research.

Signature of adult research participant

Date

Printed name of adult research participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent