

Informed Consent Form

TITLE: Mobile Health Intervention to Increase HIV Testing and Linkage to Care

NCT NUMBER: NCT05484895

IRB APPROVAL DATE: May 2, 2022

Mobile Health Intervention to Increase HIV Self Testing and
Linkage to Services for High-Risk Men in China
May 2022

**Informed Consent to Participate in Research
Intervention Trial**

Introduction/Objective:

You are being invited to participate in a research study conducted by Anhui Medical University. Collaborators for this project are Emory University, Brown University, University of Arkansas Medical Sciences, and Rutgers University (USA). The objectives of this research are to use WeChat to support people who to learn about their HIV status by using HIV self-test kits, and to provide linkage to care for people with HIV-positive self-test results. We are inviting participants who are: (a) male, (b) ages 18 years or older, (c) have had anal sex without a condom with another man in the past 6 months, (d) own a “smart” phone, (e) live in Chengdu, Suzhou, or Wuhan, (f) not planning to migrate during the next 6 months, (f) received a HIV-negative (non-reactive) self-test result during the screening process.

Procedures:

If you agree to participate, the following will happen:

- You will complete a survey on a computer or device. The survey asks about health behaviors such as sexual behaviors, general health, use of health services, and HIV prevention. The survey will take about 30 minutes. You will receive 60 RMB for completing the survey today.
- You will be assigned to one of two groups at random. The group you are assigned to depends completely on chance – like the toss of a coin- and there is a 50:50 chance that you will be assigned to either group.
 - Group A (Control Group): If you are assigned to Group A, you will receive 2 free HIV self-test kits (one oral kit and one finger-prick kit) and instructions about how to use the kit and submit your test results via a private, secure system. You will receive contact information to the local non-governmental organization to request basic HIV information or receive referrals. You will be able to request additional free HIV self-test kits at any time while enrolled in the study.
 - Group B (Intervention Group): If you are assigned to Group B, you will receive 2 free HIV self-test kits (one oral kit and one finger-prick kit) and instructions about how to use the kit and submit your test results via a private, secure system. You will receive access to a WeChat group called WeTest. You will learn about how to use the WeTest app group, and about the information provided by the WeTest app group. You will be able to request additional free HIV self-test kits at any time while enrolled in the study.
- You will provide contact information so that we can email, text, or call you to remind you about follow-up appointments.
- You will complete semi-annual survey assessments at 6, 12, and 18 months from today. You will complete the surveys on a computer or device. You will receive 80 RMB each time you complete these follow-up assessments
- If you receive a HIV-positive preliminary test result at any time while you are enrolled in this project, we will refer you to a local CDC for further HIV testing and care. If you test HIV-positive and enroll in HIV care, we will seek information

through the HIV/AIDS Care System of the Chinese CDC about your attendance at HIV health appointments, use of HIV medications, and HIV viral load.

Benefits: If you agree to participate, you will have the opportunity to receive 2 HIV self-test kits to take with you.

Potentials Risks/Discomforts: Some of the questions in the surveys ask about sensitive issues, which might be uncomfortable or embarrassing for you. You have the right to not answer any question if you do not want to. Receiving an HIV test result might lead to anxiety or emotional discomfort. You can stop participation in the study at any time and for any reason. You do not have to provide a reason for skipping a question or stopping the study early.

Compensation: You will receive 60 RMB for completing the first survey assessment. You will receive 80 RMB each time you complete one of the 3 follow-up surveys.

Confidentiality: Your participation in this study will be confidential. We will store your personal contact information in a separate file from the data that you provide. Your answers to the questions in the assessments will be used solely for the purpose of this study. No names will be reported to anyone. All HIV test result information will be private, and photographs of any HIV test results will be deleted once those results are recorded in an anonymous database.

Voluntary Participation/Withdrawal: Your participation in this research is absolutely voluntary. You are free to change your mind about participating or withdraw your participation at any time.

Contact Information: If you have any question or concern with respect to the project, please communicate with [REDACTED], the Principal Investigator in charge of the project, at the following telephone number: [REDACTED] between 10:00 a.m. to 6:00 p.m. Additionally, you can Anhui Medical University Research Protections Office at Meishan Road 81, Hefei or write to the Anhui Medical University IRB Coordinator: cf10366@qq.com

If you agree to participate in the research study, you will receive a copy of this information sheet with all this information in case you have some concerns or questions about this study.

CONSENT

You will be given a copy of this consent form to keep. Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

Printed Participant Name

Signature of Participant

Date