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

Date: 05/08/2020

NCT#: NCT05484895

ANHUI MEDICAL UNIVERSITY
INSTITUTIONAL REVIEW BOARD, HUMAN RESEARCH PROTOCOL

PROJECT TITLE:
Mobile Health Intervention to Increase HIV Self Testing and Linkage to Services for High-Risk Men in China

PRINCIPAL INVESTIGATORS:
Hongbo Zhang, PhD (Anhui Medical University), Don Operario, PhD (Brown University)
Cui Yang PhD (Johns Hopkins University), Nickolas Zaller PhD (University of Arkansas)

SUMMARY

In this 5-year NIH-funded research project (current NIH grant # R01MH123352), we propose an intervention entitled "WeTest-WeLink" that aims to (i) promote uptake of HIV self-testing among MSM in China, and (ii) linkage to care for MSM who obtain preliminary positive HIV self-test results. This proposal builds on years of formative work with MSM in China conducted by this team of investigators (previous NIH grant # R34MH106349), demonstrating promising effects from a pilot RCT and strong indication of intervention acceptability, feasibility, and cultural sensitivity. The intervention uses the "WeChat" mobile app platform, which offers multiple features built into the app that facilitate health information delivery and communication channels (e.g., capacity for private texts, group chats, video sharing, GPS, instant messaging, real-time audio and visual communication). This protocol is funded by the US National Institutes of Health, and includes three phases of research activity over 5 years. ***Phase 1*** (Year 1) involves use of online focus groups to refine the WeTest-WeLink intervention to incorporate additional and updated content regarding: the HIV care continuum, linkage to care for HIV-positive people and ART treatment; support and affirmation for those testing HIV-positive; and programming of GPS resources to assist participants in identifying care. Identification and incorporation of additional updated content will be guided by the Information-Motivation-Behavioral (IMB) theory of behavior change and Minority Stress Theory, and based on findings from focus groups to be conducted with MSM from study settings. ***Phase 2*** (Years 2-4) is a prospective 2-group RCT of 1,800 MSM recruited from 3 sites: Chengdu, Suzhou, Wuhan. Participants will be randomized to the control group or to the WeTest-WeLink intervention. Primary and secondary outcomes include: i) repeat HST at 6, 12, and 18-month follow-up, ii) linkage to care for those who test HIV-positive. Additional analysis will explore effects on behavioral HIV risk, engagement in HIV community-based prevention services, and theoretical mechanisms of behavior change. ***Phase 3*** (Year 5) involves qualitative examination with key constituents regarding implementation features specified within the CFIR.

RESEARCH PROTOCOL

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

Specific Aims

The overarching objectives for this R01 research project are to test the effectiveness of an mHealth intervention entitled "WeTest-WeLink" that will increase repeat HIV self-testing (HST) among MSM, and to examine the efficacy of "WeTest-WeLink" on linking individuals who test positive to HIV care. Based on a successful 3-year R34 NIMH-funded pilot study conducted in Hefei, Anhui Province, we established proof-of-concept for the use of the WeChat app to promote HIV self-testing with MSM. In the current 5-year R01 NIMH-funded research, we will employ a user-centered design process to refine and expand app features (e.g., app-based HIV and health promotion messages, videos, GPS maps, private groups and two-way communication channels) to support repeat HST uptake, behavioral risk reduction, stigma coping strategies, and self-efficacy to link to HIV care. With the goal of increasing sustainable behavioral changes and examining the scalability of this proposed intervention, we will subsequently conduct a formative evaluation on the implementation of the intervention. The goal of this R01 application will be accomplished by using an Effectiveness-Implementation Hybrid Type 1 design consisting of a three site, 2-arm RCT to quantitatively test the intervention's effects on primary and secondary outcomes (repeat HST, linkage to HIV-related care) as well as qualitative research to examine implementation and scalability. We will recruit 1,800 HIV negative MSM, who will be allocated to the intervention (access to the WeTest-WeLink app) or control group (basic information about HST and passive referral to HIV care for individuals who test HIV positive). We will assess participants at 6-, 12-, and 18 months to measure intervention effects on primary outcomes: use of HST (including photographic confirmation) and linkage to care for individuals who test HIV-positive. Secondary outcomes include sexual risk behaviors and use of HIV prevention services, and we will conduct mediation analysis to examine theoretical mechanisms of behavior change. We will qualitatively assess intervention-related process characteristics that enable and/or impede implementation and scalability informed by the Consolidated Framework for Implementation Research (CFIR).

The aims of this 5-year research program are the following:

Specific Aim 1. To evaluate the effectiveness of the WeTest-WeLink intervention on HST behaviors

- Hypothesis 1: Greater proportion of HST every six months, confirmed by photographic evidence of test results, in the intervention vs control group

Specific Aim 2. To evaluate the efficacy of the intervention on linkage to HIV related care

- Hypothesis 2. Greater proportion of participants who test HIV+ in the intervention will be linked to care vs control group

Specific Aim 3. To inform broad scale implementation by assessing intervention barriers, facilitators, and potential adaptations for optimal uptake and sustainability

- Hypothesis 3. Key informants will identify key intervention features that can enhance subsequent implementation and scalability in real-world, ecological settings

Background

Studies of MSM in China have found that stigma contributes to the underutilization of HIV prevention and testing services and to the underestimation of personal HIV risk behaviors. Many MSM refrain from accessing HIV prevention and testing offered through health clinics or local Centers for Disease Control (CDC) offices, out of fear of disclosing their same-sex behavior to physicians or CDC officials. A systematic review found that 62% of Chinese MSM had not been tested in the past 12 months and about half of them had never been tested for HIV in their lifetime. Low rates of testing and undiagnosed HIV infection pose substantial risks for furthering the growth of China's HIV epidemic. Interventions are urgently needed to increase rates of HIV testing for MSM in China as well as to facilitate linkage to care for those who test positive in order to disrupt the expanding epidemic in this population.

The use of mobile technologies to promote healthier behaviors ("mHealth") opens new avenues for support the use of HST. Emerging data suggest that delivery of HIV-prevention messages via mobile phone "apps" represents a feasible and acceptable way to encourage HIV testing and to lower HIV risk behaviors. In the context of HST, mobile phone apps can send text or video instruction on specimen collection and test result interpretation. In addition, automated app-delivered messages can provide timely, confidential, and convenient information to motivate risk reduction, retesting, and necessary referrals to care.

Preliminary Research

In our prior 3-year NIMH-funded project, we developed and pilot-tested the WeTest intervention to provide proof-of-concept for the use of WeChat to promote HIV self-testing. Development of WeTest involved iterative rounds of quantitative and qualitative research with MSM in China to identify intervention targets and MSM-sensitive delivery processes for app-based HIV communication, messaging, and referrals. WeChat development was based on the Information-Motivation-Behavior (IMB) theory, a widely accepted, evidence-based approach to promoting HIV-related behavior change. In accordance with this theory, WeChat provided accurate and up-to-date HIV prevention information (about HIV transmission, prevention strategies, testing recommendations, living with and treatment for HIV, local HIV epidemiology in MSM populations), messages and stories to motivate risk reduction, and guidance and self-efficacy to engage in risk reduction behaviors. In addition, WeChat was informed by Minority Stress Theory, a framework that explicates the role of social stigma as a factor contributing to maladaptive health behaviors, including risk for HIV transmission in MSM. In accordance with this theory, WeChat included messages and short articles (vignettes, first-person narratives) to support participants' MSM identities and affirm their same-gender sexuality, used empowering language, and provided information/referrals regarding local MSM-serving NGOs that advocate for the needs of this population. WeChat offered standard content – videos, fact sheets, local linkage/referral information, two-way communication feature – which was permanently available on the main WeChat landing page. WeChat also sent two additional weekly messages to participants' "message feed" – including brief informational articles about HIV, STIs, and HIV testing; first-person stories about people living with HIV; local data about HIV and STI infections among MSM; news about national policies related to HIV; and stories about general health concerns of MSM – drawn from a library of pre-prepared messages/stories for this project.

Over a 3-month outreach and recruitment period, the study team recruited and enrolled 100 MSM participants into the pilot RCT and examined the acceptability, feasibility, and 6-month outcomes on HIV testing and condom use. All participants enrolled (100%) were retained at 6-month follow-up. At follow-up, participants in the intervention group had increased uptake of oral HST following baseline procedures (adj. RR=2.17, 95%CI: 1.08-4.37) and increased trust in use of oral HST (adj. RR=2.28, 95%CI: 1.15-4.51), compared to the control. Nearly all (98%) of those who reported using HIV self-test kits uploaded and submitted photographic confirmation of their test

results to study staff via the secure WeChat project portal. This high submission rate is indicative of the potential utility for remote health workers to counsel, refer, and provide linkages to care for people who test positive. Overall, 10 individuals tested positive and all received immediate linkages to care. In qualitative exit interviews, intervention participants commented favorably about app-based approach for supporting HST and prevention, the ability to communicate with online remote counselors for questions and referrals, the discrete nature of the app as a way to avoid uncomfortable disclosure, and the focus on MSM-based support and identity affirmation. These results provide compelling support for the feasibility and acceptability of WeTest, and demonstrate the team's ability to recruit and implement a mHealth intervention for this population.

Methods

This 5-year project involves 3 phases of research.

Phase 1 involves use of online focus groups to refine the WeTest-WeLink intervention to incorporate additional and updated content regarding: the HIV care continuum, linkage to care for HIV-positive people and ART treatment; support and affirmation for those testing HIV-positive; and programming of GPS resources to assist participants in identifying care. ***Phase 2*** is a prospective 2-group RCT of 1,800 MSM. Participants will be randomized to the control group or to the WeTest-WeLink intervention Primary and secondary outcomes include: i) repeat HST at 6, 12, and 18-month follow-up, ii) linkage to care for those who test HIV-positive. Additional analysis will explore effects on behavioral HIV risk, engagement in HIV community-based prevention services, and theoretical mechanisms of behavior change. ***Phase 3*** involves qualitative examination with key constituents regarding implementation features of the program.

Recruitment and retention:

We will recruit participants using the following strategies:

1. In-person Recruitment. Study staff will approach men in known venues identified in previous research where the target population congregates (e.g., bars, cafes, bookstores). They will take individual men aside and tell them about the study, provide small study cards or fliers to interested individuals, and encourage them to contact the study office if interested. If an individual is interested and wants to set up an appointment, study staff will schedule a time for the intake.

2. Online Recruitment. Study recruitment staff will create profiles on known websites in China where members of the local target population spend time (e.g., Blued, Aloha), following recruitment procedures used successfully in the team's previous research with MSM in China. They will identify themselves as conducting a men's health study. If a member of the target population approaches study staff online, they will explain the project, and will offer to do a screener over the phone. If the potential participant is eligible, they will schedule an intake appointment with a member of the study staff.

3. Community-based Referrals. Study recruitment staff will make presentations about the study to staff at relevant community-based organizations and service agencies in each target city. They will discuss the general study, and will also leave recruitment materials. They will ask staff to refer potential participants to the study by giving men the recruitment materials and encouraging them to contact study staff if interested.

Phase 1 (Year 1): Intervention update and refinement.

The purpose of Phase 1 is to update and refine the intervention content using focus groups, which will allow us to expand app features (e.g., app-based HIV and health promotion messages, videos, GPS maps, private groups and two-way communication channels) to support uptake and repeat use of HST, behavioral change, stigma coping strategies, and self-efficacy to link to HIV care. All focus group discussions will be conducted using remote online procedures (via WeChat or Zoom).

Participants. We will conduct 12 focus groups total – 4 focus groups per research site (Chengdu, Suzhou, Wuhan). (i) We will conduct 6 focus groups with HIV-positive MSM (2 focus

groups per site; n=4 participants per group). (ii) We will also conduct 6 focus groups with HIV-negative MSM (2 focus per groups; n=4 per group) (48 Phase 1 participants total). Due to concerns related to COVID-19, focus groups will occur via the Internet.

Participants must be: aged 18 years or older; possess a mobile "smart" phone; experienced using WeChat; had condomless anal sex with another man in the past 6 months; reside in the site for at least 6 months. HIV-positive MSM focus groups will discuss their experiences receiving an HIV-status diagnosis, linkage to care, stigma coping and support needs. HIV-negative MSM focus groups will discuss anticipated challenges in repeat HST, anticipated barriers to care, risk reduction, and stigma coping and support needs. Additional focus groups may be held depending on need for data saturation. We will attempt to maximize diversity within focus groups in order to represent MSM of varying ages, education levels, and prior engagement in HIV prevention/testing. Eligible participants will receive a detailed description about the study and complete informed consent procedures. HIV-positive participants will be informed that participation will involve discussing their HIV status in the presence of other HIV-positive MSM; they will be given the option to complete individual interviews upon request.

Procedures. Individuals who respond to recruitment efforts will be screened by a project staff member, using either the WeChat calling feature or at an in-person meeting at a collaborating NGO project office. Those ineligible will be excused and receive an electronic link or physical brochure with referrals to health services and recommendations about HIV prevention and testing. Those eligible will continue with the procedures described here. Focus groups participants will be sent an invitation to a secure online/internet platform. We will begin focus groups with a demonstration of two videos that will be provided as standard content in the WeChat-WeLink app group. The first brief video, developed for use in the R34 pilot study, demonstrates use of the locally manufactured HIV-1/2 oral self-test test kits (ABON Biopharm Co. Ltd, in Hangzhou). ABON oral HIV self-test kits have 100% initial sensitivity and 99.7% specificity, and are endorsed for use by USAID and the Global Fund. The video demonstrates how to self-administer the testing device (using an oral swab, no blood required); the importance of checking for expiration date (typically two years from purchase); how to interpret the test results; what to do if results are positive; how to safely dispose of the testing device (a package for safely disposing the device is included in the kit). We will provide a second brief video demonstration about the importance of linking to an HIV care site after testing HIV-positive. This video addresses myths and stigma about receiving an HIV-positive diagnosis, and emphasizes linkage to care as a step toward obtaining ART medication and achieving viral suppression. The video will clarify that ART is provided free through the local CDC, and will underscore the importance of communication with providers, medication adherence, attendance at follow-up clinic appointments and the importance of viral suppression to minimize risk of transmission to others.

Focus group discussions will explore the appropriateness, relevance, and fit of the videos to population experiences and needs. Additional aspects of the WeChat platform and library of pre-prepared content will be presented: local linkage/referral information to MSM-affirming NGOs and health promotion sites; brief informational articles about HIV, STIs, and HIV testing; first-person stories about people living with HIV; local data about HIV and STI infections among MSM; news about national policies related to HIV; and stories about general health concerns of MSM. Focus group facilitators will encourage participants to consider strategies for improving and updating the video content, and will solicit input on additional videos, brief messages, fact sheets, vignettes/stories, and referral sites. We will demonstrate the two-way communication features, which will facilitate engagement with a study staff member for deeper advice or support, and we will demonstrate the GPS feature, which will facilitate location of and linkage to CDC offices and care clinics, local MSM-affirming NGOs, and other HIV prevention/education sites. We will ask focus group participants to consider the necessary forms of information, motivation, and behavioral skills as well as stigma coping strategies to support repeated HST and linkage to care. Focus groups facilitated by trained members of co-I Dr. Zhang's study team, will be audio recorded and participants will be compensated with 150 RMB (approximately 20 USD). An additional trained staff member will observe the discussions and take detailed notes from the

focus groups sessions, which will be summarized to reflect preferences and recommendations about message content, components, and delivery.

Qualitative Analysis. Audio recordings will be transcribed into Mandarin and translated into English by professional translation services. Following Braun and Clarke's thematic analysis framework, a team of coders will independently read the transcripts and convene regularly to discuss emerging themes. The coding process will begin with the team reading each participant interview multiple times in order to become familiar with the data. This will be followed by indexing themes and categories. All the data relevant to each category will be identified and labelled to establish categories using a systematic approach. MAXQDA software will be used for cross-indexing, sharing, and managing the data. At the conceptual level, analysis involves identification and summarizing patterns of experience related to HST self-administration, perceived facilitators and barriers to linkage to care, and preferences regarding app-based messages. At the descriptive level, the analysis involves identifying a diverse range of brief messages that can be delivered via mobile apps for motivating and encouraging repeat HIV testing and linkage. In addition, multiple coders will analyze subsets of the data and inter-rater reliability will be assessed; discrepancies will be resolved with discussion.

Based on findings from focus groups, we will update/enhance WeChat content, create/program new content, and compile additional resources that support repeat HST, linkage, and risk reduction.

Potential Risks and Benefits

1. There is a risk of loss of privacy or confidentiality of data, including sensitive data on sexual behaviors and psychological characteristics. We take this risk seriously, and we will take steps to protect participants' confidential data and anonymity. We will ensure that personal identifiers are removed from the data and any publications arising from the study. The informed consent documents will bring confidentiality risks to participants' attention. We will encourage participants to not disclose any content of the focus group discussions.

2. Participants may experience psychological discomfort while completing qualitative procedures, which will involve discussion or disclosure about HIV testing, sexual behavior, HIV status, and physical health. We will take steps to minimize any psychological discomfort. Research staff members will prepare a list of referrals to address potential psychological problems in the target populations.

3. The risk of loss of privacy will be controlled (as described above) by using unique participant ID numbers on all data rather than participant names. During the focus groups, participant will be informed that they can use a pseudonym in order to keep their identity/name unknown in the group discussions. We will develop a MOU with a professional transcription agency to assure that all names or identifiers are omitted from the transcripts, and that security protocols of all data recordings are maintained. Research staff be trained on confidentiality issues. Only essential staff members will have access to data and research files.

4. Participants may not receive any benefit for participating in this research project other than having the opportunity to learn more about HIV self-testing and HIV-related sex risk behaviors. This may lower their chance of exposure to HIV and other sexually transmitted infections in the future.

Inclusion of Women and Minorities

All (100%) of the participants will be males ages 18 and over. In accordance with the research aims, 100% of participants will be non-White racial/ethnic minority individuals. All (100%) of the participants will be Chinese (Asian).

Confidentiality

In order to protect study participants from potential risks related to the breach of confidentiality, the following steps will be taken: 1) All information provided by the participant will be referenced to a participant ID# and will be kept in locked file cabinets. The patient's ID# can be connected to the participant's name only through a single master file, accessible only to authorized senior research staff and kept locked in a file separate from the data files. All data files entered on computers will be protected by passwords and computer disks will be maintained in locked file cabinets. 2) All research staff will be trained in the importance of maintaining confidentiality of the information obtained from patients and will undergo the mandatory NIH training in protection of human research participants. 3) All data collected from the participants will be presented in aggregate form and no participants will be identified individually.

Audiorecordings will be identified only by participant ID# and interviewer. All digital audiorecordings will be stored in password-protected computer files. Participants will be made aware of the use of audiorecording during the informed consent process. Audiorecordings will be destroyed following completion of primary analyses. Transcriptions will be stored in secure, locked computer files indefinitely.

Informed Consent to Participate in Research

Study Phase 1

Introduction/Objective: You are being invited to participate in a research study conducted by Anhui Medical University. Collaborators for this project are Brown University, University of Arkansas Medical Sciences, and Johns Hopkins University (USA). The objectives of this research are to learn how to use WeChat to support people who use 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) comfortable using WeChat.

Procedures: If you agree to participate, the following will happen:

- You will participate in an online focus group discussion
- You will observe two video demonstrations about how to use the HIV self-test kit, and about the importance of HIV care for people with positive test results.
- You will participate in a group discussion about your opinions of the videos, and provide feedback about how to use WeChat to improve HIV self-testing and linkage to HIV care for MSM. If you do not want to participate in a group discussion, you can choose to participate in an individual interview instead.
- We will be recording the focus group discussion and we will transcribe the recordings. We will remove any personal identifying information from transcripts to protect your and others' privacy and confidentiality. Members of the research team will analyze the written transcripts.

Benefits: There is not a direct benefit for you for participating in this research project. If you agree to participate, you will be collaborating with Anhui Medical University and their partners to research how to improve HIV testing among men who have sex with men in China.

Potentials Risks/Discomforts: Some of the questions 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. 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 150 RMB for your participation in this study.

Confidentiality: Your participation in this study will be entirely anonymous. We will not record your name. You do not have to sign any forms. Your answers to the questions in the interview, which we will record and transcribe, will be used solely for the purpose of this study. No names will be reported to anyone.

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 Zhang Hongbo, the Principal Investigator in charge of the project, at the following telephone number: 0551-5161169-8201 between 10:00 a.m. to 6:00 p.m.

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 (Optional)	Signature of Participant (Optional)

Date

Recruitment information
(for social media and internet sites)

Volunteers Needed to Participate in a Research Project.

We want your help to develop an effective program to reduce HIV and promote health for tongzhi (local word for men who have sex with men).

Volunteers will participate in a confidential small-group discussion over the internet. Volunteers will watch brief videos about HIV testing and health services, and they will learn more about the intervention program. Volunteers' will provide feedback to help improve the intervention program.

Volunteers will receive 150 RMB for their participation.

Please email XXXXX or call XXXXX if you are interested.

WeTest – WeLink Focus Group Discussion Guide

Welcome and thank you for volunteering to take part in this focus group. You have been asked to provide feedback on a new WeChat public account /公众号 "WeTest-WeLink" we are developing to promote HIV self-testing and to assist linkage to HIV care or prevention services. We want to sincerely express our appreciation for your time and input.

Introduction: This focus group discussion is designed to gather your thoughts and feelings regarding "WeTest-WeLink". We will show you various components of "WeTest-WeLink" and ask your feedback regarding content, applicability, features, and visual attractiveness. The primary purpose of this discussion is to capture feedback from potential users like you, and thus all candid feedback is appreciated. This focus group discussion will take no more than 90 minutes. As we informed you earlier, we would like to record this audio component of this discussion to help us remember and review comments from this group discussion. If anyone has a concern with recording. We will not be recording the visual component of this discussion. If anyone has concerns about recording the audio discussion, please use the Zoom/WeChat function to notify the research assistant, and that person will discuss your concerns privately. (Switch on the recorder on Zoom/WeChat for all members who remain in the discussion).

Confidentiality: Despite being audio recorded, I assure you that the discussion will be confidential. The recording will be stored in a highly secured server until it is transcribed word for word, and then it will be destroyed. Recordings will be accessed only by the study team through secure means. The transcribed notes of the focus group will contain no information that would allow individual participants to be linked to specific statements. You should try to answer and comment as accurately and truthfully as possible. I and the other focus group participants would appreciate it if you would refrain from discussing the comments of other group members outside the focus group. If there are any questions or discussions that you do not wish to answer or participate in, you do not have to do so; however, we certainly welcome all feedback you may have during the course of the discussion.

Ground rules

- The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
- There are no right or wrong answers.
- You do not have to speak in any particular order.
- When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you, if you want to contribute.
- You do not have to agree with the views of other people in the group.

Does anyone have any questions? (answers) OK, let's begin.

Warm up
First, I'd like everyone to briefly introduce themselves. Can you tell us your given name (not your family name) or a nickname and tell us about one thing about yourself that you want to share with the group, such as your hobby.

WeTest WeLink Demonstration – First Round:

I am going to show you some sample content and layout of the content as it currently exists. I am going to show each feature, along with content examples in their entirety. Then, we will individually go through each feature and content example.

During this first round, I would like you to pay attention to the content, features, and layout.

(go over the "WeTest-WeLink" account)

First Round Discussion Questions: Overall Impression

- What are your general impressions of the content after seeing it for the first time?
- What do you think of the current layout?
- Are there features that quickly caused a positive reaction when you saw them?
- Are there features that gave you pause when you saw them?
- After seeing it for the first time, how many of you would be excited to start using it?
- Do you anticipate challenges or difficulties in using this account? If yes, what challenges do you anticipate? [continue with follow-up questioning to individuals/group members].
- What would make the account more ideal for promoting HIV self-testing and assisting people who need to access HIV care or prevention services?

Second Round Discussion Questions

OK, let's go through the demonstration a second time, but we will pause after each feature is shown.

1. HIV self-testing demonstration video

Guiding Questions:

- What do you think of the video?
  - Usability
  - Positive/negative aspects of content
  - Understandability of the content

2. HIV linkage to care demonstration video

Guiding Questions:

- What do you think of the video?
    - Usability
    - Positive/negative aspects of content
    - Understandability of the content

3. Other content: The account will house content in different forms of media (e.g. video, short readings, memes, or short mentoring vignettes)

   Showing content is designed to provide information relevant to:

    a. Knowledge of HIV (e.g. details regarding HIV testing, effectiveness of condom use, risk associated with multiple partners, pre-exposure prophylaxis, treatment as prevention etc.)
    b. Linking to HIV care (e.g, details regarding CDC locations, intake and registration, confidentiality, ART medications, regular appointments, ongoing clinical assessments)
    c. Linking to HIV prevention services (e.g. resources for testing sites, counseling and support services, behavioral prevention, biomedical prevention).

Guiding questions:

- What do you think of the types of content you viewed?
- What do you think of the specific content examples we provided?
    - Positive/negative reaction and reasoning
    - Suitability
    - Clarity
    - Relatability
- Are there other occurrences where you think receiving a notification might be needed or useful?

Wrap-up questions

- Of all the things we've seen and discussed today, what would you say are the most important issues you would like to express as the WeTest-WeLink" development process moves forward?

Conclusion

- Thank you for participating. This has been a very successful discussion.
- Your opinions will be a valuable asset to the study.
- We hope you have found the discussion interesting.
- I would like to remind you that any comments featuring in the report coming from this discussion will be anonymous. What you shared in this discussion will only be shared with the research and app development teams.

Informed Consent to Participate in Research

Study Phase 2

Introduction/Objective: You are being invited to participate in a research study conducted by Anhui Medical University. Collaborators for this project are Brown University, University of Arkansas Medical Sciences, and Johns Hopkins University (USA). The objectives of this research are to use WeChat to support people who use 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) comfortable using WeChat.

Procedures: If you agree to participate, the following will happen:

- You will complete a survey to assess
- You will observe two video demonstrations about how to use the HIV self-test kit, and about the importance of HIV care for people with positive test results.
- You will participate in a group discussion about your opinions of the videos, and provide feedback about how to use WeChat to improve HIV self-testing and linkage to HIV care for MSM. If you do not want to participate in a group discussion, you can choose to participate in an individual interview instead.
- We will be recording the focus group discussion and we will transcribe the recordings. We will remove any personal identifying information from transcripts to protect your and others' privacy and confidentiality. Members of the research team will analyze the written transcripts.

Benefits: There is not a direct benefit for you for participating in this research project. If you agree to participate, you will be collaborating with Anhui Medical University and their partners to research how to improve HIV testing among men who have sex with men in China.

Potentials Risks/Discomforts: Some of the questions 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. 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 150 RMB for your participation in this study.

Confidentiality: Your participation in this study will be entirely anonymous. We will not record your name. You do not have to sign any forms. Your answers to the questions in the interview, which we will record and transcribe, will be used solely for the purpose of this study. No names will be reported to anyone.

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 Zhang Hongbo, the Principal Investigator in charge of the project, at the following telephone number: 0551-5161169-8201 between 10:00 a.m. to 6:00 p.m.

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 (Optional)	Signature of Participant (Optional)

Date