

## **Enhancing Partner Services Among Men Who Have Sex With Men Living With HIV**

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## Background

Despite global efforts to control HIV among key populations, new infections among men who have sex with men (MSM) are still increasing.<sup>1-3</sup> In the United States (US), HIV prevalence among MSM reached levels as high as 14.5% in 2015.<sup>3,4</sup> In China, HIV prevalence among MSM increased from 0.9% in 2003 to 8.0% in 2015, and relatively unchanged since 2016.<sup>5,6</sup> In addition, alarmingly high HIV incidence rates have been observed among MSM in several cities in China. HIV incidence is as high as 10.0/100 person-years among MSM in eight Chinese cities during 2016-2017.<sup>7</sup> To address this challenge, HIV prevention strategies with high efficacy are urgently needed.<sup>8</sup>

HIV Partner Services (PS), the process of informing potential risk of exposure to sexual partners, is a cornerstone of HIV prevention.<sup>9,10</sup> PS are important for identifying cases, reducing re-infection rates,<sup>11</sup> promoting linkage to care,<sup>12,13</sup> and saving cost.<sup>14</sup> HIV PS programs have been implemented in heterosexual populations in many settings<sup>15</sup> and among MSM in many countries such as the US, Peru, and Australia.<sup>16-18</sup> Studies conducted in the US demonstrated that PS is a cost-effective way to identify new cases,<sup>10</sup> reduces the average duration of infection and reduces overall re-infection rates.<sup>11,19</sup>

However, barriers from both health providers and index patients limit its efficacy.<sup>20,21</sup> As a result, PS is underused in many countries, including China where only 15.7% of index HIV case spouses were notified.<sup>22</sup> In addition, tailored PS for MSM who usually have multiple male or female partners are limited, especially in China.<sup>23</sup> Conventional PS in China use passive referral by providing index patients with partner referral cards,<sup>24</sup> and PS via disease intervention specialists is not available in China. One study conducted among Chinese MSM revealed that only 267/1225 (21.8%) partners of the index cases were successfully notified and tested.<sup>23</sup> Our preliminary data showed that only 16.2% (18/111) of HIV infected MSM have notified their casual partners in 2016. The low frequency of routine PS programs suggests that current strategies reach only a fraction of those at risk. Many existing HIV PS programs lack a patient-centered focus and are ill-suited to addressing issues faced by many MSM. Few incorporate high-risk individual preferences are tailored to the needs and concerns of MSM, or incorporate preferences and suggestions from the local community.<sup>25</sup> Thus, identifying an innovative method to improve the efficacy of PS is critical for HIV control in China and other middle-income countries. Successful PS programs for MSM in China and other LMICs will require novel methods to reach an MSM population where condomless sex and casual sexual partnerships are common, and where severe stigmatization restricts healthcare access among MSM.<sup>25</sup>

We will apply community-based participatory research (CBPR) principles to our intervention development via crowdsourcing. By bringing together researchers and communities,<sup>26</sup> CBPR recognizes the importance of involving members of a study population as active participants in all phases of the research process.<sup>27</sup> CBPR or application of its principles to specific components of research may help reduce health disparities.<sup>27</sup> Crowdsourcing is an approach that obtains solutions from communities.<sup>28-30</sup> Crowdsourcing has been used effectively in public health to improve HIV testing,<sup>7,31</sup> promote condom use,<sup>32</sup> and monitor outbreaks.<sup>33,34</sup> Informed by CBPR theory, we will use crowdsourcing tools so that MSM and other stakeholders can contribute their voices to design participant-oriented interventions.<sup>29,30,35</sup> Based on our previous findings and a pilot PS crowdsourcing contest,<sup>31,32</sup> crowdsourced messages developed for PS may resonate

more with MSM compared to traditional PS messages, leading to increased community participation and acceptance of HIV PS, and in turn, improving the efficacy of HIV PS.<sup>30</sup>

We will use crowdsourcing (including open contest and designathon, a designathon is similar to a hackathon but focused on generating and creating designs<sup>36</sup>) to develop promotional concepts, images, and videos for delivery on smartphones or computer. After the top finalists are chosen by a judging panel, the PS crowdsourcing materials will be delivered to each sexual partner through the index partners' preferred method (send by index partner, healthcare provider, an anonymous system, or any combinations). This approach will take advantage of the widespread availability of smartphones and the internet in China to increase the notification rate, while maintaining confidentiality.<sup>37</sup> A social media-based PS program, taking advantage of smartphones and the internet, could be an important vehicle for anonymous and widely delivery of key messages to large portions of the target populations at low cost. For example, a study conducted in Peru indicated that web-based PS significantly increased the partner notification rate among MSM.<sup>38</sup> The widespread use of smartphones makes this approach feasible, not only in China, but also in other countries throughout South Asia, Southeast Asia, and the US.<sup>39-41</sup>

This study aims to describe the design of a pilot randomized controlled trial and to test the feasibility, acceptability, and preliminary impact of crowdsourced PS compared with conventional PS on promoting HIV testing uptake among partners of newly identified MSM cases in China. We hypothesize that a crowdsourced HIV PS approach, as compared to conventional PS using referral cards (standard of care in China), will yield more sexual partners reporting for HIV testing; and more sexual partners with confirmed HIV.

## Methods and study design

### Study design overview

This study will use a pilot RCT comparing the crowdsourced PS intervention to standard PS. In China, a passive referral is the only existing PS model for HIV PS.<sup>42</sup> We will conduct a pilot study to refine the components and procedures of the intervention and test the feasibility and acceptability of the crowdsourced PS intervention. Newly identified MSM HIV cases will be recruited from Guangzhou. After completion of a baseline survey, eligible MSM will be randomized individually to either the crowdsourced intervention or conventional PS (control arm) in a 2:1 ratio. In both arms, partners will be instructed to report to the study site sites for HIV testing and will complete a brief sexual history questionnaire upon presentation. We will re-contact them within three months of enrolment to confirm whether the intervention or control PS procedures were implemented by the index. The primary outcome will be 1) the feasibility and acceptability of the intervention; 2) the preliminary impact of the intervention: by comparing the proportion of partners getting HIV testing between the intervention and control groups. Secondary outcomes will be the number of partners getting notified, the number of testing partners with confirmed HIV, and risk behaviors of partners. We will also observe these secondary outcomes among main male partners and casual partners separately. We hypothesize that: 1) a crowdsourced PS approach is feasible and acceptable, 2) as compared to conventional PS, will yield: a) more sexual partners reporting for HIV testing; b) more sexual partners getting notified; c) more sexual partners with confirmed HIV; and d) a set of sexual partners with greater STI risk behaviors, such as more receptive anal intercourse, and less condom use.

## **Study site**

The study will take place in Guangzhou MSM community service center. The center is supported by the Guangzhou CDC to provide HIV testing for MSM. Guangzhou MSM community center provides services for 8000 MSM each year, and all the newly identified MSM HIV positive cases in Guangzhou will be referred to the center for additional service. Given 12 months of enrolment, we have a strong ability to recruit 120 eligible MSM (Guangzhou city newly identified 950 MSM HIV cases in 2017).

## **Eligibility**

Eligibility criteria include: (1) being born as a male, (2) 18 years old or elder, (3) at least one male or transsexual oral or anal sexual partner in the past six months, (4) newly identified as HIV positive, and (5) currently live in Guangzhou and no plan to leave Guangzhou in the following two months. To establish linkages for follow-up surveys, unique ID and access codes will be issued to each participant. Participants' phone number, email address, WeChat ID and Blued ID will be collected as tracking information for follow-up. Use of WeChat to contact participants will be particularly helpful given its broad uptake—846 million monthly active users as of November of 2016 and our previous experience in using WeChat to follow up over 80% of participants (1381 MSM).<sup>7</sup> Unlike with phone numbers, people usually maintain a single WeChat account, even if they switch to a new phone number. Signed informed consent will be required from all participants.

## **Baseline questionnaire**

After enrolment, participants will complete a brief self-administered baseline questionnaire. Study staff will be available to assist in the event of confusion about specific questions or if participants do not have a sufficient reading level to complete the survey on a tablet. The questionnaire will address socio-demographic characteristics and HIV testing history. A more detailed, partner-centric sexual history will be obtained by focusing on sexual partners in the previous six months. The sexual history will include specific behaviors with individual partners, including receptive/insertive anal sex, performing/receiving oral sex, condom use, and frequency of each type of intercourse. Information on sexual orientation and sexual orientation disclosure status will also be collected. Detailed contact information will be obtained for the participants and sexual partners for the past six months. Contact information will include phone number, email address, WeChat ID, QQ ID, and smartphone-based sex-seeking applications ID (i.e., Blued ID).

## **Randomization**

Eligible participants will be randomly assigned to the crowdsourced PS arm (intervention arm) or conventional PS (control arm) in a 2:1 ratio. Since information under the control situation is already available from Guangzhou, a 2:1 ratio will allow us to spend more resources on intervention, and collect more primary outcome relevant data from participants in the intervention group (especially for the measure of the feasibility and acceptability). This approach ensures that the index participants in each arm will be evenly distributed. The number of partners

may vary somewhat across the two arms, as the number of partners of the index participants is variable. However, the total number of partners in the two arms should be comparable.

### Sample size and power

This is a pilot RCT, and the primary outcomes of this study are: 1) to test the feasibility and acceptability of the crowdsourced intervention, and 2) to pilot the preliminary impact of crowdsourced PS intervention in promoting HIV testing among partners of the newly identified HIV cases. In addition, this pilot RCT aimed to collect preliminary data for the designing of a full RCT, which aimed to measure the efficacy of the crowdsourced PS intervention in promoting PS. Thus, the sample size of this study is not designed and will be not powered enough to test the difference between the two arms. However, with a sample size of 120 (80 for intervention arm and 40 for the control arm, respectively), this pilot study would collect enough information to measure the feasibility and acceptability of the intervention, and it will be able to observe the differences between the two arms and collect preliminary data for an adequate sample size calculation of a full RCT. With a sample size of 120 (ratio of 2:1), alpha=0.05, power=0.80, and the partner return rate in the conventional PS arm is 30% (around 31% in 2016 in Guangzhou), the minimal detectable effect size would be 26.7% for this pilot study.

### Intervention

Crowdsourced PS procedures: After randomization, the procedures for the crowdsourced intervention arm will be explained to the MSM HIV index cases in this arm. Final procedures will be determined upon completion of crowdsourcing events. The expected procedures are shown below:

1. MSM in the intervention arm will *receive the crowdsourced intervention* at the study site.
2. Index MSM will *choose specific crowdsourced materials* to use for notification of each partner.
3. The index cases will then *choose the procedure* to be used for delivery of the intervention: a) personally send to partner, b) have the study coordinator send, c) have the CBO send, d) send through an anonymous email/phone number system, or e) any combinations of the above-mentioned procedures.  
The crowdsourced intervention package may be delivered by text, WeChat, gay dating apps, and/or email. If the index is not ready to send the message to the partner at the time of the clinic visit, he may contact the research coordinator at any time within 6 weeks to request that the materials be sent.
4. The index patients will *select a message* about the crowdsourced intervention. The texts/emails will include a unique ID, address of the center, and phone number/WeChat ID of the study coordinator at the center. The specific content will be refined in the crowdsourcing events.
5. *The message will be sent to the partners* through a prechosen delivery channel, coupled with prechosen crowdsourced intervention materials.
6. *Partners* who view the intervention materials *will be prompted* to enter a phone number, email address, WeChat ID, and usernames for Blued (A popular gay dating mobile application with 43 million users in China). These data allow us to link partners who view the intervention materials to the index cases.
7. At the conclusion of the intervention materials, *information will be provided* about the MSM community centers where HIV testing is available, research coordinator's contact information, and instructions to retain the email/text to present at the center. If the partner is willing to provide a phone number or email address, *a message will be automatically generated* including the center and coordinator information.
8. *Partners will be encouraged* to present for testing within one week of notification.

9. *Index MSM will also be given PS cards*, comparable to the standard PS arm, in case they choose to inform partners this way

In addition, after introducing the crowdsourced intervention to the participants in this group, a short survey that aims to evaluate the feasibility and acceptability of the crowdsourced intervention will be carried out.

Conventional PS procedures: The index cases in the conventional PS arm will be provided with referral cards that include the unique ID to link index and partners, as well as the address of the study centers where they can present for free HIV testing and the phone number of the study coordinator. The index cases will be encouraged to remind their partners to bring the referral card with them when they present. On the reverse side of the card, we will provide instructions to facilitate forwarding of test results if the partner chooses to attend a different clinic. Guangzhou CDC will also coordinate with other clinics in the city to collect the cards and a brief consent to capture the HIV result.

Partner linkage: Partners will be linked to the indexes through the unique ID on the referral cards. Partners without unique ID information will be matched to the index using a sequential matching algorithm using all index identification information provided. If a partner is unable to produce the card/text/email, we will ask him/her how he/she was originally notified of the need for testing. If the partner indicates he/she was informed by intervention materials, we will ask him/her to identify the phone number, email address, or username to which the message was delivered. We will also ask him/her to provide the date that he reviewed the intervention materials. If a partner was given a referral card but cannot present the card, we will ask him/her to give the name or contact information of the person who gave him/her the card. We will also obtain the date that the card was provided. Partners without card/text/email will be matched to the index using a sequential matching algorithm using all index identification information provided.

## **Index follow-up survey**

Three months after enrolment, index participants in both arms will be re-contacted by phone or email and provided a link to an online survey. A small incentive (mobile top-up) will be provided. The survey will further evaluate the acceptability and feasibility of the crowdsourced intervention among participants in the intervention group. We will also evaluate the potential challenges and advantages of the crowdsourced intervention. The survey will be comparable to the baseline survey. Sexual contact with specific partners, named previously, will be elicited, as well as new partners. The survey will also address whether the specific partners were notified by the index, underwent HIV testing, and how testing was performed.

## **Study measures and outcomes**

### **Primary outcomes**

The primary outcomes are: 1), the feasibility of the study and the feasibility of the intervention. The feasibility of the study will be measured in the ability to enroll 120 newly identified MSM HIV cases as index participants in the study center in a 12-month period, and the ability to

contact the index MSM (follow-up rate) and their partners at 3 months after enrolment (proportion of the surveyed partners response to the survey). The feasibility of the intervention will be used to measure whether the crowdsourced intervention is successfully used or carried out. This will be measured in the frequency of the partners in the intervention arm receiving the crowdsourced intervention and the frequency of the partners taking action after they receive the intervention (whether go for HIV testing). 2), the acceptability of the crowdsourced intervention: this will be measured at baseline among index participants and the partners of the index participants in the intervention arm. We will ask the index participants and their partners whether the crowdsourced intervention is acceptable to them. 3), the preliminary impact of the intervention: the proportion of partners returning for HIV testing within 3 months of the index participant's enrolment in the study, determined based on the partners presenting to the centers and those verified from the CDC electronic medical record central database.

## **Secondary outcomes**

Secondary outcomes will include: 1) The proportion of partners being notified by indexes among all reported partners; 2) the number of tested partners, normalized to the number of index participants (i.e. the mean number of partners getting notified per index participant); 3) the proportion of positive HIV tests among tested partners; 4) the number of tested partners with a positive HIV test, normalized to the number of index participants (i.e. the mean number of partners with HIV per index participant); 5) the proportion of reported partners getting HIV testing who are not spouses or regular partners, and 6) the proportion of condom use by presenting partners during the last anal intercourse.

## **Additional measures**

In addition to the primary and secondary outcomes, we will collect index and presenting partners' socio-demographics, sexual orientation, sexual orientation disclosure status, HIV and other STDs testing history and HIV PS history.

## **Data management**

For the baseline and follow-up surveys for the indexes and the survey for partners, all data are directly entered into computers as participants complete the surveys. Data can be readily downloaded and converted to the format of commercially available statistical software. During collection of the online portion of the study, all data will be transmitted securely using SSL (TLS) 128 bit encryption across the Internet (HTTP). SSL provides users with the assurance of access to a valid, "non-spoofed" site, and prevents data interception or tampering with sensitive information. The SSL certificate that will be used for this project will use 128-bit encryption, the preferred security level of government and financial institutions. 128-bit encryption offers protection that is virtually unbreakable. Data will be located in a secured server at UNC Chapel Hill. The server will be configured with redundant hard drive array to ensure reliability. Access to the data will be password protected within the server's firewall. Only the PI and a designated senior staff member will have the password to access to the "key" that links the non-descript identifier to personally identifiable information. IP addresses of participant's computers will not be collected at any time. Cookies will not be used in any way to track participant activity. A

quick link will exist on each survey page to provide participants a rapid way to switch to an innocuous website if their privacy is interrupted while completing the survey.

No presentation or publication of the study results will refer to participants individually. Manuscripts published regarding this work will be based on the accumulated database. Exceptions to confidentiality for participants are those required by law and include suspicion of child abuse, elder abuse, and threat of imminent action on suicidal or homicidal ideation. Participants will be informed of these exceptions in the informed consent process.

## Statistical Analysis Plan

For the primary outcomes of feasibility and acceptability of the intervention: this will be analyzed through descriptive analysis to assess the feedback on the feasibility and acceptability of the crowdsourced PS intervention among index MSM and their partners in the intervention group. For the primary outcome of the proportion of partners returning for HIV testing within 3 months of the index participant's enrolment in the study, log-binomial regression (generalized linear model with binomial distribution and log link) will be used to calculate 95% confidence intervals for the proportion of notifiable partners visiting by arm. Risk differences and risk ratios will also be calculated in these models. As this study is a pilot RCT, and we will only recruit 120 index MSM, and they will be randomly assigned in a 2:1 ratio, adjustment for covariates would be necessary if the two study arms are not balanced. In secondary analyses, we will adjust for pre-specified potential confounding variables that might bias the estimate if not accounted for (e.g. index age, index marital status). If a partner reports more than one index referred him, he will be counted as a returning partner for each identified index.

*Table 1* Analysis strategies for secondary outcomes

Secondary Outcome	Population	Model Type
The proportion of reported partners being notified by indexes among all reported partners	Reported sexual partners	Binomial regression, robust variance
Mean number of partners tested per index participant	Index participants	Poisson or negative binomial regression, robust variance
The proportion of positive HIV tests among tested partners	Tested sexual partners	Binomial regression, robust variance
Mean number of partners with HIV (case-finding) per index participant	Index participants	Poisson or negative binomial regression, robust variance
The proportion of reported partners getting HIV testing who are not spouses or regular partners	Reported casual male sexual partners	Binomial regression, robust variance
The proportion of presenting partners reporting condom use during the last anal intercourse	Presenting sexual partners	Binomial regression, robust variance

Subgroup analyses will be performed by partner type (e.g. main male partner vs. casual male partner). For secondary outcomes, analysis approaches are provided in Table 1. For count variables expressed as the mean number of partners, we will use either Poisson regression or negative binomial regression if overdispersion is identified. In addition, we will assess which secondary outcomes seem to have meaningful discriminatory power in a future study. We will include the potential secondary outcomes that are important and meaningful discriminatory

power in the future study. In addition, we will use the information we obtain in the pilot RCT to conduct sample size estimation for the later trial.

## **Summary and Impact**

HIV PS is underused among key populations around the world, and crowdsourced PS could potentially enhance the effectiveness of PS. Innovative approaches to designing PS interventions are needed, yet many HIV campaigns repackage old ideas. Crowdsourcing leverages the high internet use and willingness to participate in online forums among MSM to transform the design and implementation of partner services. Upon completion of the study, we will provide the scientific community with a strategy to develop crowdsourced PS interventions, and test its feasibility and acceptability. In addition, this pilot study can reform the existing HIV PS for MSM, and assess the preliminary impact of the crowdsourced intervention, which will be helpful for designing a full RCT, which aimed to evaluate the efficacy and cost-effectiveness of the intervention. If successful, this strategy has the strong potential to be implemented in similar countries/regions.

## **Ethical approvals**

The study was reviewed and approved by the Institutional Review Boards at the Guangzhou Center for Diseases Control and Prevention (IRB#2019001).

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## Online Informed Consent Form

**Research purpose:** We invite you to participate in a survey project jointly initiated by SESH (Social Entrepreneurship to Spur Health) and Guangzhou CDC to promote sexual partner disclosure among HIV-positive partners. Sexual partner notification refers to the general term for a series of services such as taking a certain way to inform recent sexual partners of the positive result of their HIV status, and guiding them to medical institutions for testing, treatment, health education, and consultation.

**Main content:** The survey is mainly conducted through questionnaires. The baseline questionnaire will be distributed by the investigators at the outpatient clinic to you. The questionnaire contains your basic information, sexual behavior history, HIV testing history, and intention to disclose to each sexual partner. The investigation time is about 20 minutes. At the same time, we encourage you to mobilize your sexual partners to take the test. For each successful mobilization of a sexual partner to test and return the results, you will receive a subsidy of 50 yuan per person. Three months later, the investigator will send you a follow-up interview questionnaire via WeChat, asking about the situation and consequences of the disclosure by your sexual partner. After successfully completing the follow-up questionnaire, you will receive a subsidy of 50 yuan.

**Voluntary participation:** Participation in this project is voluntary, and you may refuse to participate or withdraw from the project for any reason. In addition, you do not waive any legal claims or rights by participating in this survey.

**Confidentiality principle:** All information you provide will be kept strictly confidential. Among them, you may provide the contact information of your sexual partner, which will only be used to assist medical staff to inform and check HIV testing status. All staff members and survey subjects of this survey, including yourself, must abide by the confidentiality requirements of the project, and unauthorized staff cannot view relevant data. The data in this study are only used for scientific research and not for any commercial use.

**Possible benefits and risks:** This project will provide you with free self-test reagents, which you can directly bring to your sexual partners for testing, or apply for postal self-test reagents through the QR code on the card given to you by the staff. You can access partner disclosure services in this study to help you make effective partner disclosure in a safe and supported manner. You can get a certain financial reward for completing the follow-up questionnaire and successfully mobilizing your sexual partner for testing, and your sexual partner will also receive a subsidy of 30 yuan when returning the test result. At the same time, the information collected during the study will help us develop safer and more effective partner notification services, ultimately enhancing the health of the Chinese gay community.

We will ask you for important information such as your sexual behavior and sexual partner, and you may feel uneasy about answering sensitive questions; if you choose auxiliary notification, you need to tell us the contact information of your sexual partner, which may worry about privacy leaks. In order to avoid the above risks, our investigators are strictly trained, and the final investigation data will remove sensitive information. If you feel uncomfortable or have any other problems due to the investigation, you can stop at any time, or seek advice and help from the relevant person in charge. The staff have been specially trained and will deal with your problems in a timely manner.