

BMJ Open Community-engaged mHealth intervention to increase uptake of HIV pre-exposure prophylaxis (PrEP) among gay, bisexual and other men who have sex with men in China: study protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction The large number of key populations in China who would benefit from HIV pre-exposure prophylaxis (PrEP) in the context of limited health system capacity and public awareness will pose challenges for timely PrEP scale-up, suggesting an urgent need for innovative and accessible interventions. This study aims to develop and pilot test a theory-informed, tailored mobile phone intervention that was codeveloped by young gay men, HIV clinicians and public health researchers to increase engagement in PrEP education and initiation among Chinese gay, bisexual and other men who have sex with men (GBMSM), who bear a disproportionate burden of HIV infections and remain underserved in the healthcare system.

Methods and analysis This two-phase study includes a formative assessment using in-depth interviews (N=30) and a 12-week experimental pilot study using a two-arm randomised controlled trial design (N=70). The primary intervention is delivered through a WeChat-based mini-app (a program built into a Chinese multipurpose social media application) developed by young GBMSM from a 2019 crowdsourcing hackathon. Using mixed methods, we will further investigate the specific needs and concerns among GBMSM in terms of using PrEP as an HIV prevention strategy, how their concerns and PrEP use behaviours may change with exposure to the mini-app intervention during the study period and how we can further refine this intervention tool to better meet GBMSM's needs for broader implementation.

Ethics and dissemination This study and its protocols have been reviewed and approved by the Institutional Review Boards of the University of North Carolina at Chapel Hill, USA (19-3481), the Guangdong Provincial Dermatology Hospital, China (2020031) and the Guangzhou Eighth People's Hospital, China (202022155). Study staff will work with local GBMSM community-based organisations to disseminate the study results to participants and the community via social media, workshops and journal publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The intervention app prototype was cocreated by the gay, bisexual and other men who have sex with men (GBMSM) community, HIV clinicians and public health researchers through a gay-friendly doctor finder hackathon—a crowdsourcing strategy that solicits innovative public health solutions directly from the end-user community, increasing the intervention's acceptability and potential impact among target communities.
- ⇒ The intervention content development was guided by the Information, Motivation and Behavioral Skills Model, a theoretical model of behavioural change that has been widely applied in HIV-related behavioural intervention studies among different populations including Chinese GBMSM.
- ⇒ Mobile health interventions for HIV prevention and sexual health promotion are feasible and highly acceptable among Chinese GBMSM due to their privacy, portability and convenience, facing the broad spread of HIV-related and gay-related stigma in Chinese society.
- ⇒ The study design follows the best practice of intervention development that includes a formative assessment of unmet needs, cocreation with the community, pilot testing for preliminary evidence of efficacy and providing preliminary data for a future larger-scale intervention study.
- ⇒ The intervention allows participants to make online pre-exposure prophylaxis (PrEP) appointments at the only local HIV hospital in the study city, and an initial in-person clinical visit is still required for PrEP prescription. It is also a timely response to China's recent approval of tenofovir-emtricitabine as PrEP in 2020, which we believe could facilitate a rapid scale-up of PrEP among populations at risk of HIV infection in China.

Trial registration number The study was prospectively registered on clinicaltrials.gov (NCT04426656) on 11 June 2020.

INTRODUCTION

HIV prevalence among gay, bisexual and other men who have sex with men (GBMSM) in China has steadily increased over the past 5 years.^{1–3} In Guangzhou, a major economic centre in southern China, the HIV prevalence among sexually active GBMSM increased from 3.9% in 2009⁴ to 11% in 2017.⁵ Individual and contextual risk factors associated with HIV acquisition among Chinese GBMSM include condomless sex, high rates of ulcerative sexually transmitted infections (eg, syphilis), use of recreational drugs during sex, gay entertainment venues (eg, public bathhouse) and social and sexual networking mobile phone applications.^{1 6–11} Taken together, these risk factors suggest that Chinese GBMSM could benefit from additional HIV prevention strategies such as pre-exposure prophylaxis (PrEP).

However, the overall awareness of PrEP among Chinese GBMSM remains relatively low and varies across samples. Generally 20%–75% of GBMSM respondents reported having heard of PrEP in China-based studies.^{12–14} By July 2021, there was an estimated number of 6000–6500 PrEP users reported from official demonstration projects in this country.¹⁵ Cross-sectional surveys^{12 16–24} and PrEP clinical trials^{25–27} and in-depth interviews with HIV-negative GBMSM^{26 28} have reported perceived barriers to PrEP uptake among Chinese GBMSM including concerns about side effects, financial cost and low HIV risk perception. Yet, little is known about multilevel barriers to PrEP uptake and maintenance in China, especially from those with PrEP using experience. Further, there is widespread HIV-related and gay-related stigma and discrimination in clinical settings^{29–31} that may inhibit the effective delivery of PrEP drugs and related services for GBMSM.³²

The China National Medical Products Administration approved tenofovir–emtricitabine (TDF–FTC) as HIV PrEP in China on 11 August 2020. However, the aforementioned gaps highlight the need for innovative, culturally appropriate and GBMSM-friendly tools that prepare GBMSM for PrEP uptake, to pave the way for a rapid scale-up. Facing the broad spread of HIV-related and gay-related stigma in Chinese society, mobile health (mHealth) interventions for HIV prevention and sexual health promotion are feasible and highly acceptable among Chinese GBMSM due to their privacy, portability and convenience.^{33–35} Health hackathons as a crowdsourcing approach are an effective and convenient way to mobilise GBMSM communities in generating innovative mHealth solutions to meet their own health needs,³⁶ which could further potentially contribute to reductions in internalised stigma and an increase in community resilience among sexual minority populations.^{37 38}

Globally, limited data exist on the efficacy of app-based interventions aimed to increase PrEP uptake among GBMSM. Among the few published mHealth PrEP

intervention efficacy studies, text messaging has been effective in improving PrEP adherence in GBMSM via reducing missed doses.^{39 40} More mHealth PrEP uptake intervention studies are underway, however, all are in high-income countries.^{41–44} To date, little is known about the optimal design and efficacy of using mHealth-enabled interventions for PrEP promotion in Chinese populations, especially among GBMSM.

Aims and objectives

This study focuses on developing and testing a tailored mobile app-based intervention built on our previous work from a gay-friendly doctor finder hackathon in China,⁴⁵ aiming to increase engagement in PrEP education and initiation and generate hypotheses that explain potential behavioural pathways to PrEP uptake among Chinese GBMSM. The study site is Guangzhou, a major economic centre of southern China. To this end, the study has two phases: Phase I collects formative data using in-depth interviews to assess unmet needs in HIV prevention (PrEP in particular) and sexual health among HIV-negative GBMSM and test and refine the usability of the mini-app. Phase II will implement a two-arm randomized controlled trial (RCT) to assess the feasibility and preliminary evidence of the efficacy of the refined mini-app in increasing intention to use PrEP and PrEP initiation among HIV-negative GBMSM. Specific aims include:

Aim 1

Generate hypotheses around behavioural pathways explaining PrEP uptake among Chinese GBMSM with different PrEP using experience (eg, PrEP-naïve, former and current PrEP users) by analysing qualitative data from in-depth interviews of the formative assessment (phase I, n=30).

Aim 2

Assess the feasibility and preliminary efficacy evidence of a mobile phone-based PrEP education intervention tool (the mini-app) compared with the standard of HIV prevention care in increasing individual intentions to use PrEP and actual PrEP initiation rate through a two-arm pilot RCT (phase II) with 70 HIV-negative GBMSM (18 years old and above) in Guangzhou, China.

METHODS AND ANALYSIS

Theoretical foundation for intervention

Figure 1 presents the study's conceptual model. The intervention content development is informed by the Information, Motivation and Behavioral Skills Model (the IMB model). The IMB model proposes a mediational framework that hypothesises that the performance of many health-related behaviours is determined by three core constructs: information, motivation and behavioural skills.⁴⁶ With years of application in HIV research, the IMB model has been widely applied in intervention studies and adapted to promote specific HIV-related behaviours,

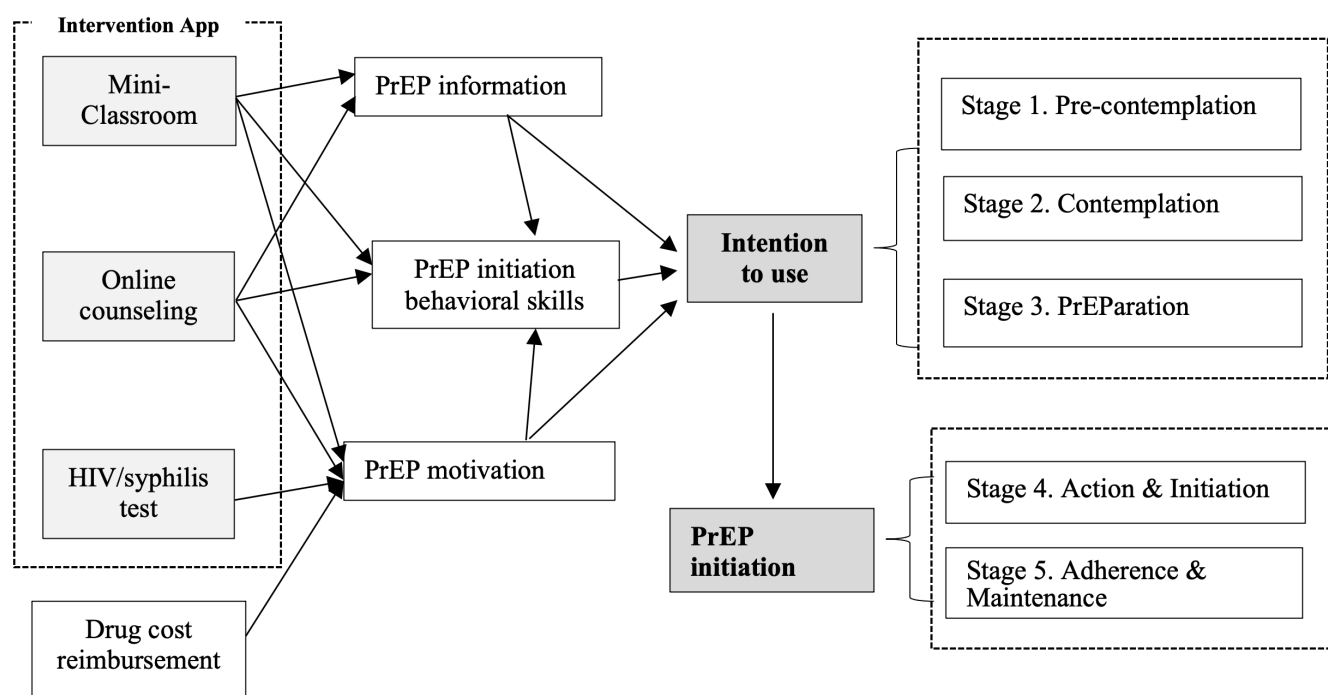


Figure 1 The conceptual model of the WeChat mini-app pre-exposure prophylaxis (PrEP) intervention.

including PrEP care-related behaviours.^{47–49} Among Chinese GBMSM, the IMB model was also found useful in explaining HIV preventive behaviour such as condom use.⁵⁰ We also use the Motivational PrEP Cascade (MPC),⁵¹ originally proposed by Parsons *et al* who combined the concept of PrEP care cascade⁵² and the transtheoretical model of behavioral change, to inform the measurement of the several stages of behavioural change culminating in PrEP initiation. The MPC outlines stages of readiness to make a behavioural change, including precontemplation, contemplation, preparation, action and maintenance of the change.⁵³ A 2018 survey study based on the MPC among a sample of 708 HIV-negative GBMSM from multiple major cities in China showed that 53% of the respondents who were PrEP eligible were in the precontemplation stage, 36% were in contemplation stage, 9% were in preparation stage, 2% were in PrEP action and initiation stage and none were in adherence and maintenance stage.¹⁷ Given variable awareness about PrEP and the wide range of age of the target population, measuring the stages of change toward PrEP initiation will help us better tailor and refine the intervention.

Patient and public involvement: development of the intervention tool – PrEP education WeChat mini-app

The intervention is delivered via a WeChat-based mini-app (a program built within an existing commercial application) that was developed by a team of young GBMSM from a GBMSM-friendly doctor finder hackathon contest.⁴⁵ This hackathon contest was part of a series of crowdsourcing events that aimed to engage the GBMSM community in generating public health innovations

in HIV and sexual health promotion in China. From February 2018 to March 2018, the Shenzhen University College of Mass Communication, the non-profit organisation Social Entrepreneurship to Spur Health (SESH) and Blued (the largest gay social networking app in China) held a crowdsourcing contest for designing concepts of a mobile phone-based, GBMSM-friendly doctor mobile app. In July 2018, four focus group discussions with 38 GBMSM in Guangzhou and Shenzhen were subsequently conducted to solicit participants' feedback on refining the app design.⁵⁴

From December 2018 to April 2019, UNC Project China with support from SESH and Blued hosted a GBMSM-friendly doctor finder hackathon in Guangzhou, during which the participants were asked to develop a mobile phone-based doctor finder prototype based on the work from previous events. A total of 38 participants grouped into eight teams attended the final hackathon contest and developed eight prototypes after a 72-hour hacking. Four prototypes adopted the mode of a mini-app embedded within WeChat, and three prototypes were designed as stand-alone apps and one was designed as a tool that can be adjusted to multiple platforms. One of the WeChat mini-app prototypes was adapted for use in the current study. WeChat (Android and iOS) is a social platform in China with over one billion active users⁵⁵ that has been widely used for public health education by Chinese health administrations and private organisations.⁵⁶ The WeChat app allows developers to build new app programs (ie, the mini-app) within the platform that are accessible without additional download or installation.

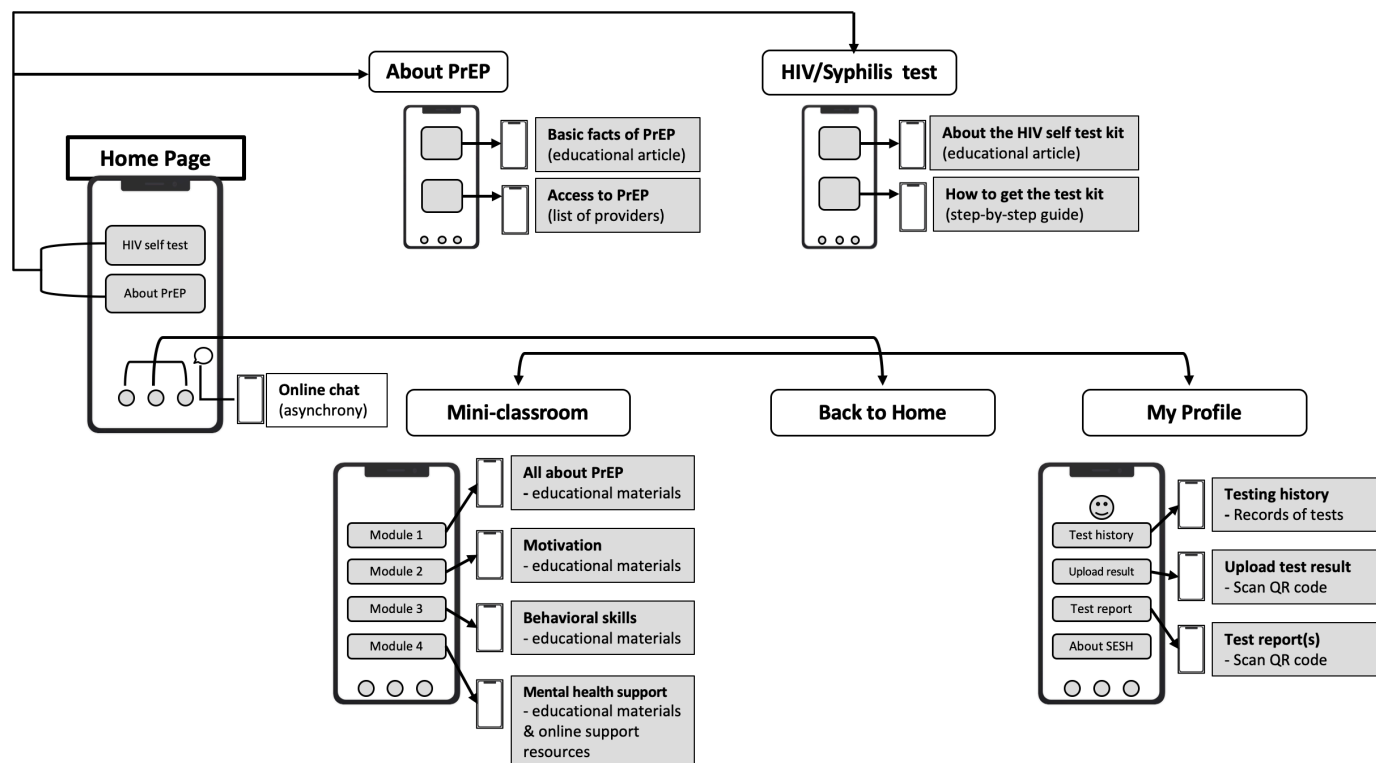


Figure 2 Wireframe of the mini-app pre-exposure prophylaxis (PrEP) intervention. SESH, Social Entrepreneurship to Spur Health.

Before testing and evaluating the mini-app in the current study, we invited a group of key community stakeholders including gay men, sex educators and local HIV-related community-based organisation (CBO) workers to test the mini-app prototype and provide valuable feedback in user-interface design and choice of educational materials. The main features of the version of the interventional mini-app for the current study include: (1) the mini-classroom; educational materials which cover topics of HIV and sexually transmitted infections (STI), PrEP and postexposure prophylaxis and mental health, aiming to change participant's information, motivation and behavioural skills to initiate PrEP; (2) an at-home HIV/syphilis dual testing kit ordering system; (3) chat-based online counselling; (4) and a user profile centre (their account in the mini-app is automatically linked to their WeChat account with the user's permission). The overall structure of the mini-app is illustrated in figure 2 and a detailed description of the main features is presented in online supplemental table 1.

Phase I: formative research – needs assessment and mini-app testing

Study design

In phase I, we conduct in-depth interviews among Chinese GBMSM to understand the key barriers and facilitators of using PrEP. We also assess participants' perceived usability of the intervention mini-app during the interview. All one-on-one interviews are conducted by the principal investigator via videoconference

(audio-recorded with participants' permission) and last 60–90 min. The principal investigator (CL) is a PhD candidate in health behavior with over 10 years training in public health and 5 years research experience in HIV prevention and LGBTQ health among Chinese populations in particular. We use a semistructured interview guide (online supplemental table 2) with tailored questions for participants with and without PrEP experience. Interview topics cover knowledge, attitudes and willingness to use PrEP and/or PrEP use history, preference over PrEP regimens (daily vs event-driven dosing, oral vs long-term active injectable PrEP) and delivery modes and past pathways, barriers and facilitators to HIV testing and PrEP services. During the interview, participants are introduced to the mini-app design and features, use the mini-app for 5–10 min, complete a 10-item app usability scale (System Usability Scale^{57 58}) and discuss the app's design, contents and ease of use. Following the interview, each participant completes a brief demographic survey via Wenjuanxing, an online survey tool in China. All interviews will be transcribed in Chinese and analysed using the qualitative analysis platform, Dedoose.⁵⁹ The qualitative analysis will be conducted in Chinese with the translation of exemplary content for English-language publications. The principal investigator (CL) will take the lead role in applying a thematic analysis-based approach⁶⁰ for identifying, analysing and reporting patterns within the data. The other research team members will be actively engaged in the monitoring of data collection process and proving continuous

feedback on data analysis and interpretation via regular meetings with CL.

Participants

To represent the variety of experience GBMSM has had with PrEP, we will conduct in-depth interviews with 30 Chinese GBMSM at different stages of the PrEP care continuum, including approximately 20 PrEP naive individuals, 5 prior PrEP users who are not currently on PrEP and 5 current PrEP users. This sample size is generally considered sufficient for thematic analysis to reach information saturation among a relatively homogenous group.⁶¹ While the mini-app is primarily designed for PrEP-naive GBMSM, including the perspectives of past and current PrEP users is intended to gain feedback on the intervention design and content based on experiences across the stages of change in PrEP adoption. Participants will be recruited through research advertising on Chinese social media and referral by local GBMSM-related organisations.

Eligibility criteria for phase I are: Chinese citizen and current resident, assigned male sex at birth, age 18 years and above, any lifetime anal sex with another man and willingness to sign (or e-sign) informed consent. Exclusion criteria include: self-reported HIV-positive status or reporting or demonstrating mental health issues which may compromise participant safety, including memory loss, cognitive impairment, intellectual disability or communication disorders.

Mini-app refinement

Before starting phase II, we will refine the mini-app based on participants' feedback on the app design from phase I formative assessment. Potential adjustments to the mini-app may be feasible in changing content and graphic and text appearance, but not functionality or structure of the app. All requests regarding functionality and app structure will be recorded and considered for future iterations of the app.

Phase II: pilot randomised controlled trial

Study design

Phase II will evaluate the feasibility and preliminary evidence of the efficacy of the mini-app in increasing intention to use PrEP and PrEP uptake through a two-arm pilot RCT comparing the mini-app to the standard of HIV prevention care (figure 3). The study is estimated to last up to 12 weeks, where the first 8 weeks is the active intervention period and the last 4 weeks is postintervention observation.

Study setting

A convenience sample will be recruited in Guangzhou, China, via SESH and local LGBTQ-related CBOs. Our partners—SESH, CBOs and the study hospital (the Guangzhou Eighth People's Hospital)—have extensive experience in providing research support on GBMSM-related and HIV-related studies in Chinese settings. The study physicians at Guangzhou hospital have years

Phase 2 Pilot RCT procedure

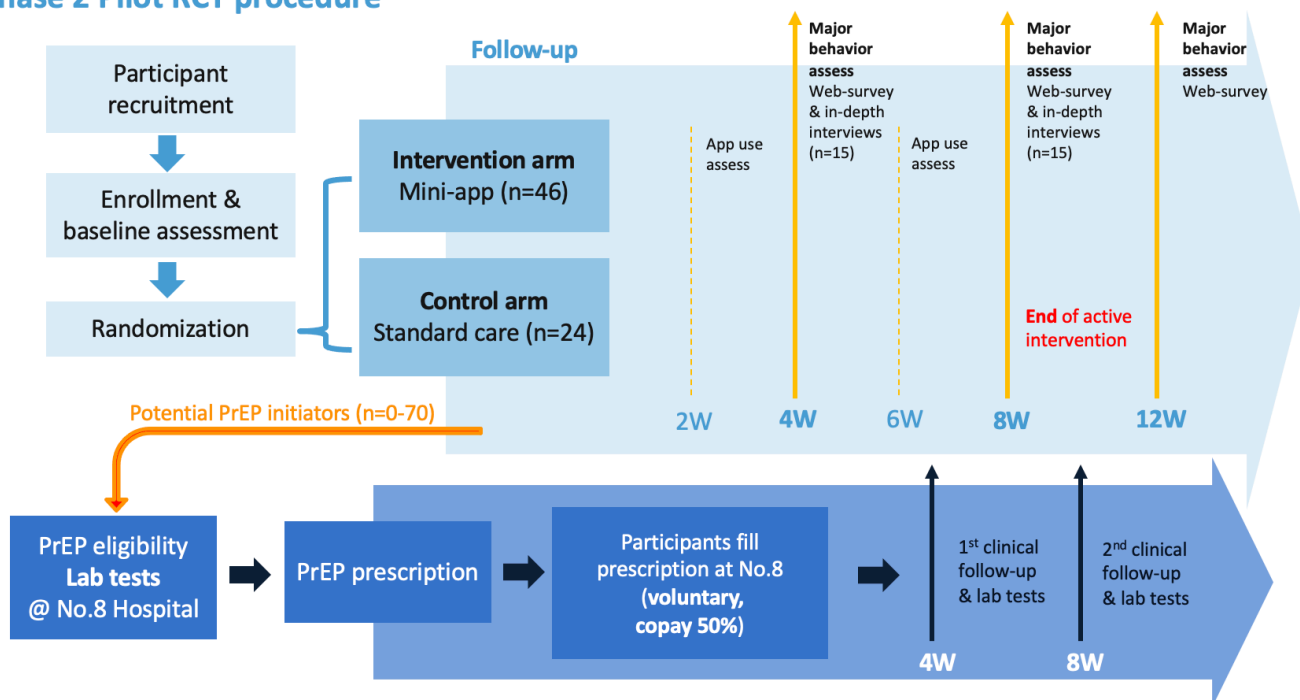


Figure 3 Phase II study design, a two-arm randomized controlled trial. Note: Participants can purchase PrEP medicines (TDF-FTC) from the study hospital. Participants pay for the medicine out of pocket and are reimbursed 50% of the cost at each monthly follow-up visit. PrEP, pre-exposure prophylaxis; TDF-FTC, tenofovir-emtricitabine.

Box 1 Pre-exposure prophylaxis (PrEP) mini-app phase II pilot randomized controlled trial inclusion and exclusion criteria

Inclusion criteria: Individuals must self-report:

- ⇒ Having a smartphone with WeChat installed.
- ⇒ Assigned male sex at birth, HIV negative, age 18 years and above, ever having had anal sex with another man, currently residing in Guangzhou, identifying as a Chinese citizen, able to sign written informed consent and participate in the study procedures as required.
- ⇒ At least one characteristic associated with the risk of HIV infection in the previous 6 months:
 - ⇒ Unprotected (condomless) receptive anal intercourse with a male partner(s).
 - ⇒ More than two male partners (regardless of condom use and HIV serostatus).
 - ⇒ Reported sexually transmitted infection, such as syphilis, herpes simplex virus (HSV-2), gonorrhoea, chlamydia, chancroid or lymphogranuloma venereum.
 - ⇒ Reported use of postexposure prophylaxis.
 - ⇒ Have a sexual partner living with HIV.

Exclusion criteria:

- ⇒ People living with HIV.
- ⇒ Currently taking oral PrEP based on self-report before enrolment.
- ⇒ Symptoms of acute HIV infection in the previous 30 days (eg, fever, flu-like symptoms).
- ⇒ Suspected exposure to HIV in the previous 72 hours.
- ⇒ Contraindications for taking oral PrEP.
- ⇒ Personal diagnosis or family history of haemophilia (self-report).
- ⇒ Participating in another research intervention study related to HIV or PrEP.
- ⇒ Having serious chronic disease, including metabolic diseases (such as diabetes), neurological or psychiatric disorders.
- ⇒ Mental health issues may compromise adherence or safety, including memory loss, cognitive impairment, intellectual disability or communication disorders.

of experience in both clinical practice and research with GBMSM patients. All study team members have completed the Collaborative Institutional Training Initiative (CITI) training in good clinical practice before the study starts.

Participants

A convenience sample will be recruited via partner CBOs and online advertising on Chinese major social medias, including WeChat and Sina Weibo. The generally recommended sample size of pilot trials ranges from 24 to 100.^{62 63} In this pilot test, we plan to enrol 70 participants to assess preliminary evidence of efficacy and feasibility for a future main trial. Those interested in the study will complete a verbal eligibility screening by the principal investigator (box 1). Those screened eligible will be scheduled for an initial in-person clinic visit or a virtual enrolment via videoconferencing. During this visit, they will complete informed consent and a baseline survey and be randomised to one of the two study arms.

Randomisation

We will conduct a permuted block randomisation that assigns the 70 participants to either the mini-app arm or the control arm in a 2:1 ratio. Randomisation sequence will be created using Stata V.16.0 (StataCorp LLC, College Station, Texas) with block size of six. The 2:1 allocation will be used to ensure the capture of the range of users' reactions to the mini-app and its content. The randomisation process will be conducted by a research assistant after the full consent process.

Study arms

Intervention condition: the PrEP education mini-app

The PrEP education mini-app (figure 4 presents the screenshots) serves as the primary participant-facing component of the intervention. Usage of the mini-app will be at participants' discretion or preference. Weekly reminders that encourage participants to use the mini-app will be sent out through WeChat messages. At this stage of development, the mini-app will not be able to track individual user information or activity. Self-reported app usage will be assessed in bi-weekly follow-up surveys and in-depth interviews at the 4th and 8th weeks. After week 8, participants in the intervention arm will no longer receive reminder messages but may continue using the mini-app throughout the whole study period—up to 12 weeks from the time of enrolment or continue using to the end of their first 2 months of PrEP use.

Standard of HIV prevention care

Participants in both study arms will receive standard HIV prevention care during the initial and final study visits, including printed or electronic HIV prevention materials about PrEP and HIV/STI testing, referrals to local prevention services and a description of the standard procedure to access PrEP through the study clinic.

PrEP initiation

Participants in both arms can choose to initiate PrEP through the research study at any time point from enrolment through the end of week 8. Participants who decide to start PrEP after week 8 will still be able to receive standard PrEP care at the study clinic, but they will not be eligible to receive complimentary physical examinations that are covered by this research project (please see details in Incentives section). Participants can contact the study team via phone call, text messages or the chat function in the mini-app (intervention arm only) to communicate their interest in PrEP initiation. Interested participants will be referred to the department of infectious diseases at the study hospital to consult a clinician regarding HIV risks and PrEP eligibility. As per protocols in the study hospital, participants starting PrEP will undergo standard of care comprehensive physical examinations including routine blood and urine examinations, hepatic and renal function tests and HIV/syphilis/HBV (hepatitis B virus)/HCV (hepatitis C virus) tests.

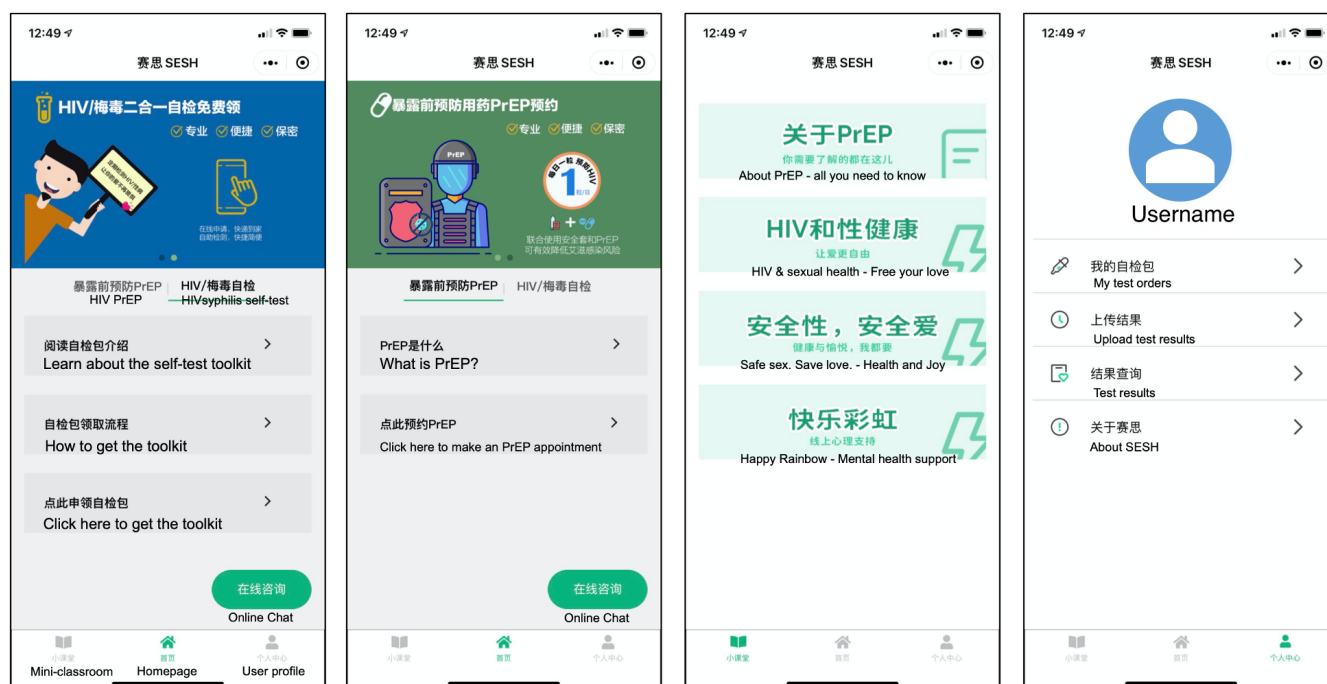


Figure 4 Screenshot of the mini-app from left to right: (1) Homepage 1: at-home test kit, (2) homepage 2: PrEP appointment, (3) the mini-classroom and (4) user profile centre. PrEP, pre-exposure prophylaxis. SESH, Social Entrepreneurship to Spur Health.

During this clinical encounter, participants who are confirmed to be HIV negative and without any relative contraindications for PrEP initiation will be prescribed a 30-day supply of TDF-FTC. Participants can choose from two PrEP medicines that is available for prescription at the study clinic during the study period: Truvada (before reimbursement: 1980 CNY/ 30 pills) or the generic Keaike (1180 CNY/ 30 pills). Once starting PrEP, participants will be required to complete two monthly clinic visits during their first 2 months of PrEP use to monitor their medication adherence, HIV/STI tests and overall physical health status and receive another 30-day supply of TDF-FTC. Participants may follow the daily oral regimen or event-driven regimen based on their discretion and they will be given education on the two PrEP regimens during their initial PrEP counselling and through the mini-classroom in the mini-app. PrEP prescriptions may be filled at the study clinic's pharmacy or a private pharmacy.

Study assessments and evaluation

Behavioral assessments

Baseline assessments will be conducted at enrolment, with follow-up surveys conducted at weeks 4, 8 (end of active intervention) and 12 (post intervention) via self-administrated web-based surveys on Wenjuanxing. Participants will be asked to complete follow-up surveys within 1 week; reminders through WeChat message will be sent on days 7 and 10 of the survey window, as needed. The time points of assessment are presented in [table 1](#). The

full list of study measures is included in online supplemental table 3. To track app use activities, two questions will be sent via the mini-apps chat box during the active intervention period at the end of weeks 2, 4, 6 and 8.




Qualitative progress evaluation

When close to the 4th week of intervention, a subgroup of 15 participants (10 intervention, 5 control) will be purposively sampled prioritising those who have initiated PrEP to complete two in-depth interviews at weeks 4 and 8. Another group of participants (up to 5) who started PrEP between week 4 and week 8, regardless of the study arm, will receive a one-time in-depth interview at week 8. Interviews will focus on participants' experiences using the app and any changes in their perceptions and/or behaviours related to PrEP and HIV prevention practices during the study period (online supplemental table 4). Interviews will be conducted one on one in private spaces or via videoconferencing software (eg, Zoom or Tencent Meeting), which last for 60–90 min and will be audio recorded with participants' permission.

Primary outcome measures

The primary outcomes for phase II pilot RCT include the intention to use PrEP, progression along the stages of change to PrEP initiation and PrEP initiation. PrEP use intention will be constructed as a continuous variable (range –3 to 3, from very unlikely to very likely) according to the participant's response to the question

Table 1 Phase II pilot randomized controlled trial assessment time points

		Week					
	(Day 1)	2	4	6	8	12	
Assessments							
Enrolment	X						
Informed consent	X						
Randomisation	X						
Baseline assessment	X						
Interventions							
Mini-app							
Weekly reminder messages to use the mini-app							
Control							
Mini-app access							
Standard HIV prevention care							
Follow-up survey (long)			X		X	X	
App-use survey (short)*		X		X			
In-depth interviews†			X		X		
*Only performed in participants in the intervention arm.							
†Only performed in a subgroup of participants.							

‘How likely are you to start using PrEP?’ PrEP initiation will be a binary variable, such that participants who successfully started PrEP (either through the study clinic or other PrEP providers) during the study period (weeks 0–8) will be recorded as ‘1’, otherwise as ‘0’. Individual progression along the stages of change to PrEP initiation will be measured by a set of eight questions evaluating their contemplation, preparation and actions to start PrEP and maintenance of using PrEP.⁶⁴ This will be constructed as a discrete variable ranging 0–4 (0=precontemplation, 1=contemplation, 2=preparation, 3=action, 4=maintenance).

Secondary outcome measures

Secondary outcomes include: (1) feasibility variables, including the length of time for recruitment and enrolment, participants’ retention rate (staying in the study) throughout the study course and self-reported mini-app usage; (2) PrEP knowledge (five-item quiz,⁴⁸ response options: true/false, total score: 0–5); (3) number of HIV/syphilis tests (≥ 0 , continuous) ordered through the mini-app, tracked by the backend data; (4) PrEP adherence, measured by self-reported missed doses in the past week (a continuous variable, ranging from 0 to 7); (5) PrEP stigma (five-item scale,⁴⁸ five-point Likert response scale from strongly disagree to strongly agree, total averaged score ranging from 1 to 5 with higher scores

indicating higher perceived PrEP stigma; (6) PrEP attitudes, an averaged score of the participant’s responses to a five-item PrEP attitudes scale⁴⁸ with a five-point Likert response scale from strongly disagree to strongly agree, with higher scores indicating more positive attitudes toward PrEP (a continuous variable, ranging from 1 to 5); (7) and PrEP self-efficacy, an averaged score of the participant’s responses to an eight-item PrEP self-efficacy scale⁴⁸ with a five-point Likert response scale from very difficult to very easy, with higher scores indicating higher self-efficacy to use PrEP (a continuous variable, ranging from 1 to 5).

Risks and referrals

HIV remains a stigmatised disease in many places in the world, including China. Same-sex sexual behaviours can also be associated with stigma and lack of social acceptance. The potential social harm that may cause to the participants by participation in our study may include emotional distress, embarrassment and breach of confidentiality. During the study implementation, every effort will be made to ensure that study participants are protected from these risks and to maintain confidentiality and discretion throughout all research procedures and data management and analysis. If at any time during the study a participant divulges that he is at risk for harm, measures will be taken to ensure their safety. Reporting will be done as appropriate to the situation and the legal statutes, and referrals will be provided to appropriate support, counselling or treatment resources.

In the case of an initial positive HIV test done through the study, participants who have initiated PrEP will be instructed to discontinue PrEP dosing. Participants testing positive will be referred to the study hospital—the Guangzhou Eighth People’s Hospital for confirmation tests or other testing places if needed. The Guangzhou Center for Diseases Prevention and Control will be notified of confirmed positive results following China’s public health reporting laws, a procedure that will be explained to participants at consent. For positive syphilis testing results, participants will be referred to as STI treatment at the Guangzhou Eighth People’s Hospital. The study team will follow-up with participants testing positive for HIV or STI to encourage participants to seek appropriate care. For participants who want to continue using PrEP after the study ends, they can contact the study team and a list of local PrEP providers will be provided.

Data management

In-depth interviews will be audiotaped, transcribed verbatim (in Chinese), summarised in English based on the interview guide and organised and managed using Dedoose cloud-based qualitative data analysis software (www.dedoose.com). The web-based survey will be collected through a Chinese professional secure electronic survey platform Wenjuanxing (www.wjx.cn). Survey data will be downloaded from Wenjuanxing and will be stored on password-protected encrypted

study computers along with other electronic study files. All study files will have a back-up copy stored on UNC secure server space that only study personnel will have access to.

Statistical analysis plan

All statistical data analyses will be conducted in Stata V.16.0. An intention-to-treat analysis approach will be used.⁶⁵

Descriptive analysis

Descriptive statistical analyses will be first conducted to report baseline characteristics of participants, actual PrEP initiation rates, distribution of outcome variables and other control variables at different time points throughout the study period (for a full list of control variables, please see online supplemental table 2). Examples include demographic characteristics, behavioural history of recreational drugs, alcohol and tobacco products, HIV risk perception, general stress, etc. For continuous outcome variables, we will first examine the mean changes from baseline to follow-up for the entire sample using statistical tests and then estimate whether there are differences in net gains between the mini-app group and the control group and between frequent mini-app users (use the mini-app once a week or more) and less frequent users. Observed effect sizes will be reported, to inform future study designs.

Bivariate analyses

Bivariate correlation analyses will be conducted to assess variables (including predictor and control variables) relating to PrEP use intention and PrEP initiation rate at week 4 and week 8. For the binary dependent variable, 'PrEP initiation' in particular, we will use the χ^2 test to compare the difference in PrEP initiation between the intervention group and the control group. Unadjusted OR will be calculated and reported.

Multivariate analyses

Common confounder variables (eg, age, education, income and other sociodemographic characteristics) and theoretical construct variables (ie, PrEP knowledge, self-efficacy, stigma and attitudes) will be adjusted for in multivariate analyses for each outcome of interest.

Given that the data collected in the pilot RCT are a longitudinal dataset with repeated measures at three time points, we will apply multilevel linear regression models to assess the association between continuous outcome variables and predictor variables. Missing data will be replaced with predicted values by multiple imputations, and sensitivity analyses will be conducted to compare the multiple imputation approach with analysis with complete cases only. If we have less than 50 participants retained at week 8, or the multilevel model does not converge, we will run regression models and control for change over time.

Phase II qualitative analysis

The analytic approach for qualitative interviews from participants in phase II will be similar to that applied in phase I. Besides, we will conduct a trajectory analysis⁶⁶ to understand participants' experience throughout the intervention period, including user experience of the mini-app, study engagement, evolving PrEP-related perceptions and PrEP use behaviours. As we will purposively sample participants who have initiated PrEP during the study and those who show less engagement for the interview, this approach will allow us better to understand the changing or non-changing process of individual PrEP use intention and initiation.

Incentives

Participants in phase I will be provided remuneration at the end of each completed interview in the form of a 75 CNY (~10 US\$) gift card or equivalent. Participants in phase I will not be eligible for phase II as they will have been exposed to the intervention before randomisation.

Participants in phase II will receive a 50 CNY (~7 US\$) gift card for the in-person initial visit or baseline assessment and another 20 CNY (~3 US\$) gift card for completing each web-based follow-up survey via Wenjuanxing at weeks 4, 8 and 12. Participants who complete all required study activities in phase II will receive a bonus of 50 CNY (~7 US\$) at the end of the study. Phase II participants who are sampled for in-depth interviews will receive 75 CNY (~10 US\$) for completing each interview (up to two interviews for each participant). For participants who initiated PrEP through this research study, the cost of physical examinations (including required lab tests) and PrEP prescription will be covered by the study team. Participants will need to pay for PrEP medications out-of-pocket first and get 50% of the cost reimbursed at the monthly follow-up clinic visits, only if they fill the prescription at the study clinic or designated private pharmacies. After reimbursement, the total estimated cost to a participant in phase II who starts PrEP is from 590 CNY (about 85 US\$, for 1-month generic PrEP supply or 30 pills) to 2000 CNY (about 286 US\$, for 2-month Truvada supply or 60 pills).

Ethics and dissemination

This study was reviewed and approved by the Institutional Review Boards of the University of North Carolina at Chapel Hill, USA (IRB# 19-3481), the Guangdong Provincial Dermatology Hospital, China (IRB# 2020031) and the Guangzhou Eighth People's Hospital, China (IRB# 202022155). All participants will be provided online consent and sign it electronically before taking part in the study. Our study team will work with local GBMSM CBOs to disseminate the study results to participants and the community via social media, journal publication and offline workshops at local CBOs. This research addresses a critical need as

GBMSM bear a disproportionate burden of China's HIV infections and remain underserved in the health-care system.

DISCUSSION

Despite the high prevalence of HIV infection and risk factors among Chinese GBMSM, PrEP use is quite limited.⁶⁷ A theory-informed, GBMSM-friendly and innovative behavioural intervention to facilitate PrEP uptake among Chinese GBMSM may help to increase the awareness of PrEP among this population through timely information and strengthened motivation and skills. It may also help to link individuals to providers and clinics where they can receive PrEP. While PrEP campaigns in China have to date failed to engage relevant communities,⁶⁸ initiatives in other settings have successfully used GBMSM-tailored approaches to promote PrEP,^{41–44} including using mHealth technologies to approach GBMSM 'where they are'. In an online survey of 1035 Chinese GBMSM in 2017, about 75% of the participants mainly met their sex partners online⁶⁹ and Chinese GBMSM have been using the internet frequently to search for HIV-related information, counselling or testing services.³⁵

A large body of evidence has suggested that HIV-related and sexual health interventions delivered through internet-enabled platforms are feasible and acceptable in Chinese settings,⁷⁰ including interventions through websites, text message and mobile apps that have shown effectiveness in reducing HIV-related risk behaviours, increasing linkage to care and improving medication adherence.⁴⁷¹⁷² Thus, an mHealth-enabled intervention, like this PrEP education mini-app, which leverages the platform of a popular Chinese social media app, could facilitate the rapid scale-up of PrEP use in China. In contrast to the traditionally top-down health mandates or researcher-led intervention projects, the PrEP mini-app tested in our study was cocreated by a team of young gay men, HIV clinicians and public health researchers through a crowdsourcing hackathon. This not only helps to generate innovative approaches to address their own social and health needs but also increases the acceptability and potential impact of the intervention in target populations.

Developing and testing theory-driven interventions around HIV prevention and care is challenged by rapid developments in the field, which can influence the pertinence or timeliness of interventions—a case in point concerns PrEP in China. The Chinese government has taken several crucial steps in introducing PrEP to China, including launching large-scale PrEP studies in multiple provinces and cities in 2018, developing implementation guidelines for PrEP in China⁶⁸ and officially approving TDF–FTC for HIV PrEP in August 2020.⁷³ Nevertheless, the large population of GBMSM who would benefit from PrEP will encounter significant challenges for timely scale-up. The PrEP

education mini-app developed by this study aims to meet the pressing need for innovative, easily accessible and broadly acceptable modes of promoting and supporting PrEP among Chinese populations.⁷⁴

We also expect some challenges in the study implementation given the rapidly evolving conditions of the global COVID-19 pandemic and its impact on human activities and interpersonal interactions. The field-work is expected to take place between summer 2020 and summer 2021, while international travel of our research team members will be significantly delayed or restricted because of the global mitigation strategies to control COVID-19. In order not to bring significant delay to the study progression as well as encourage participants' engagement, our research team has been working remotely with local collaborators regarding GBMSM recruitment and enrolment. All data collection activities including in-depth interviews and surveys will be conducted electronically via videoconferencing systems or web-based survey tools, to ensure participants' and the research team's safety. The mHealth-based feature of the proposed intervention does not require in-person interaction between the participants and the research team, though study enrolment currently includes clinic-based lab tests and follow-up visits among PrEP users.

Whether globally or in China, limited data exist on the efficacy of app-based interventions aimed to increase PrEP uptake and adherence among GBMSM. If successful, this research study may help inform the implementation design of a rapid PrEP roll-out in China by examining whether an mHealth intervention can promote PrEP uptake and other HIV prevention services. Promoting such services among GBMSM is of great importance as this population bears a disproportionate burden of China's HIV infections and remains underserved in the healthcare system.

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