The Development of a Mobile-based App to Increase Uptake of Pre-Exposure Prophylaxis (PrEP) by Men Who Have Sex With Men in China

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Guangzhou PrEP Project
Consent to Participate in a Research Study
Adult Participants Aim 2 – pilot trial consent form

University of North Carolina at Chapel Hill and Guangzhou Eighth People's Hospital

US IRB Study # 19-3481
US IRB: University of North Carolina at Chapel Hill

China IRB Study # 202022155
China IRB: Guangzhou Eighth People's Hospital

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Title of Study: IGHID 12001 - Develop a mobile-based app to increase uptake of pre-exposure prophylaxis by young men who have sex with men in China

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CONCISE SUMMARY

We are doing a research study to learn about HIV prevention needs of men who have sex with men (MSM) in Guangzhou in order to improve HIV prevention services and their effectiveness. During the study we will test a WeChat-based mini-app program to promote pre-exposure prophylaxis (PrEP) uptake in China.

This study is being done by the University of North Carolina at Chapel Hill and Guangzhou Eighth People's Hospital, and is funded by the National Institute of Health. If you are eligible and decide to participate, we will invite you to complete a 12-week study that includes one in-person or virtual initial visit at the Guangzhou Eighth People's Hospital (about 30 minutes) and

five follow-up web-based surveys at weeks 2,4,6,8, and 12. The risks of study participation are breach of confidentiality and possible discomfort with the finger stick for blood draws. Study participants will receive comprehensive physical examinations and up to 2-month doses (equivalent to 60 pills) of PrEP (TDF/FTC) at reduced price. Some participants may also opt to be interviewed in a private space with one of our trained study staff. In the surveys and interviews, you will be asked about your experiences with HIV/STD testing and healthcare services, barriers you have experienced accessing those services, your knowledge of and attitudes toward PrEP, how you think of accessing PrEP and using PrEP as an HIV prevention strategy. If you would like to learn more please continue to read the information below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to understand how people think of HIV pre-exposure prophylaxis (PrEP), and how a mobile phone-based application could help increase people's knowledge of PrEP and their willingness to start using PrEP.

Are there any reasons you should not be in this study?

You should not be in this study if you are under 18 years, currently not residing in Guangzhou, not a Chinese citizen, or being HIV-positive.

How many people will take part in this study?

Approximately 110 people will take part in this study.

How long will your part in this study last?

This is a 12-week study, during which you will have a 30-minite initial visit (in-person or virtual) at the Guangzhou Eighth People's Hospital, and followed by biweekly web-based

surveys at weeks 2, 4, 6, 8, 12. Surveys at weeks 4, 8 and 12 will take approximately 15 minutes to complete. Surveys at weeks 2 and 6 will take 1 minute to complete.

Some participants may opt to be interviewed in a private space with one of our trained study staff, up to two times and each lasting about 45-60 minutes.

What will happen if you take part in the study?

If you are eligible and decide to participate in this study, you will:

(1) Initial enrollment visit to the Guangzhou Eighth People's Hospital: you can choose to do this in-person or virtual. It will take about 30 minutes when the research staff will explain the study design in details, and assist you complete a web-based baseline survey. In the surveys you will be asked about your experiences with HIV/STD testing and healthcare services, barriers you have experienced accessing those services, your knowledge of and attitudes toward PrEP, how you think of accessing PrEP and using PrEP as an HIV prevention strategy.

(2) At the enrollment visit, the study staff will randomly assign you to the intervention group (i.e. having access to the PrEP education mini-app) or the standard of care group (i.e. no access to the PrEP education mini-app) at 2:1 ratio. You will not be allowed to choose the which group you are assigned to. Regardless of study group, all participants will receive written educational materials about HIV prevention and PrEP, and how to access PrEP and other HIV prevention services through the study clinic.

(3) Follow-up: You will be asked to complete web-based follow-up surveys at weeks 2, 4, 6, 8 and 12.

(4) Interviews: You will also be asked if you will be willing to participate in one-to-one in-depth interview (about 45-60 minutes) with a research staff at week 4 and week 8. During these interviews you will be asked about your experiences with HIV/STD testing and healthcare services, barriers experienced, your knowledge of and thoughts about PrEP, and opinions of access to PrEP.

(5) PrEP initiation: If you are interested in starting PrEP during the study period, we will refer you to the PrEP clinic at the Guangzhou Eighth People's Hospital, where you will receive standard care for people on PrEP, including physical examinations and PrEP counseling. The cost for physical examination and PrEP counseling will be fully covered by this research project.

(6) PrEP cost reimbursement: If you are eligible for starting PrEP and have been prescribed PrEP by a PrEP provider, you will get a 50% reimbursement of the cost for your first two months of PrEP doses filled at the in-house pharmacy of the Guangzhou Eighth People's Hospital.

(7) Mini-app use: If you are assigned to the intervention arm, you will have access to a PrEP education-focused mini-app (built in WeChat) for up to 16 weeks. How to use the mini-app is totally at your discretion, but the research team will send you weekly reminder messages to encourage app engagement.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be obtaining information about HIV prevention and PrEP, and referral to the PrEP clinic at the Guangzhou Eighth People's Hospital to receive PrEP initiation counseling

and physical examinations.

What are the possible risks or discomforts involved from being in this study?

There is a minimal risk of breach of confidentiality. The study team has procedures in place to help protect your privacy. Some of the topics of HIV and medical care can be sensitive to discuss with the research staff or providers at the study clinic. Some of the questions we ask may make you feel uncomfortable or upset. The trained study team will do their best to make participants feel comfortable when talking about these topics.

If you are in the intervention arm where you can order at-home HIV/syphilis toolkit through the PrEP education mini-app, the HIV/syphilis self-test kit requires finger prick to collect blood samples. This procedure may cause local discomfort, bleeding, or bruising; rarely small clot or infection can occur at the blood draw site. This practice should not be considered greater than minimal risk in and of itself given its routine use in general health care delivery. Detailed instructions will be provided with home-testing kits.

There may be uncommon or previously unknown risks. You should report any problems to the research team.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Will I receive any other clinical results?

For participants who choose to start PrEP and complete PrEP inition couseling at the Guangzhou Eighth People's Hospital during the study period, the clinically relevant results of your physical examinations for PrEP initiation will be communicated with you directly from the PrEP provider at the Guangzhou Eighth People's Hospital, including HIV/syphilis lab-test results, kidney and liver function test, blood and urine routine test, HBV and HCV test. The study team will not have access to your medical record information.

How will information about you be protected?

We will take the highest precautions to protect your privacy and confidentiality. This includes:

- You will be assigned a study ID number which we will use to keep track of your information.
- The information we collect will be stored in a locked file cabinet within the study investigator's locked office.
- All information is entered into an encrypted, password protected computer.
- Only the study team members will have access to the data collected.
- You will not be identified in any report or publication about this study. Every effort will be made to keep research records private.

If you also participate in the in-depth interview at week 4 and week 8, we will digitally audio record the interviews.

- No information that could identify you will be included on this recording.
- The recorded files and transcripts will be stored on an encrypted, password protected computer and will be deleted at the end of the study.
- During the interview, you may ask to have the audio recorder turned off at any point.
- The de-identified data from the interview may be used for future research studies without additional consent from you.

Please check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal。

Will you receive anything for being in this study?

You will be receiving up to 340 Chinese Yuan for taking part in this study. You will receive a gift card right after your completion of each research activity. The break-down is:

- Initial enrollment visit: 50 Chinese Yuan
- Baseline assessment: 20 Chinese Yuan
- Follow-up surveys (long) at 4th, 8th, and 12th weeks: 20 Chinese Yuan for each survey, up to 3 surveys in total
- Follow-up surveys (short) at 2nd and 6th weeks: 5 Chinese Yuan for each survey, up to 2 surveys in total
- In-depth interviews at 4th and/or 8th weeks: 75 Chinese Yuan for each interview, up to 2 interviews in total
- At the end of study if you have completed all required research activities: additional 50 Chinese Yuan

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the NIH National Institute of Allergy and Infectious Diseases

(NIAID) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. In addition, Joseph Tucker, a faculty advisor on this study, is the founder of SESH Global LLC, a company involved in this study, and participates in unpaid activities for SESH which are not part of this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports.

If you would like more information, please ask the researchers listed in the first page of this form.

What is a Certificate of Confidentiality?

In addition to the efforts of the study staff to help keep your personal information private, we have a Certificate of Confidentiality. This certificate means that researchers cannot be forced to tell people who are not connected with this study about your participation. The Certificate of Confidentiality will not be used to prevent disclosure if required by law, such as mandatory reporting requirements for communicable diseases. It will also not be used if disclosure is for other scientific research, if allowed by US and China regulations protecting research participants or for any purpose you have consented to in this informed consent document.

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. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial is available on https://clinicaltrials.gov/ct2/show/NCT04426656, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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, or if you would like to obtain information or offer input, you may contact the UNC Institutional Review Board at +001-919-966-3113 or by email to IRB_subjects@unc.edu; or contact the Guangzhou Eighth People's Hospital Institutional Review Board at +86-020-83838688. It needs to point out that you may need to be able to speak in English in order to contact IRB at UNC; otherwise, you may want to have an English interpreter to assist your communication.

Participant's Electronic 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 Research Team Member Obtaining Consent	Date
Printed Name of Research Team Member Obtaining Consent	
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)	Date
Printed Name of Witness	