

Integrating a Combination HIV Prevention Intervention into a Widely Used Geosocial App for Chinese MSM: Pilot Study Protocol and Baseline Data

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Abstract

Background: HIV disproportionately affects men who have sex with men (MSM) in China, but the use of HIV prevention services is low due to privacy concerns and nondisclosure of sexual identity. These concerns are addressable through home-based services.

Objective: This study aimed to assess feasibility and acceptability of Blued+, a combination HIV prevention intervention that integrated combination package of HIV prevention services into the Blued mobile application platform, for Chinese MSM.

Methods: This study was a single-arm pilot study with a repeated cross-sectional design as a comparison. A cohort of MSM was recruited from Beijing and Chengdu, China. A three-month standard-of-care period with measurement at enrollment and month 0 (baseline) was followed by a 12-month intervention period with measurement at months 3, 6, 9, and 12. Standard of care included the existing Blued app and local health services. During the intervention period, participants received the enhanced version of the Blued app with HIV testing, linkage to care for those testing HIV positive, free condoms and lubricants, in-app screening and provision to PrEP. A series of cross-sectional surveys at months 0, 6, and 12 were administered to MSM residing in Beijing and Chengdu who were not in any HIV prevention study. The primary outcome was the uptake of home HIV testing, condom, and PrEP prescription. The intervention acceptability was measured by the score of the system usability scale.

Results: This study enrolled 423 participants in the pilot cohort and 1314 participants for cross-section comparison at baseline. Participants in the cohort were young. More than two-thirds obtained a college degree or above. More than a third of them were at a high level of income. Participants reported a high prevalence of condomless sex (63%) and HIV testing (71%) in the last three months. Most participants (96%) had heard of PrEP, and over a quarter had used PrEP. Participants in the comparison had comparable sociodemographic characteristics, but reported a lower proportion of people who had condomless sex (41%) and HIV testing (58%) in the last three months, and lower PrEP awareness (85%) and PrEP use (21%).

Conclusions: This pilot study will provide preliminary evidence for an efficacy trial of HIV prevention intervention that is integrated in an existing geosocial networking app among Chinese MSM by evaluating the feasibility and acceptability of this intervention. Clinical Trial: This is not a clinical trial.

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Original Manuscript

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Abstract

Background:

HIV disproportionately affects men who have sex with men (MSM) in China. However, the use of HIV prevention services among MSM remains limited, in part due to privacy concerns and nondisclosure of sexual identity to service providers. These concerns might be addressed through online, home-based services.

Objective:

This study was designed to assess the feasibility and acceptability of Blued+, a combination HIV prevention intervention that integrates a HIV prevention services package into a geosocial networking app commonly used by Chinese MSM.

Methods:

The study design was a single-arm pilot of the Blued+ intervention among MSM, with repeated cross-sectional surveys of a different, external MSM population used for comparison. For the pilot study, a cohort of MSM was recruited from Beijing and Chengdu, China. A three-month standard-of-care period with measurement at enrollment and month 0 (baseline) was followed by a 12-month intervention period with measurement at months 3, 6, 9, and 12. During the intervention period, participants received the enhanced version of the Blued app (Blued+) with HIV testing, linkage to care for those testing as living with HIV, choice of condoms and condom compatible lubricants, and pre-exposure prophylaxis (PrEP) services. PrEP was provided through in-app counseling and prescription, followed by lab tests at local clinics and mailed medication. Three cross-sectional surveys at months 0, 6, and 12 were administered to MSM residing in Beijing and Chengdu who were not in any HIV prevention study. For both the standard of care period and the comparison surveys, participants had access to the standard Blued geosocial networking app and local health services. The primary outcome of feasibility was determined by the uptake of home HIV testing and PrEP. The co-primary outcome of intervention acceptability was measured with ratings of the intervention platform with the system usability scale.

Results:

At baseline, the pilot study enrolled 423 participants and the cross-sectional comparison enrolled 1314 participants. Participants in the pilot were young (mean $\pm$ SD age = 30 $\pm$ 7 years) and educated (72%, 324/423 reported a college degree or higher), and most (71%, 302/423) reported HIV testing in the three months before completing the survey. Most participants (96%, 404/423) had heard of PrEP, and over a quarter had used PrEP (27%, 113/423). Participants in the comparison population had comparable sociodemographic characteristics, but slightly lower percentages reporting HIV testing (58%, 763/1314) in the prior three months, PrEP awareness (85%, 1110/1314), and PrEP use (21%, 202/1314).

Conclusions:

This pilot study will provide preliminary evidence regarding the feasibility and acceptability of the Blued+ intervention. The study findings will provide evidence setting the foundation for future research that involves embedding prevention platforms into apps that are already widely used. If preliminary impact is observed, future research would include a hybrid effectiveness implementation trial of the Blued+ intervention.

Trial Registration: NCT06647173

International Registered Report Identifier (IRRID): Not applicable.

Keywords: HIV; men who have sex with men; telemedicine; mHealth; protocol



Introduction

Gay and bisexual men who have sex with men (MSM) have been disproportionately affected by HIV in China,[1, 2] where the population of MSM was estimated to be approximately 21 million in 2018.[3] HIV prevalence among MSM was estimated to have increased from 1% to 6% between 2001 and 2018.[4] The estimated HIV incidence among MSM is much higher than for all populations identified as being at risk of HIV in China since 2010.[5] In Beijing, a cohort study of MSM documented 7.8% annual incidence[6] – a level similar to the highest incidence estimates among MSM subgroups in the United States.[7] In Chengdu, a southwestern city in China, estimated incidence was 6.0/100 person-years between 2012 and 2018[8] and 4.3% between 2018 and 2022.[9]

Despite the substantial epidemic, the use of HIV prevention services, including condoms, HIV testing, and HIV pre-exposure prophylaxis (PrEP), is low among Chinese MSM. In 2012-2016, fewer than half of MSM reported consistent condom use with male partners.[10-12] After a national intervention to expand HIV testing that started in 2007, the annual HIV testing rate increased from 21% to 38% by 2012, which was still suboptimal.[13] To effectively control HIV transmission, a combination of multiple HIV prevention strategies, including biomedical (e.g., PrEP use), behavioral (e.g., HIV testing, condom and lubricant use), and structural (e.g., addressing stigma) approaches, is needed.[15, 16] Therefore, adopting a combination HIV prevention approach that strategically and simultaneously leverages several types of interventions to address the specific needs of priority populations is needed. This is essential to achieve more comprehensive and sustained outcomes in HIV preventions.[15]

Smart mobile devices have become ubiquitous in China and smart mobile apps have proliferated, offering an efficient approach to reach Chinese MSM with HIV prevention services.[17] Blued is an example of an MSM-focused mobile app that provides a wide range of health behavior change functionalities.[17] Telehealth interventions utilizing mobile apps have shown promising outcomes in improving practices such as consistent condom use and HIV testing to address disparities in sexually transmitted infections.[18-22] However, many innovative mHealth interventions, using smartphone applications, have encountered challenges and issues in post-trial scale-up due to the lack of sustainable funding and limited technical expertise to support transitioning mHealth study apps into the marketplace.[23, 24] Additionally, from the user perspective, having to manage and utilize many mobile apps for different purposes can result in information overload, which is associated with mobile application use discontinuation.[25] To address these challenges, and in response to NIH's call to develop and evaluate the feasibility and acceptability of combination HIV prevention interventions,[15, 16] we adopted a low-touch digital intervention approach in this pilot study, seeking to overcome future problems with scale-up by placing the prevention platform onto a pre-existing, widely used mobile application. This pilot study was developed on the Blued LGBTQ+ geosocial networking (GSN) app. Launched in 2012 in China, Blued has gained considerable popularity both within China and globally, with 6 million active monthly users in China, including over 480,000 MSM in Beijing and 221,000 MSM in Chengdu (Guodong Mi, PhD, e-mail communication, September 2018). Similar to other dating apps, Blued allows users to share their current locations to chat with and date users who are near them, share photos and videos, and broadcast live streams.

The aim of this pilot study was to assess the acceptability and feasibility of integrating a fully featured combination HIV prevention package into a widely used GSN mobile app. Our scientific premise is that the HIV prevention services continuum for MSM should be stronger, and that integrating services into a mobile app already used by Chinese MSM will be feasible and acceptable, providing preliminary data to inform future assessment in a hybrid effectiveness implementation trial.

Methods

Study Design

This study was a single-arm pilot with repeated cross-sectional design as comparisons (**Figure 1**). This research was funded as part of the National Institutes of Health (NIH) Methods for Prevention Packages Program (MP3), which was focused on the development of combination HIV prevention interventions and therefore did not allow for randomized assessment. [26] To increase rigor in the absence of randomization, we included a three-month run-in period and a series of repeated cross-sectional surveys in an external (comparison) population to assess pilot intervention performance. The set of three comparison groups allows the investigation of secular trends and potential impacts of panel attrition.

For the pilot study, a cohort of MSM was recruited from Beijing and Chengdu. Enrollment was followed by a three-month standard-of-care (run-in) period, during which data on behaviors were collected but no HIV prevention content was provided, and a 12-month intervention period. Self-reported behavioral measures for the pilot study participants were at enrollment, baseline (month 0), and months 3, 6, 9, and 12. The set of three comparison groups was a series of cross-sectional surveys among MSM not enrolled in the intervention study, and administered at the same time intervals as the pilot study baseline (month 0) and months 6 and 12. Eligibility criteria for cross-sectional surveys were identical to those for the pilot study, with the additional exclusionary criterion for being enrolled in the intervention cohort. The set of three comparison groups were largely independent because they were advertised broadly to the whole city until the sample size of the study was obtained, although we did not exclude participation in subsequent comparison groups. For the intervention group, we also conducted an exploratory assessment of PrEP adherence among PrEP users at month-12 follow-up with a blood-based biomarker test (detailed below).

Recruitment

Participants for the pilot study and repeated cross-sectional surveys were recruited using the direct message function in the Blued app. The targeted inbox messages were sent to men who lived in the Beijing and Chengdu metropolitan areas. When interested men clicked on a link in the message, they were taken to a landing page containing basic information about the study. A brief screener survey then determined study eligibility.

Eligibility

Eligible participants for both the pilot study and repeated cross-sectional surveys were registered Blued app users who self-reported male sex at birth, male gender identity, age ≥ 18 years, having had anal sex with a man in the last six months, having HIV-negative or unknown HIV status, residing in Beijing or Chengdu, and being eligible for PrEP according

to China's consensus statement.[27] According to the consensus statement, MSM are eligible if they ever used PrEP/post-exposure prophylaxis (PEP) before or are willing to use PrEP/PEP, or meet at least one out of the following four criteria in the past six months: (1) engaged in any condomless anal or vaginal sex, (2) injected drugs or shared needles, (3) had a serodifferent partner known to be living with HIV, or (4) were diagnosed with a sexually transmitted disease.[27] .

Enrollment

The advertisement and enrollment process for the pilot study and repeated cross-sectional surveys were similar. Study advertisements were sent as direct messages to Blued users in Beijing and Chengdu based on their login geolocations in the prior three months. Preliminarily eligible participants were asked to provide their contact information and complete the consent process. Given the remote nature of consent, we verified understanding of the key elements of the consent form with a brief quiz. Correct responses and brief explanations of key components in the consent form were shown when participants selected the incorrect options. Upon successful completion of the consent quiz, participants indicated consent by electronically affirming their decision to participate in the study.

Intervention development

To inform intervention design, we obtained information about app preferences and user experience with the existing app, Blued. We conducted three in-person activity-based focus group discussions (FGD) in Beijing with a range of 6-10 Blued users in each group in April-May 2021. Eligible criteria were the same as the criteria above for the pilot study and repeated cross-sectional survey. The length of Blued use ranged from two to nine years. During the FGD, participants were first asked to review the HeHealth portal in the existing Blued app, including the home, condoms/lubricants, and HIV testing kits pages. Then participants were provided with visual illustrations of concepts regarding how PrEP care components could be incorporated into the Blued+ app, including PrEP education information, PrEP screening quizzes, no-cost PrEP care and referrals, reminders, and peer communication. A rapid qualitative analysis of the FGDs was conducted to summarize participants' feedback on each function to inform Blued+ app development.

In general, FGD participants expressed a preference for simple and easy-to-navigate page design. Regarding the HIV testing kits page, participants suggested a graphic display mode to present different types of test kits clearly. For condom and lubricant products, participants preferred thin condoms with good quality from reputable brands. Regarding PrEP care services to be added in Blued+, participants suggested that the page should be tailored to meet the needs of MSM. Participants also suggested that adding expert-delivered videos on PrEP efficacy and potential side effects could increase the credibility of PrEP care services on Blued+. For PrEP screening quizzes, participants were concerned about the lack of explanation about the results and the only purpose of the quiz was to lead people to purchase PrEP medication. To access PrEP care, most participants preferred to talk to a doctor to obtain PrEP prescriptions and medication, but they also worried about potential discrimination and stigma attitudes in clinics. When considering PrEP care support services like reminders and peer communication, participants suggested that the reminder service could be offered as an optional service, but peer communication would be

unnecessary. To address concerns about PrEP efficacy, side effects, and access to prescriptions and medication, participants suggested the need for an in-app clinician for consultation.

Standard of Care

During the three-month standard of care period in the pilot study and for the cross-sectional comparison assessments, participants were able to access the existing Blued app (i.e., without the additional PrEP features described above). Blued began as a community-based organization and maintains a strong community presence. This includes a network of HIV testing locations and a series of HIV testing promotion ads in Blued. In 2020, Blued started to offer a set of digital sexual health services in a for-profit model, HeHealth. It provides users with access to mailed home HIV tests, mailed standard condoms and water-based lubricants at cost, similar to retail pharmacy services. HeHealth also offers pharmacy PrEP services, with users who already have a PrEP prescription from their local clinic able to receive PrEP through package delivery. The package delivery services were timely (within a week), reliable, and anonymous (no real name or product information shown on the package).

Intervention

During the intervention period, pilot study participants received the enhanced version of the Blued app: Blued+. The installation was integrated with a regular Blued app update to avoid disrupting users. A notification about the update was sent to study participants. Once study participants agreed to update the Blued app on their smartphone, the update to the enhanced Blued+ version was automatic.

The theoretical foundation that structured the integration of the HIV prevention services into this app environment was the Extended, Unified Theory of Acceptance and Use of Technology (UTAUT2). UTAUT2 is a frequently used model for development and assessment of technology-based health interventions, with over 20,000 citations and recent validation for mobile technology assessment in China.[28, 29] Domains relevant to Blued+ were performance expectancy (PE), effort expectancy (EE), social influence (SI), and habit (H) (Table 1). Blued+ sought to provide users services in a manner they deem valuable (PE), to decrease expected effort expended by using functions and design layout consistent with the existing Blued app (EE), to leverage communications in the existing app for peer-support (SI), and to use reminder systems to help users build HIV prevention habits (H).

Figure 2 shows screenshots of some pages from the Blued+ app, translated into English. Services in the HIV prevention intervention package included PrEP provision, in-home HIV tests and linkage to care, and prevention supplies such as condoms and lubricants. Additionally, participants received weekly health messages focused on PrEP, sexual health, and self-care. All these services were provided at no cost. A video walkthrough of the app and the intervention functions is available in **Supplement 1**.

Health messages

Health messages were adapted from a set of messages used in an app-based messaging and services intervention (M-cubed study) that was found to increase HIV testing and PrEP use among men in the U.S.[30] The messages were initially translated into Chinese by staff in the research team, then reviewed and revised by staff at Blued to ensure their cultural and

contextual appropriateness for Chinese MSM. In this study, a health message was first sent out every week in the first six months, then every other week for the remaining six months. A total of 29 messages were sent out to each participant.

Topics included promotion of PrEP use (n=11), condom and lubricant use (n=6), HIV testing (n=6), engagement in healthcare (n=2), and health-positive messages encouraging self-care (n=3). PrEP use support messages included information on PrEP and PrEP medication, PrEP effectiveness, PrEP costs, side effects, dealing with PrEP stigma, and how to access PrEP. Condom use messages included traditional messages encouraging consistent condom use and encouraging condom use with lubricants for pleasure. HIV testing messages included information about rapid testing, where to get tested, and encouraging regular testing every six months. Messages about engagement in healthcare encouraged users to talk to their healthcare providers and offered the in-app clinician counseling option. Positive self-support messages were adapted from a set of self-care and self-love messages provided by a community PrEP educator who focused on mental wellbeing and harm reduction behaviors. For example, one of the self-love messages was “To love oneself is the beginning of a lifelong romance. – Oscar Wilde”. A team-based translation approach was used to translate these messages into Chinese. Two bilingual staff from the research team and two bilingual local staff members worked together to ensure the messages were accurate and culturally appropriate. For most messages, a hyperlink with an appropriate destination was included within the message. For instance, a hyperlink within a PrEP use message “Could PrEP be right for you? Chat with our Blued+ provider” would direct users to the page where they could consult with a PrEP provider. A hyperlink within the message “Got a hot date? Don’t go unprepared. Get some free condoms and lube today!” would direct users to the page to order condoms and lubricants. A full version of all health messages with English translations can be found in **Supplement 2**.

PrEP care

The clinical eligibility for PrEP use in China are: (1) laboratory confirmed HIV-negative; (2) no contraindications to emtricitabine/tenofovir disoproxil fumarate (FTC/TDF); (3) creatinine clearance of at least 60 mL/min [reported by a laboratory], (4) willingness to adhere to a PrEP regimen, and (5) willingness to attend PrEP maintenance visits every three months.

Participants interested in accessing PrEP could click on the link in PrEP use messages or access directly in the Blued+ app to schedule a PrEP counseling with an in-app clinician. After counseling, participants who decided to initiate PrEP could get lab tests for HIV, syphilis, Hepatitis B surface Antigen (HBsAg), and serum creatinine from any local tier-2 or tier-3 hospital. The age and weight of the participant were also collected by self-report to calculate the creatinine clearance rate (CrCl). Prior to the study launch, eight staff from Blued (four in each city) went to a hospital of their choice and got lab tests to trial the process and estimate its cost. The cost associated with completing these lab tests was estimated to be up to 70 USD (350CNY). The reimbursement was sent once participants uploaded the test results to Blued+ in the app. The test results were reviewed by a study clinician and participants were prescribed PrEP in the platform if they were eligible for PrEP. After the prescription, research staff received a notification and shipped the medication within one week of an order, in batches of 90 pills to cover daily PrEP use for three months. Participants received tracking numbers once the medicine was shipped.

Participants could refill every three months if they received appropriate laboratory testing specified in the Chinese guidelines.[27] PrEP medicine used in this study were pills containing 200 mg emtricitabine (FTC) and 300 mg tenofovir disoproxil fumarate (TDF).

In-home HIV test and linkage to care

In Blued+, participants could order in-home HIV tests by clicking a link in HIV testing health messages or clicking a tab in the Blued+ app. The ordering page was designed to be easy to navigate to reduce users' effort expectancy. Similar to the procedures for shipping PrEP medication, once the order was placed, the Blued+ pharmacy received a notification and prepared the shipment. Three types of in-home HIV test kits, using capillary blood, urine, or oral swabs, were offered to maximize participant choice. During the intervention period, each participant could order a package of ten blood test kits, one urine test kit, or one oral test kit. The aim of offering ten blood test kits (anticipated to be the most frequently selected option) was to provide enough test kits for the 12-month intervention period, allowing participants to test as frequently as they would like. Participants could upload photos of their test results to the app and receive free counseling (regarding the test kit and result interpretation) and linkage to care when appropriate from study coordinator at Blued. A free message app account number of the in-app clinician was also provided to participants so that they could reach out for HIV test counseling and other related questions. Participants were able to use the Blued+ platform to voluntarily upload their HIV self-test result for further counseling. Experienced counselors would provide further explanation of the test result and referral to clinics for confirmatory tests, when necessary, through phone calls.

Other prevention supplies (condoms and lubricants)

Three types of condoms with different thicknesses and brands (ultra-thin vs standard, premium vs budget brand) and water-based and silicone-based condom-compatible lubricants were available for participants to order from the platform. The types of condoms and lubricants were selected based on our target users' preferences as assessed during FGDs (see above). The ordering process for condoms and lubricants was similar to ordering HIV testing kits. When participants added condoms to their "cart" in Blued+, a note would pop up reminding participants to add lubricants to use with condoms.

For condoms, each participant was offered 48 condoms per quarter. This number was based on two to three sexual activities per week, a common sex frequency for MSM in China.[31] The Blued+ platform allowed participants to choose luxury condoms of either Premium Brand A (ultra-thin 20 condoms) or Premium Brand B (air-feel 20 condoms). This gave participants the opportunity to try different brands and thicknesses. Additionally, each participant could order 28 standard condoms from a budget brand.

It is recommended that 5 to 10 ml of condom-compatible lubricant is used with each anal sexual activity.[32, 33] Participants were offered a total of 340 ml of lubricants per quarter, which included one container of water-based lubricant (100 ml) and two containers of silicone-based lubricant (120 ml each).

Differences between standard of care and intervention

Although the standard of care has some similarities to the intervention, there were notable differences. The health page in the intervention was designed to be simpler and easier to

navigate. Health messages in the intervention covered a wide range of HIV prevention-related topics and health positive self-care messages; whereas the health messages in standard of care only covered a narrower range of HIV prevention topics such as condom use and HIV testing. For HIV prevention products, the health portal in Blued+ offered options of different condoms, lubricants, and in-home HIV test kits based on user preferences. For PrEP care access, the intervention offered in-app PrEP counseling and prescribing, and medication mailing when appropriate. All these services were provided at no cost to participants in the pilot.

Data collection

Pilot cohort survey and cross-sectional survey

Data were collected through Sojump, a widely used and secure online survey platform in China that offers survey design features including multiple question types and branching logic. The survey link was sent to participants through the direct message function in the Blued app. Blued user IDs, tied to unique phone numbers, were used to identify and exclude duplicate responses within the cohort survey as well as between the cohort survey and repeated cross-sectional survey.

The enrollment survey included questions in the domains of (1) sociodemographic characteristics, (2) relationship status, (3) sexual history, (4) HIV/STI testing history, (5) PrEP knowledge/attitudes, (6) PrEP intention and use (including adherence), (7) HIV knowledge, (8) PrEP stigma, (9) mental health, and (10) prevention supplies order history. The full enrollment survey can be found in **Supplement 2**. Follow-up surveys include the domains of (1) relationship status, (2) sexual history, (3) HIV/STI testing history, (4) PrEP knowledge/attitudes, (5) PrEP intention and use, (6) prevention supplies order history, and (7) acceptability of Blued+. HIV knowledge, PrEP stigma, and mental health were only included in the month 6 and month 12 follow-up surveys because they were believed to be less labile. Acceptability of Blued+ was measured by a widely used systema usability scale assessing the subjective usability of products and systems [34, 35]. The acceptability questions were only included in the month 12 follow-up survey. Questions in pilot cohort survey and cross-sectional survey were identical. The average survey completion time ranged from 10 to 20 minutes across participants at each time point. A compensation of 15 USD (100 CNY) was provided for each of the cohort surveys and repeated cross-sectional surveys. An additional 60 USD (400 CNY) was provided for each participant who completed all six cohort surveys in the pilot study.

Dried blood spot (DBS)

In addition to self-report data regarding PrEP adherence collected from the cohort survey, we conducted an exploratory assessment of suitability and acceptability biomarker data to measure drug levels in blood samples. Participants who initiated PrEP were asked at an interim visit between months 9 and 12 to visit a local laboratory for collection of a blood specimen to create a dried blood spot (DBS) to measure tenofovir-diphosphate (TVF-DP) levels in plasma. For this procedure, participants were first asked to complete a supplemental survey and to receive an HIV screening test. The survey asked PrEP pill usage in greater detail than in the cohort survey to evaluate adherence to their regimen of either daily use or on-demand use in the past two months. A trained phlebotomist at the

designated local laboratory then collected finger-prick blood onto a paper card to create a dried blood spot card for future testing for TFV-DP. For daily pill use, TVF-DP levels provide an indicator of the mean number of days per week that PrEP is ingested over a period of approximately one to two months. For daily users, a cut point of >700 fmol/punch TVF-DP indicates >4 doses/wk and thus serves as a surrogate for substantial protection from HIV infection. For event-based PrEP users, adherence was determined by evaluating if the TVF-DP level matches with the self-report behavior data on sexual frequency. An additional 45 USD (300 CNY) compensation was provided for each participant who completed the dried blood spot collection.

Statistical Analysis Plan

Primary analysis

The primary analysis will be focused on the feasibility and acceptability of the pilot intervention, assessed based on a series of benchmarks (**Table 2**). The intervention will be determined as feasible if a minimum proportion of participants receive services for home HIV testing (30%) and PrEP prescription (20%) at month 12. Minimum targets were determined based on modeling in modeling and other contexts that indicate levels of service uptake required to substantially influence an HIV epidemic.[36] The intervention will be considered acceptable if it reaches a Systems Usability Scale rating benchmark score of 'good' (≥ 71 out of 100).

Statistical power and sample size

This is a pilot study assessing feasibility and acceptability; therefore, our sample is not powered to detect significant differences in the intervention period compared to the standard-of-care period (before baseline) or to the set of three cross-sectional comparisons. A sample of 200 pilot study participants per intervention city was selected based on budget and time constraints. This sample size is also anticipated to provide estimates of key parameters with sufficient precision. For instance, a 95% confidence interval for the prevalence of our binary benchmarks (home HIV test orders, condom package orders, PrEP medication orders) would have a half-width of 5.1 percentage points. This is calculated assuming an estimated population standard deviation (SD) of 0.5 and $\text{Pr}(w)=0.9$, [37] where $\text{Pr}(w)$ represents the probability that the width of a future confidence interval will not exceed 95% and accounts for the fact that the SD is not known and will therefore lead to confidence intervals that vary from sample to sample.[38]

Additional analysis

Additional analysis will include assessing preliminary efficacy with descriptive endpoints, measuring changes from baseline to intervention periods in HIV testing, condom use, and PrEP use. Descriptive analyses will include outcome proportion in the pilot and the set of three comparison groups (**Table 2**). Longitudinal analyses will assess trends within the pilot cohort while accounting for autocorrelation, using models such as generalized estimating equations (GEE) to measure predictors of the binary outcome of HIV testing, condom use, and PrEP uptake. Models will contain the seven time periods with primary comparisons of 0-month (first baseline) measurement to 6-month (end wash-out baseline period) measurement and to 12-month (end intervention period) measurement. Time will

be considered as a fixed effect to compare proportion tested across intervals, with a random intercept for individuals. TVF-DP data will be reported descriptively to provide context for the self-report PrEP use data.

Results

The study was approved by the Emory Institutional Review Board (IRB) and Blued IRB (IRB00116983) in January 2020 and launched in July 2022. A total of 440 participants were pre-enrolled in the pilot study, and after the three-month standard-of-care period, 423 were retained to start receiving the intervention. For the cross-sectional comparison, the baseline cross-sectional survey recruited 1314 participants.

Sociodemographic and behavioral characteristics at baseline for each group are presented in **Table 3**. Participants enrolled in the pilot had an average age of 30 years (SD=7.4). Slightly more pilot participants resided in Beijing higher than in Chengdu. More than two-thirds of the pilot participants had obtained at least a college degree and about three-quarters reported working full-time. Over a third of the participants had a high monthly income as over 1,400 USD, based on the average income level of urban non-private position employees. Most participants were self-identified as homosexual. In terms of behaviors, over half of the participants (63%) reported having had condomless sex in the prior three months. About two-thirds (71%) of the participants had been tested for HIV in the prior three months. PrEP awareness was high – nearly all participants (96%) had heard of PrEP, among whom 28% had used PrEP. Of the 103 participants who had used PrEP, two-thirds (70%) had used PrEP in the prior three months.

Participants in the cross-sectional comparison group had similar sociodemographic characteristics to those in the pilot study, except the comparison group had a slightly higher proportion of participants residing in Beijing (64%) compared to the pilot study participants (55%) ($P<.001$). Lower proportions of participants in the comparison group reported having condomless anal sex (41%) ($P<.001$) and testing for HIV in the prior three months (58%) ($P<.001$), compared to the pilot study population. Lower proportions of participants in the comparison group also reported PrEP awareness (85%) ($P<.001$), ever PrEP use (21%), and PrEP use in the prior three months (15%).

Discussion

This protocol describes a pilot study assessing the feasibility and acceptability of an mHealth intervention that integrated HIV services into an existing GSN mobile app for MSM in China. Integrating interventions into a widely used app may overcome challenges of “translation” and obtaining “downloads” that our team previously identified as primary barriers to bringing app research into practice.[39] Translation is a common implementation challenge. Effective health apps developed by researchers may never be translated into a sustainable model for public and long-term use. Translating a study app into a marketable business product with sufficient profit to sustain the intervention is often out of the scope of research studies and out of the capability of researchers, who frequently lack expertise and financing to accomplish this critical task. [20-22] The challenge of downloads is that once the app is translated into the market, convincing eligible individuals to download the app may be challenging unless they are aware of the app and see a clear benefit of having it.[39] Given these barriers, we offered HIV prevention services in an app that already has a sustainable model and is widely downloaded by the Chinese MSM, rather than developing a new app. Study results may inform future efforts to optimally leverage

mHealth resources, by determining the feasibility and acceptability of building prevention models into existing apps.

Participants in the pilot and comparison groups were similar at baseline with respect to age, education and income level, employment status, sexual orientation, and PrEP use. We sought to minimize differences between pilot study participants and cross-sectional comparison participants by using similar recruitment strategies in terms of advertisements, delivery, and eligibility criteria. Yet the specifics of recruitment differed slightly due to different consent forms, different lengths of participation, and different overall incentive amounts (more study activities for pilot participants). There were some differences in participant characteristics, with pilot participants being more likely to come from the Chengdu, report condomless anal sex, recently test for HIV, and have higher awareness of PrEP. Differences may introduce some bias in comparison, with higher levels of HIV testing and PrEP awareness perhaps indicating higher pre-existing engagement in prevention care among pilot participants. Exploratory analyses in results assessment may seek to describe the possible impact of these differences.

Limitations

The outcome measures of this study rely on self-report data. To account for potential social-desirability and recall biases, levels of TDF-DP in the blood will be measured to provide context to the self-report PrEP use data. Given that there was no randomized control group in this pilot study, there could be selection and secular time biases that are only partially addressed by our inclusion of a three-month standard-of-care period and a series of repeated cross-sectional surveys among MSM who did not participate in any HIV prevention study as comparison.

Conclusion

This study provides a unique opportunity for scalability and wide public health impact by assessing the feasibility and acceptability of integrating an HIV prevention intervention into a widely used GSN app in China. Study results can inform future research such as hybrid effectiveness implementation studies to determine the effectiveness and implementation strategies of the intervention. If successful, these interventions have the potential to reach millions of MSM in China to provide sustainable HIV prevention services.

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Conflict of interest

None declared.

Abbreviation

DBS: Dried blood spot

FGD: Focus group discussion

FTC/TDF: Emtricitabine/tenofovir disoproxil fumarate

GEE: Generalized estimating equations

GSN: Geosocial networking

IRB: institutional review board

MSM: Men who have sex with men

NIH: National Institutes of Health

PrEP: Pre-exposure prophylaxis

TVF-DP: Tenofovir-diphosphate

UTAUT2: Unified theory of acceptance and use of technology

Figure 1. Study design overview of a study of HIV prevention service delivery to men who have sex with men through an HIV social networking app, China, 2022-2024.

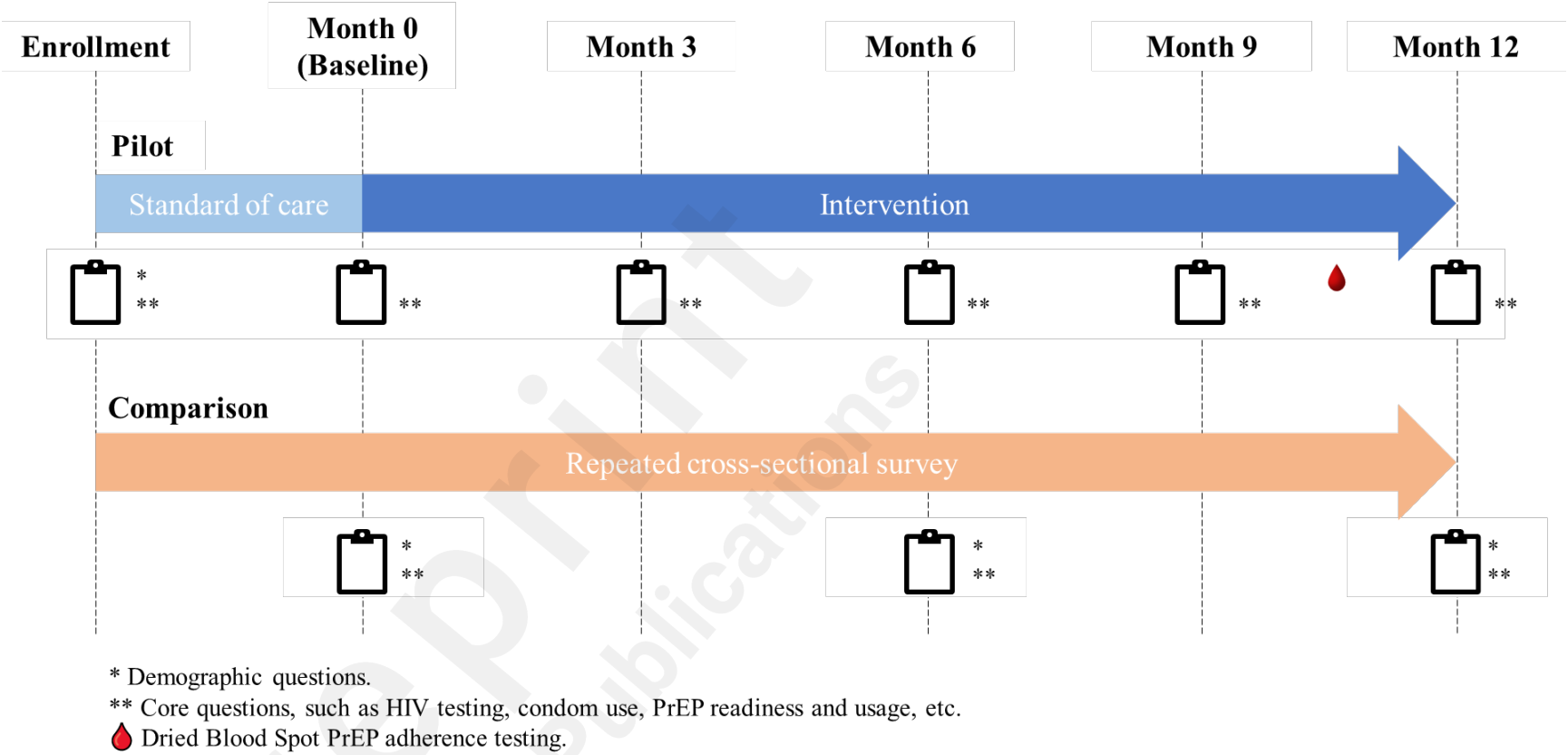


Figure 2. Screenshots of interventions in the Blued+ app.

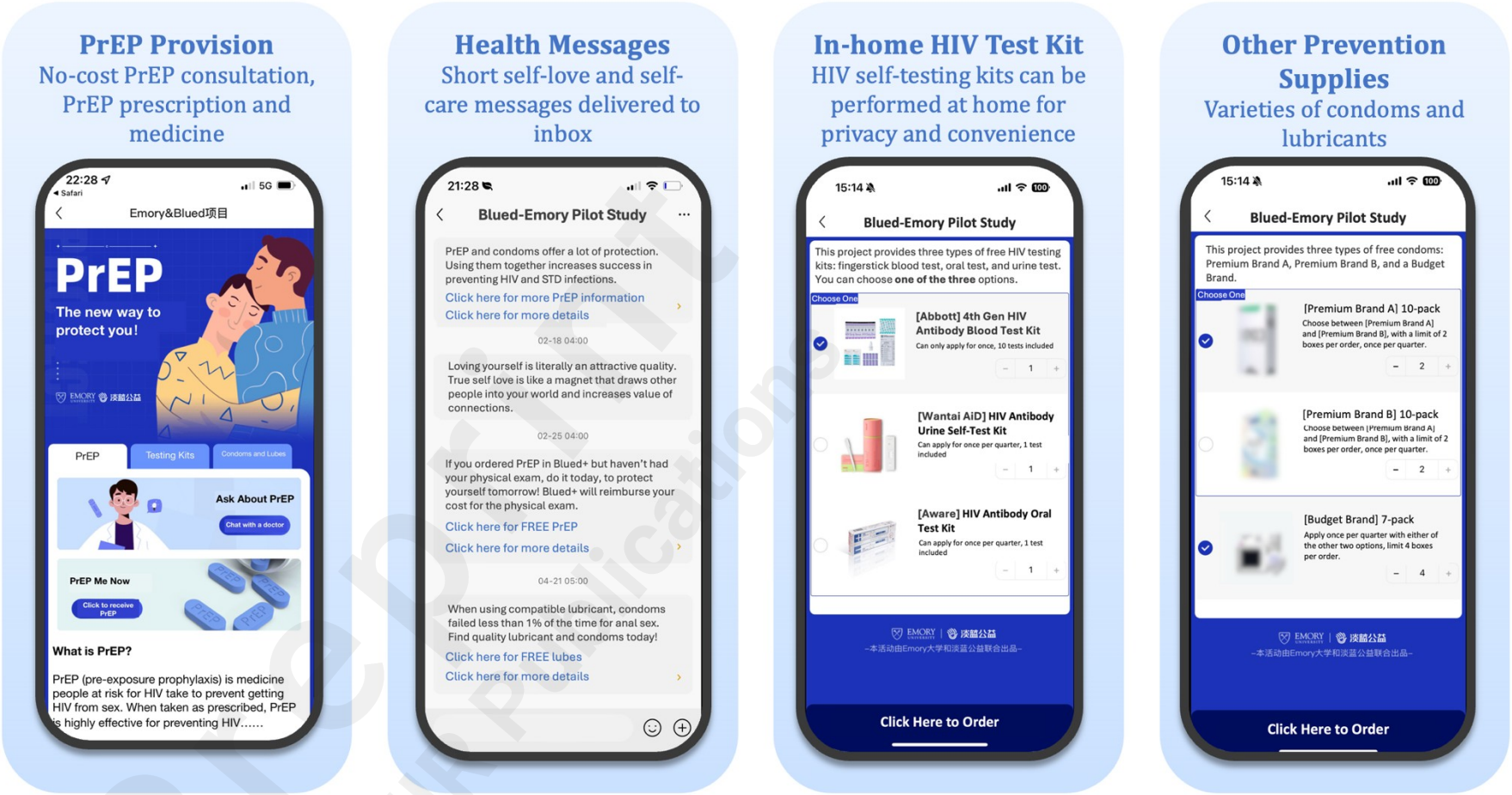


Table 1. Theoretical framework domains and intervention design.

Extended, Unified Theory of Acceptance and Use of Technology (UTAUT2) Constructs	Definition	Intervention design
Performance expectancy (PE)	The degree to which an individual believes that using the system will help him or her to attain gains in health.	Provide in-home HIV testing kit, condoms, lubricant, and PrEP at no cost.
Effort expectancy (EE)	The degree of ease is associated with the use of the system.	Use functions and design layout consistent with the existing Blued app.
Social influence (SI)	The degree to which using the new system is appreciated in the social network that is important to the individual.	Leverage communications in the existing Blued app for peer support, and send highly rated self-care messages from peers.
Habit (H)	The extent to which people tend to perform behavior automatically because of learning.	Use health messaging to help build habits of using HIV prevention services on the enhanced Blued app.

Table 2. Study measures, sources of data, and definitions for primary and secondary outcomes for a pilot study of integration of biomedical prevention services in an existing social networking app for Chinese MSM, Beijing and Chengdu, 2022.

	Construct	Measure	Data Source	Definition	Analysis
Primary Outcomes	Feasibility	Home HIV test orders	Order fulfillment	Proportion of participants sent a home HIV test	$\geq 30\%$
	Feasibility	PrEP initiation	Clinical site data	Proportion of participants receiving a PrEP prescription	$\geq 20\%$
	Acceptability	System Usability Scale [34, 35]	Survey	10-item scale, good score is ≥ 71	Good score (≥ 71 out of 100)
Secondary Outcomes (preliminary efficacy assessment)	HIV testing	HIV testing	Survey	Change in the proportion of participants reporting HIV testing in the last three months	Descriptive, longitudinal analysis ^a
	Condom use	Condom use	Survey	Change in proportion of participants reporting always using condoms for anal sex in the last three months	Descriptive, longitudinal analysis ^a
	PrEP use	PrEP use [40]	Survey	Change in proportion of participants with protective levels of TDF-DP ^b	Descriptive report

^a Descriptive analysis: outcome proportions over time; longitudinal analysis: GEE model to measure predictors of outcomes.

^b Tenofovir diphosphate.

Table 3. Sociodemographic and behavioral characteristics of study participants in the pilot and comparison groups at baseline, Beijing and Chengdu, 2022

	Pilot (n=423)		Comparison (n=1314)		P-value ^b
	n	(%)	n	(%)	
Age (years)^a	30	7.4	31	7.7	.17
City					<.001*
Beijing	230	54.9	837	63.7	
Chengdu	193	45.2	477	36.3	
Education					.11
Post graduate and above	89	21.0	298	22.7	
College or university	235	55.6	706	53.7	
Associate's degree and/or technical school	84	19.9	228	17.4	
High school and below	15	3.5	82	6.2	
Employment Status					.06
Employed full-time	328	77.5	1038	79.0	
Employed part-time	31	7.3	62	4.7	
Full-time student	43	10.2	147	11.2	
Part-time student	2	0.5	4	0.3	
Unemployed/retired	13	3.1	57	4.3	
Others	6	1.4	6	0.5	
Income (monthly, in USD)					.77
>1,400	173	40.9	538	40.9	
980 to 1,400	96	22.7	318	24.2	
420 to 979	95	22.5	298	22.7	
< 420	59	13.9	160	12.2	
Sexual Orientation					.15
Homosexual	357	84.4	1057	80.4	
Bisexual	65	15.4	247	18.8	
Heterosexual and others	1	0.2	10	0.8	
Condomless Anal Sex, past 3 months					<.001*
Yes	265	62.6	542	41.2	
No	158	37.4	772	58.8	
HIV testing^b					<.001*
Yes	302	71.4	763	58.1	
No	121	28.6	551	41.9	
Heard of PrEP					<.001*
Yes	404	95.5	1110	84.5	
No	19	4.5	204	15.5	
PrEP use, ever					.02
Yes	113	26.7	275	20.9	

No	310	73.3	1039	79.1	
PrEP use, past 3 months					.11
Yes	79	18.7	202	15.4	
No	344	81.3	1112	84.6	

^a Reported as means with corresponding standard deviations.

^b T test for age, Fisher exact test for the rest.

* $P < .005$, below Bonferroni-adjusted critical value.

Supplement 1. Illustration Video of Blued+ app

Supplement 2. Table S1. Health Messages

Supplement 3. Enrollment Survey



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Supplementary Files

Multimedia Appendixes

Illustration video of Blued+ app.

URL: <http://asset.jmir.pub/assets/5d8e02714a70ee7ed745249cd261f37d.mp4>

Table S1. Health messages.

URL: <http://asset.jmir.pub/assets/552a60cdb55a6b0551bb56d892039cc9.docx>

Enrollment survey.

URL: <http://asset.jmir.pub/assets/e3fa3b4e570b50473215fd0857ce63d8.docx>

Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

Summary Statement.

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