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Tapping the Wisdom of The Crowds to Enhance Condom Use Among Men who have Sex with Men and Transgender Individuals: A Study Protocol

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Version 1.0

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ABSTRACT

Introduction

Crowdsourcing has been used to spur innovation and increase community engagement in public health programs. Crowdsourcing is the process of giving individual tasks to a large group, often involving open contests and enabled through multi-sectoral partnerships. Here we describe a crowdsourced video intervention in which a video promoting condom use is produced through an open contest. The aim of this study is to determine whether a crowdsourcing intervention is as effective as a social marketing intervention in promoting condom use among high-risk men who have sex with men (MSM) and transgender male-to-female (TG) in China.

Method

We held an open contest to develop a crowdsourcing video and obtained a social marketing video from an advertising company. The crowdsourcing contest involved an open call for videos. Entries were judged on capacity to promote condom use, to be shareable or “go viral”, and to give value to the individual. 1170 participants will be recruited for the randomized controlled trial. Participants need to be MSM age 16 and over who have had condomless anal sex in the last 3 months. Recruitment will be through an online banner ad on a popular MSM webpage and other social media platforms. After completing an initial survey, participants will be randomly assigned to view either the social marketing video or the crowdsourcing video. Follow-up surveys will be completed at both 3 weeks and 3 months after initial intervention to evaluate condomless sex and related secondary outcomes. Secondary outcomes include condom social

1 norms, condom negotiation, condom self-efficacy, HIV/syphilis testing, frequency of sex acts
2 and incremental cost.

3 **Ethics and dissemination:**

4 Approval was obtained from the ethical review boards of the Guangdong Provincial Center for
5 Skin Diseases and STI control, the University of North Carolina at Chapel Hill, and the
6 University of California at San Francisco. The results of this trial will be made available through
7 publication in peer-reviewed journals.

8
9 **Trial registration number:** This trial was registered in ClinicalTrials.gov (NCT02516930).

12 **Strengths and Limitations of this study protocol:**

- 13 • This study protocol was prospectively registered
- 14 • This study will be a pragmatic, non-inferiority, randomised controlled trial
- 15 • Participants will be self-selecting

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1 INTRODUCTION

2 *Male Sexual Health*

3 Male condoms have long been recognized as an effective method for reducing the risk of HIV
4 and other sexually transmitted diseases (STDs)^{1 2}, but men who have sex with men (MSM)
5 infrequently use condoms in China³⁻⁶. The resulting high incidence of HIV and STDs among
6 MSM suggests the need for novel health promotion campaigns. One systematic review⁷ and one
7 literature review among MSM⁸ demonstrate that social marketing campaigns are effective in
8 promoting condom use, but the persistence of these behavioural changes over time is unclear.
9 We propose that crowdsourcing may substantially improve on existing methods for developing
10 condom promotion campaigns.

11
12 *Crowdsourcing*

13 Crowdsourcing is the process of giving individual tasks to a large group, often involving open
14 contests and enabled through multisectoral partnerships. While the process originated in the
15 private sector⁹, intended to aid research, development and dissemination, it has since been widely
16 adopted. In 2010, the Executive Office of the President of the United States urged federal
17 agencies to utilize crowdsourcing as a method to develop innovative approaches to governmental
18 initiatives¹⁰. A crowdsourcing method differs from a social marketing method in several ways¹¹.
19 Crowdsourcing is a bottom-up approach, utilizing the community for idea generation through
20 implementation rather than relying on the expertise of public health experts. This ensures a
21 higher degree of community engagement than approaches utilizing social marketing do, which
22 tends to be a top-down approach. Crowdsourcing promotes innovation because it removes
23 cognitive fixation, in which innovation is hampered due to new ideas being strongly influenced

1 by prior examples¹²⁻¹⁶. By engaging more people with less experience, this phenomenon is
2 avoidable and allows for a more creative process¹⁷. Our team has previously used crowdsourcing
3 successfully to develop an effective HIV testing promotion video and images promoting sexual
4 health.¹⁸

6 OBJECTIVES

7 *Aims and Hypotheses*

8 Specific Aim 1: To compare the effect of a crowdsourced one-minute video to a social marketing
9 one-minute video in promoting condom use among MSM and transgender male-to-female (TG)
10 in China. This will be evaluated using data from follow-up surveys at 3 weeks and 3 months
11 post-video.

12 Hypothesis 1: Crowdsourced videos are not inferior to social marketing videos to promote
13 condom use among MSM and TG in China.

15 Specific Aim 2: To compare the cost of using crowdsourcing compared to social marketing
16 methods for developing short videos focused on promoting condom use among MSM and TG
17 individuals in China.

18 Hypothesis 2: A crowdsourced video is cost saving compared to a social marketing video for
19 promoting condom use.

21 Specific Aim 3: To compare the effect of a crowdsourced one-minute video to a social marketing
22 one-minute video in changing condom use self-efficacy and self-reported behaviour among
23 MSM and TG individuals in China.

Hypothesis 3: Crowdsourced videos are not inferior to social marketing videos in changing condom use self-efficacy and self-reported behaviour among MSM and TG in China.

METHODS

Trial design

This study will be a pragmatic, non-inferiority, randomized controlled trial comparing two groups – MSM who watch a crowdsourced video and MSM who watch a social marketing video. Allocation to each arm will be done with a 1:1 ratio using a computer-based algorithm. The study is projected to run from November 2015 to February 2016.

Setting

This study survey will be made available to MSM across China through a popular online portal, Danlan and gay mobile dating app, Blued. Danlan.com is an online gay community that allows MSM to connect with each other for relationships, events, and communication. The website is maintained by a private corporation, Danlan, which also developed the for-profit app Blued. Blued has become very popular among the MSM population, recently reaching 15 million users¹⁹. User personal information is protected and secure. Studies have shown that the Internet has become a popular method for MSM to find partners, with a reported 28.3-88.4% of MSM using the Internet to seek sexual partners²⁰. While Internet-based interventions have yet to be widely dispersed in mainland China, early studies show that such e-technology-based approaches would be well received²¹.

1 Recruitment

2 Participants will be recruited using a banner link on a popular MSM app “Blued” (Danlan,
3 Beijing, China), as well as through announcements sent via Danlan’s social media (Weibo, a
4 microblogging platform, WeChat, a messaging platform, and QQ, a messaging platform). Blued
5 is China’s most popular social networking mobile application among MSM. Blued has 15
6 million followers with 24% (3.6 million people) daily activity rate¹⁹. Danlan has over 17,000
7 followers on social media platform Weibo and forwards news via WeChat and QQ to over
8 429,000 followers²².

10 Eligibility

11 The survey is voluntary, and to be eligible, participants must state that they were born
12 biologically male, had anal sex with men at least once during their lifetime, have had condomless
13 anal/vaginal sex in the past three months, and are at least 16 years of age. All participants must
14 agree to an online informed consent and provide their cell mobile number. Participants who do
15 not meet these criteria will not be allowed to proceed with the survey.

17 Formative work

18 Prior to survey development, we will interview key informants specifically about conducting an
19 Internet survey among MSM in China. Survey development will be done drawing on previous
20 surveys and a review of existing literature, focusing on English and Chinese language studies.
21 The survey will be developed in both English and Chinese. The Chinese version of the survey
22 will be piloted online with 150 volunteers to gauge post-intervention condom usage rates and to
23 estimate the necessary sample size for the non-inferiority study. The survey will also be piloted

with Danlan to ensure there are no problems with distribution. Feedback will be solicited online regarding question wording and interpretation. Pilot data will not be included in the final analysis. The purpose of this extensive formative research is to ensure that the online survey is simple and easy to complete. The CONSORT-Ehealth checklist for online surveys²³ will be used to ensure completeness. The online survey will be created using Qualtrics Survey Software (Qualtrics, Provo, Utah) and the videos will be hosted on Tencent Video (Tencent, Shenzhen, China).

Interventions

The development of the crowdsourcing video was publicized via open contest. We posted a public call on social media platforms (Weibo, WeChat) for videos promoting condom use awareness. For further promotion, we hosted in-person events at several different college campuses in Guangzhou, China and worked with local community-based organizations to publicize the contest. In-person events included didactic sessions, interactive feedback sessions, and community-driven events. Ten judges, including community health leaders, doctors, business leaders, and researchers, evaluated the videos. . Each judge scored the video entries on a scale of 1-10 (10 the highest score) and a single winner was identified. The winning video will be included in the survey as the intervention arm of the RCT. The one-minute video depicts a group of men dressed as cartoon villains attempting and failing to break down a wall, followed by an image of condoms. Our team will delay announcement of the contest winner to allow time for adequate intervention implementation and comparison. The winning video will be announced 2 weeks after the intervention is evaluated using the 3-month follow-up survey.

1 The social marketing video was commissioned from a working group in Jinan. This one-minute
2 video contains audio of two men about to engage in intercourse, but stopping to discuss condom
3 use and sexual health as a symbol of love. Script of the video was written by experts in San
4 Francisco and modified by experts and the gay community in Jinan and Qingdao. The video was
5 shot by an advertising company based in Jinan.

6 *Data collection*

7 A survey will be developed using the Qualtrics survey tool. Participants will answer 150
8 questions on socio-demographic information, sexual behaviour, social norms, condom self-
9 efficacy, HIV testing, and community engagement. At the end of the survey, participants will be
10 randomly assigned to one of two intervention arms, the crowdsourcing video or social marketing
11 video, and will view the appropriate video. Participants will not be informed of the video options
12 upon randomization, and will not see the alternate intervention video. Participants will provide
13 mobile telephone numbers, and will receive text message reminders three weeks after initial
14 survey completion to complete the three-week follow-up survey. After completion of the three-
15 week survey, participants will be compensated for the first portion of the study (about \$15.87
16 USD). Three months after completion of the initial survey, participants will again receive a
17 mobile telephone reminder to complete the three-month survey. After completion participants
18 will receive the second portion of their compensation (about \$7.93 USD).
19 A data monitoring committee will not be required as this study employs low risk behavioural
20 interventions.

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1 1 *Measures*

2 2 Data from survey items on socio-demographics and sexual behaviours will be collected using
3 3 standardized survey instruments immediately before video watching, at three weeks after video
4 4 watching, and at three months after video watching. Socio-demographic characteristics include
5 5 participants' age, place of residence, highest level of education completed, annual income,
6 6 marital status, sexual orientation, and sexual orientation disclosure. Behavioural variables
7 7 include number of sex acts in the past three weeks, condomless sex with men, condomless sex
8 8 with women, condom self-efficacy, and other secondary outcomes (See Appendix 1).

9

10 10 **OUTCOMES**

11 11 *Primary Outcomes*

12 12 The primary outcome will be any condomless vaginal or anal sex (with any sex partner) among
13 13 MSM and TG individuals following the video intervention. Using a post-intervention survey,
14 14 participants will be asked with what frequency they have used condoms since watching the
15 15 video: all, most, some or none of the time. Individuals who have not had sex in the interval will
16 16 be classified as having no condomless sex. Condomless vaginal or anal sex will be defined as
17 17 condomless sex of any frequency (e.g. using a condom none, some or most of the time).

18

19 19 *Secondary Outcomes*

- 20 20 • Post-intervention sex acts
- 21 21 • Condom use social norms
- 22 22 • Condom self-efficacy
- 23 23 • Condom use negotiation

- HIV testing and self testing
- Syphilis testing and self testing
- Incremental cost of intervention associated with respective video interventions per individual reporting increased condom use or no sex since intervention. Other cost-related data from organizations involved in making the intervention videos will be collected.

More detailed explanations of secondary outcomes can be found in Appendix 1.

Sample size calculation

Sample size for this non-inferiority trial was determined assuming an equal probability of reporting condomless sex in the crowdsourced video and social marketing video arms. Assuming a 50% probability of condomless sex in each arm, a one-sided significance level (α) of 2.5%, a non-inferiority limit of 10%, and loss to follow-up of 10%, a total sample size of 1170 individuals was required (585 in each arm) to have 90% power ($1-\beta$). The sample size was calculated using the formula²⁴:

$$n = f(\alpha, \beta) \frac{[\pi_s (1 - \pi_s) + \pi_e (1 - \pi_e)]}{(\pi_s - \pi_e - d)^2}$$

where π_s and π_e are the true probabilities of reporting condomless sex in the social marketing video (standard) and crowdsourced video (experimental) intervention groups, respectively, d is the non-inferiority limit, and $f(\alpha, \beta) = [\Phi^{-1}(1-\alpha) + \Phi^{-1}(1-\beta)]^2$ where Φ denotes the cumulative distribution function of the standard normal distribution.

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3 1 *Randomization and allocation*

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5 2 Participants will be randomly assigned to one of the two intervention videos using an electronic
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7 3 randomizer tool available through Qualtrics. Randomization will occur independently of any
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9 4 other data collected, with participants allocated in a 1:1 ratio to one of the two arms. Participants
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11 5 will not be informed of which video (crowdsourcing or social marketing) they are assigned to.
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17 7 **DATA ANALYSIS**

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19 8 *Primary analysis*

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21 9 The primary analysis will evaluate the non-inferiority hypothesis comparing the two
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23 10 interventions, as well as the superiority hypothesis. The difference in proportions having
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25 11 condomless sex (crowdsourced - social marketing) will be computed, with a corresponding two-
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27 12 sided 95% Wald confidence interval. The crowdsourced intervention will be declared non-
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29 13 inferior to social marketing if the upper confidence limit is below 10%. If the upper confidence
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31 14 limit is below 0%, then the crowdsourced intervention will be declared superior to social
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33 15 marketing.
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43 18 *Effect modification analysis*

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45 19 Effect modification analyses will be under taken based on prior exposure to the condom
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47 20 promotion video viewed by the participant to assess whether this exposure modified the effect of
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49 21 video intervention arm upon the primary condom use outcome. A linear probability model will
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51 22 be used to evaluate effect modification by testing for an interaction between intervention and
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53 23 prior video watching.
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Missing data plan

If the primary outcome is missing for <11% of participants, then the primary analysis will use a complete-case approach. If the primary outcome is missing for 11 to <20% of participants, then a sensitivity analysis using multiple imputation based on the PROC MI procedure in SAS (Cary, NC) will also be used. If the primary outcome is missing for $\geq 20\%$ of participants, then multiple imputation will be used in the primary analysis.

Secondary analysis

Comparison will be made between the two trial arms with respect to each of the secondary outcomes enumerated above and in Appendix 1. Non-inferiority comparisons will also be made between study arms for the subset of individuals who reported sex during the follow-up period (3 weeks and 3 months respectively) and causal inference methods will be employed to account for post-randomization selection bias.

ETHICS AND DISSEMINATION

Ethical review

IRB approval was obtained from the Guangdong Provincial Center for Skin Diseases and STI Control, University of North Carolina at Chapel Hill, and University of California San Francisco.

Informed Consent

All participants will be provided an online consent form immediately prior to survey commencement. This online informed consent describes personal data to be collected, explaining that data will be used for research purposes. Contact information is provided to participants to

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1 address further questions. Participants will be required to sign the consent and provide a mobile
2 telephone number as agreement to proceed with the survey.

4 *Confidentiality*

5 Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted
6 securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured
7 Qualtrics server in the United States. The server is configured with redundant hard drive array to
8 ensure reliability. Access to the data will be password protected within the server's firewall.
9 Survey responses will be kept separately from participants' email addresses; the two files will be
10 linked with a non-descript, unique, randomly generated identifier.

11 Participants will provide mobile telephone numbers, which will be kept separately from data
12 containing answers to survey items. These telephone numbers will be accessible only to two
13 researchers solely for the means of sending reminders, follow-up surveys and mobile top-up
14 incentives.

16 *Dissemination*

17 The results of this study will be prepared and submitted for publication in a peer-reviewed
18 journal. Study findings will also be shared through conference abstracts and presentations,
19 workshops, and to our partnering organizations.

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Contributors

CW and JT conceived the study, CL, JM, TW, WT, LT ST, WZ, YQ, KM, MG, CW and JT contributed to study design. WT, ST, KM, and MG helped with statistical support and endpoints. CW, JM and TW designed data collection tools. JT, WT, CL and JM drafted and revised the manuscript. All authors contributed critical intellectual input and approved the final manuscript.

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Guangzhou, China. The funding source had no role in the design of the study and will not have any role during its execution, analyses, interpretation of data, or decision to submit results.

Competing Interests

None of the authors declare any conflicts of interest.

Ethics Approval

Ethical approval has been obtained from the ethical review boards of the Guangdong Provincial Center for Skin Diseases and STI control, the University of North Carolina at Chapel Hill, and the University of California at San Francisco.

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1 **Table 1: Sample size for 90% power and one-sided 0.025 significance level**

Probability of primary outcome in control group *	Probability of primary outcome in experimental group *	N evaluable per arm	Total sample size for RCT
0.50	0.50	526	1170
0.45	0.45	521	1158
0.40	0.40	505	1124
0.35	0.35	479	1066
0.30	0.30	442	984

2 *Based on the pilot study, 9 of 25 participants (95% confidence interval: 18% to 57%) had
3 condomless sex at least once in the three-week period immediately following the video
4 intervention. According to a similar RCT we conducted in 2014, the loss to follow up rate was
5 about 10%; adjustment for loss to follow up required (N evaluable per arm)/(1- 0.1) to be
6 enrolled. A non-inferiority limit of 0.1 was used for all calculations.
7

Table 2. Incremental costs associated with social marketing and crowdsourced arms.

Phase	Financial costs	Economic costs
Contest development	<i>Inputs to be capture, can all directly be found in the project financial accounts, main challenge is to allocate across components and to allocate SESH overhead costs</i>	<i>Extra inputs not already captured by financial costs</i>
Video contest (including production)	Money paid for planning and implementation	For social marketing arm: <ul style="list-style-type: none"> • Personnel of CBOs/CDC (director of movie, actors, film editors) • Rental of professional video equipment (if applicable) • Building cost (office renting) for CBOs/CDC* • Equipment and software cost (if applicable) * For crowdsourced arm: <ul style="list-style-type: none"> • Personnel of SESH (although all volunteer) • Judging opportunity cost (volunteer) • Steering Committee planning meeting (three one-hour meetings) • Building cost (office renting)* • In-person promotion costs
Survey start up	Money paid to launch the survey (start-up)	<ul style="list-style-type: none"> • SESH personnel costs, to design and maintain the program • Equipment cost of SESH (computer and other items)* • Software (Qualtrics)*
Survey implementation and intervention	Money paid to the participants (implementation) Money paid for the software used for follow up (implementation)	<ul style="list-style-type: none"> • SESH personnel costs
Testing		<ul style="list-style-type: none"> • Cost for condoms (from CDC)

*The cost will be annualized and we will calculate a proportion of the cost to account for items only being used the study time frame. The key idea is that some of these phases are like capital goods, where they only need to be done once but have benefits for longer (thus requiring annualisation of costs), while the implementation phase has a life only as long as the survey is running.

Appendix 1. Secondary outcomes measured as part of this RCT.

Secondary Outcome	Definition
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective video interventions (development, start-up, implementation, condom use, intervention – see Table 2 for details) per individual who reported no sex or sex with a condom during the follow-up period.
<i>Female condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with a woman divided by the total number of men who viewed the video in that arm.
<i>Male condomless sex</i>	Frequency of men, defined as number of men who reported condomless anal sex with a man divided by the total number of men who viewed the video in that arm
<i>Post-video condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with any partner within three weeks following the video intervention divided by the total number of men who viewed the video in that arm
<i>Frequency of sex acts</i>	Frequency of men, defined as the number of men who had decreased total number of sex acts in the three weeks following the intervention compared to the three weeks immediately preceding the intervention in that arm
<i>Condom use social norms</i>	Frequency of men, defined as number of men who report higher levels of social norms when comparing their pre-intervention and post-intervention condom use norms*
<i>Condom self-efficacy</i>	Frequency of men, defined as number of men who had an increase in self-efficacy when comparing their pre-intervention and post-intervention self-efficacy**
<i>Condom negotiation</i>	Frequency of men, defined as the number of men who attempted to convince an unwilling partner to use a condom within three weeks following the video intervention divided by the total number of men who viewed the video in that arm
<i>HIV testing</i>	Frequency of men, defined as the number of men who reported being tested for HIV during the interval between watching the video and following up divided by the number of men who followed up
<i>Syphilis testing</i>	Frequency of men, defined as the number of men who reported being tested for syphilis (excluding HIV during the interval between watching the video and following up divided by the number of men who followed up

*Condom use social norms will be measured using six survey items that are each on a five point Likert scale. Increased condom use social norms will be defined as having an increase from baseline in any two of these six survey items and dichotomized accordingly. The condom use social norm outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

**Self-efficacy will be measured using seven survey items that are each on a five point Likert scale. Increased self-efficacy will be defined as having an increase from baseline in any two of these seven survey items and dichotomized accordingly. The self-efficacy outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

Supplementary File: Online Survey

Men's Health Study (Final)

About this Study:

You are being asked to take part in a research study that will help us better understand sexual behavior and condom use among men in China. Your participation in this project will allow us to develop better interventions to promote condom use and to improve sexual health among men across China.

What's Involved?

If you participate in this study, you will be asked to complete an online questionnaire and a subset of participants will be asked watch a one minute video. A subset of participants will also be asked to complete up to two additional follow-up questionnaires. The questionnaires will ask you to provide sociodemographic information and information about your sexual behaviors. In order to ensure that your privacy is protected, all of your online responses will be encrypted and securely transferred to our data servers.

Upon completion of this study and a 3-week follow up survey, **you will receive 100 RMB credit** to your mobile phone. Eligible participants who also complete the follow-up questionnaires can **receive up to 150 RMB credit** to their mobile phone.

If you have any questions about the research or your participation in the study, feel free to contact

A. Basic Information (Eligibility Survey) (Q1-5)

- A1. Were you born biologically male or female?
- ☐ Male
 - ☐ Female (Not eligible to take this survey – Skip to End of Survey)
- A2. What is your date of birth?
- ☐ dd.mm.yyy (*Calendar input*) (Not eligible to take this survey if year is greater than Launch day + 1999 or < 16 y/o – Skip to End of Survey)
- A3. In your lifetime have you ever had anal sex with another man?
- ☐ Yes
 - ☐ No (Not eligible to take this survey – Skip to End of Survey)
- A4. In the last three months, did you have any anal and /or vaginal sex without a condom with any sex partner?
- ☐ Yes
 - ☐ No (Not eligible to take this survey – Skip to End of Survey)
- A5. Will you agree to provide us your Chinese mobile phone number? (Answering this question is required to participate in the survey and to receive your reward for participating. We will not distribute your number to any agency or individual. Thank you for your cooperation.)
- ☐ Agree
 - ☐ Decline (Not eligible to take this survey – Skip to End of Survey)
- Which carrier are you using right now?
- ☐ China Mobile
 - ☐ China Unicom
 - ☐ China Telecom

Online Consent Form

Title of Study: Men's Health Study

IRB study number: 15-1522

Principal Investigator: Dr. Joseph Tucker

Dr. Joseph D. Tucker, UNC Project-China, Number 2 Lujing Road, Guangzhou, China,

What are some general things you should know about research studies? You are being asked to participate in a research study. To join this research study is voluntary. You may for whatever reason refuse to join or withdraw your consent to be in the study at any time, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about joining this research study.

What is the purpose of this study? Innovative approaches to condom promotion campaigns are urgently needed. The current strategy to developing many of these campaigns is to repackage old ideas rather than create new ones. The purpose of this research study is to understand how crowdsourcing can be used to leverage both the high Internet use and willingness to participate in online forums of young MSM (men who have sex with men) to transform the design and implementation of condom promotion campaigns. Crowdsourcing is the process of taking a task traditionally performed by a single individual or organization, and instead outsourcing the task to a large group to complete in the form of a contest or open call, often enabled by the Internet.

How many people will take part in this study? If you decide to participate in this research study, you will be one of approximately 1170 individuals recruited across China.

What will happen if you take part in the study? Your part in this research study will last approximately 20 minutes. During this study, you will be asked to first complete an online questionnaire, and depending on your responses, you may be asked to watch a one minute video afterwards. Upon completion of this initial questionnaire, you will be asked to input your mobile phone number as a means for the research team to prevent duplicate responses, to send reminders, and to distribute rewards for participation. Additionally, some participant will be asked to complete up to two additional follow-up questionnaires after three-week and twelve-week's times. If you do not respond to the initial follow-up request, you will receive a message reminder. To do this, we will also ask you to provide your QQ number. The study questionnaires will ask you to provide sociodemographic information as well as details about your sexual health and sexual activity.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. The proposed study will make important contributions to the sexual health literature. The field of condom interventions among young MSM in resource-limited settings is in its infancy. The results from this study will help the research team develop a MSM targeted, community-level intervention that will be fielded and evaluated in the Chinese setting. Your participation will also help design better interventions to promote condom use among MSM in China.

What are the possible risks or discomforts involved from being in this study? We will ask participants to provide sensitive information about their sexual partners and practices. Participants may feel embarrassed, anxious, or otherwise distressed by providing information of such a personal nature. Participants may also experience fatigue in response to the proposed evaluations (e.g. from looking at a computer screen). Some participants might fear that refusal to participate in the study might jeopardize their sexual orientation identity – especially if the participant has not come “out” to him or herself and/or the community). Other participants may fear that the research staff might “out” them or discuss their private details with other (MSM and non-MSM) members in their community. While the risk is minimal, there is still the possibility for breaches of confidentiality.

How will your privacy be protected? All data are directly entered into computers as participants complete the questionnaires. Programs to ensure accuracy, completeness, and internal consistency are automated. 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 providers 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. For example, if a hacker could crack a standard 40-bit SSL session in a day, it is estimated that it would take well beyond a trillion years to accomplish the same thing against a 128-bit SSL session. A dedicated server, which eliminates security issues involved with shared hosting environments where hundreds of websites and users reside on one shared web server as well as ensuring both physical and network security, will be used to house the data. 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. Survey responses will be kept separately from participants’ email addresses; the two files will be linked with a non-descript, unique, randomly generated identifier. Only the PI and a designated senior staff member will have the password to access to the “key” that links the nondescript identifier to personally identifiable information. Cookies will not be used in any way to track participant activity.

What if you want to stop before your part in the study is complete? If at any point in the study you do not want to answer a question or no longer want to participate, you can stop and withdraw from this study without penalty. The investigators also have the right to stop your participation if you have an unexpected reaction, have failed to follow instructions, etc.

Will you receive anything for being in this study? Will it cost anything? Participants who are asked to watch a one-minute video will have the opportunity to earn up to 150 RMB credit on their mobile phone – this credit will be distributed as two separate 100 and 50 RMB mobile phone recharges. Participants will receive a 100 RMB phone recharge upon completion of the first questionnaire and 3-week follow up survey, and 50 RMB for the 3-month follow up survey if that they are eligible for. There are no costs associated with participating in this research study.

What if you have questions about this study? If you have any questions, complaints, or concerns about the research or your participation in the study, feel free to contact

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns, or if you would like to obtain information or offer input, please contact the UNC Institutional Review Board at 1-919-966-3113 or by email to IRB_subjects@unc.edu. You may also contact the Guangdong Provincial Skin Diseases & STI Control Center IRB at 020—83027652 or by email to sesh@seshglobal.org.

If you understand and agree to participate in this research study, please select “Agree” from the options below. We thank you for your participation!

- ☐ Agree
- ☐ Decline (Skip to End of Survey)

Survey Access (Q6-7)

6. How did you find out about our research study?

- ☐ Blued's banner ad
- ☐ Danlan webpage banner ad (www.danlan.org)
- ☐ Weibo banner ad
- ☐ Weixin banner ad
- ☐ Friend referral
- ☐ SESH referred me through QQ
- ☐ SESH referred me through SMS

7. What device are you using to access our research study?

- ☐ Desktop or laptop computer
- ☐ Mobile phone
- ☐ Tablet device

A. Sociodemographics (Q8-15)

The next set of questions will ask you to provide some information about yourself.

A6. What province or province-level city do you currently live in?

- ☐ Beijing
- ☐ Tianjin
- ☐ Hebei
- ☐ Shanxi
- ☐ Inner Mongolia
- ☐ Liaoning
- ☐ Jilin
- ☐ Heilong Jiang
- ☐ Shanghai
- ☐ Jiangsu
- ☐ Zhejiang
- ☐ Anhui
- ☐ Fujian
- ☐ Jiangxi
- ☐ Shandong
- ☐ Henan
- ☐ Hubei
- ☐ Hunan
- ☐ Guangdong
- ☐ Guangxi
- ☐ Hainan
- ☐ Chongqing
- ☐ Sichuan
- ☐ Guizhou
- ☐ Yun An
- ☐ Xizang (Tibet)
- ☐ Shaanxi
- ☐ Gansu
- ☐ Qinghai
- ☐ Ningxia
- ☐ Xinjiang
- ☐ Hong Kong
- ☐ Aomen

A7. What city do you currently live in? _____ (Text input) (Do not display if answered

北京, 上海, 重庆, 天津, 香港, 澳门 to A6)

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5 2 A8. What is your current legal marital status (referring to women)?
6 3 ☐ Not married
7 4 ☐ Engaged or Married
8 5 ☐ Separated or Divorced
9 6 ☐ Widowed
10 7
11 8 A9. Are you currently enrolled as either a full-time or part-time student?
12 9 ☐ Yes
13 10 ☐ No
14 11
15 12 A10. What is the highest level of education that you have **completed**?
16 13 ☐ High school or below (including Zhongzhuan)
17 14 ☐ Some college (Dazhuan)
18 15 ☐ College/Bachelors
19 16 ☐ Masters/PhD
20 17
21 18 A11. What is your total individual **monthly** income from all sources?
22 19 ☐ Less than 1500 RMB
23 20 ☐ Between 1500 and 3000 RMB
24 21 ☐ Between 3001 and 5000 RMB
25 22 ☐ Between 5001 and 8000 RMB
26 23 ☐ Greater than 8000 RMB
27 24
28 25 A12. What do you primarily consider yourself to be?
29 26 ☐ Gay
30 27 ☐ Bisexual
31 28 ☐ Straight/Heterosexual
32 29 ☐ Transgender
33 30 ☐ Unsure/Other
34 31
35 32 A13. Have you spoken with a physician or other health professional (e.g. HIV testing counselor,
36 33 pharmacist) about your sexuality or sexual history with men?
37 34 ☐ Yes
38 35 ☐ No
39 36
40 37 **B. MSM Basic Situation (Q16-38)**
41 38 *The next set of questions will ask you about your sexual behaviors with other men.*
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1 *A “primary partner” is someone who you have sex with regularly and/or have an emotional*
2 *commitment to. A “casual partner” is someone who you have sex with and do not have an*
3 *emotional commitment to.*

6 B1. How old were you during your first insertive sexual encounter?

7 _____years old (*Number input*)

9 B2. Was your first insertive sexual encounter with a male or female?

10 ☐ Male (Skip to B4)

11 ☐ Female

12 ☐ Other

14 B3. How old were you when you had sex with another man for the first time?

15 _____years old (*Number input*)

17 B4. Were you insertive (1) or receptive (0) during your first sexual encounter with another man?

18 ☐ Insertive (1)

19 ☐ Receptive (0)

20 ☐ Both insertive (1) and receptive (0)

22 B5. Did you use a condom during your first sexual encounter with another man?

23 ☐ Yes

24 ☐ No

26 B6. In general, where do you usually go to meet your sex partners (Select all that apply)?

27 ☐ Pub, disco, tearoom, or club

28 ☐ Spa or bath house, sauna, foot or body massage parlor

29 ☐ Park, public restroom, public lawn

30 ☐ Internet

31 ☐ Other

33 B7. In the last three months, approximately how many male sex partners have you had?

34 _____male sex partners (*Number input*) (If answer <1, skip to end of section)

36 B8. Of the men you have had sex with in the last three months, would you consider one of them
37 to be a primary sex partner?

☐ Yes

○ No (Skip to B16)

B9. In the last three months, approximately how many times per week did you have anal sex with your primary partner?

sex encounters per week

B10. How long have you and your primary sex partner been in a relationship?

- Less than three months

- Between three and six months

- Between six and twelve months

- Between one and two years

- More than two years

B11. In the last three months, when you had anal sex with your primary partner, what role did you assume?

- Always insertive (always 1) (Do not display B15)

- Mostly insertive (mostly 1)

- Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)

- Mostly receptive (mostly 0)

- Always receptive (always 0) (Do not display B14)

☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B14 and B15)

B12. In the last three months, when you had sex with your primary partner, how frequently did you or your partner use condoms? (Do not display if “No anal sex, only oral sex” to B11)

☐ Never used (Skip to B14)

- Sometimes used

○ Mostly used

○ Always used (Do not display B14, B15)

B13. In the last three months, when you had sex with your primary partner did a condom ever slip off, tear, or otherwise fail?

☐ Yes

☐ No

B14. When you are insertive, the reason(s) you do not use a condom with your primary partner include (select all that apply):

☐ I do not want to use one (e.g. personal preference, uncomfortable)

☐ Neither of us has a condom

- 1 1 ☐ My partner does not want me to use one
- 2 2 ☐ The condom is of poor quality
- 3 3 ☐ I do not have time to use one
- 4 4 ☐ I believe that my partner is loyal to me
- 5 5 ☐ I am loyal to my partner
- 6 6 ☐ I am drunk or high
- 7 7 ☐ I am HIV negative or I do not believe I am infected with HIV
- 8 8 ☐ My partner is HIV negative or I do not believe he is infected with HIV
- 9 9 ☐ Other
- 10
- 11 11 B15. When you are receptive, the reason(s) your primary partner does not use a condom with
- 12 12 you include (select all that apply):
- 13 13 ☐ He does not want to use one (e.g. personal preference, uncomfortable)
- 14 14 ☐ Neither of us has a condom
- 15 15 ☐ I do not want him to use one
- 16 16 ☐ The condom is of poor quality
- 17 17 ☐ He does not have time to use one
- 18 18 ☐ I believe that my partner is loyal to me
- 19 19 ☐ He believes that I am loyal to him
- 20 20 ☐ He is drunk or high
- 21 21 ☐ He is HIV negative or does not believe he is infected with HIV
- 22 22 ☐ I am HIV negative or does not believe I am infected with HIV
- 23 23 ☐ Other
- 24
- 25 25 B16. In the last three months, have you had sex with another man who was not your primary
- 26 26 partner?
- 27 27 ☐ Yes
- 28 28 ☐ No (Skip to B23, Should not say "No" to B8 and B16)
- 29
- 30 30 B17. In the last three months, approximately how many times per week did you have anal sex
- 31 31 (all casual sex partners combined)?
- 32 32 _____ sex encounters per week
- 33
- 34 34 B18. In the last three months, when you had anal sex with a casual partner, what role did you
- 35 35 assume?
- 36 36 ☐ Always insertive (always 1) (Do not display B22)
- 37 37 ☐ Mostly insertive (mostly 1)
- 38 38 ☐ Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)

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- ☐ Mostly receptive (mostly 0)
 - ☐ Always receptive (always 0) (Do not display B21)
 - ☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B21 and B22)
- B19. In the last three months, when you had sex with a casual partner, how frequently did you or your partner use condoms? (Do not display if B17 is “0” or B18 is “无肛交，只有口交（既不是 1 也不是 0）”)
- ☐ Never used (Skip to B21)
 - ☐ Sometimes used
 - ☐ Mostly used
 - ☐ Always used (Do not display B21, B22)
- B20. In the last three months, when you had sex with a casual partner did a condom ever slip off, tear, or otherwise fail? (Do not display if answer to B19 is “Never used”)
- ☐ Yes
 - ☐ No
- B21. When you are insertive, the reason(s) you do not use a condom with a casual partner include (select all that apply):
- ☐ I do not want to use one (e.g. personal preference, uncomfortable)
 - ☐ Neither of us has a condom
 - ☐ My partner does not want me to use one
 - ☐ The condom is of poor quality
 - ☐ I do not have time to use one
 - ☐ I am drunk or high
 - ☐ I am HIV negative or I do not believe I am infected with HIV
 - ☐ My partner is HIV negative or I do not believe he is infected with HIV
 - ☐ Other
- B22. When you are receptive, the reason(s) your casual partner does not use a condom with you include (select all that apply):
- ☐ He does not want to use one (e.g. personal preference, uncomfortable)
 - ☐ Neither of us has a condom
 - ☐ I do not want him to use one
 - ☐ The condom is of poor quality
 - ☐ He does not have time to use one
 - ☐ He is drunk or high
 - ☐ He is HIV negative or he does not believe he is infected with HIV

- 1 ☐ I am HIV negative or he does not believe I am infected with HIV
- 2 ☐ Other

4 B23. In the last month, did you have any anal sex without a condom with any male partner? (Do not display if answer "1" to B7 and "Always" to B19)

- 6 ☐ Yes
- 7 ☐ No

9 **C. Heterosexual Sex Situation (Q39-54)**

10 *The next set of questions will ask about your sexual behaviors with women.*

12 *A "primary female partner" is someone who you have sex with regularly, have an emotional commitment to, and/or have married or engaged to be married. A "casual female partner" is someone who you have had sex with but do not have an emotional commitment to.*

16 C1. Have you ever had vaginal, anal, and/or oral sex with a female partner?

- 17 ☐ Yes
- 18 ☐ No (Skip to End of Section)

20 C2. In the last six months, did you have any vaginal and/or anal sex with a female partner?

- 21 ☐ Yes
- 22 ☐ No (Skip to End of Section)

24 C3. In the last six months, approximately how many female sex partners have you had?

25 _____ female sex partners (*Number input*) (If answer <1 then skip to End of Section)

27 C4. In the last six months, have you had a primary female sex partner?

- 28 ☐ Yes
- 29 ☐ No (Skip to C9)

31 C5. In the last six months, approximately how many times per week did you have vaginal and/or anal sex with your primary female partner?

33 _____ sex encounters per week

35 C6. In the last six months, when you had sex with your primary female partner, how frequently did you or your partner use condoms?

- 37 ☐ Never used (Skip to C8)
- 38 ☐ Sometimes used
- 39 ☐ Mostly used

☐ Always used (Do not display C13; Skip to End of Section if “Always” to C6)

C12. In the last six months, when you had sex with a casual female partner did a condom ever slip off, tear, or otherwise fail?

- ☐ Yes
☐ No

C13. The reason(s) you do not use a condom with a casual female partner include (select all that apply):

- ☐ I do not want to use one (e.g. personal preference, uncomfortable)
☐ Neither of us has a condom
☐ My partner does not want me to use one
☐ The condom is of poor quality
☐ I do not have time to use one
☐ I am drunk or high
☐ I am HIV negative or I do not believe I am infected with HIV
☐ My partner is HIV negative or I do not believe she is infected with HIV
☐ Other

C14. In the last month, did you have sex without a condom with any female partner? (Do not display if answer "1" to B7 and "Always" to B19)

- ☐ Yes
☐ No

D. Sexual Behavior (Q55-63)

The next set of questions will ask about any "risky" sexual behaviors that you may or may not have engaged in with other men and/or women.

D1. In the last three months, did you ever have sex while you were drunk (from drinking alcohol)?

- ☐ Yes
☐ No

D2. In the last three months, was you partner ever drunk (from drinking alcohol) while you had sex?

- ☐ Yes
☐ No (Skip to D4 if "No" for D1 and D2)

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- D3. In the last three months, how often did you have sex while you and/or your partner was drunk?
- ☐ Never
- ☐ Rarely
- ☐ Occasionally/Sometimes
- ☐ Very often
- ☐ Always
- D4. In the last twelve months, did you ever use “meth” before or during sex?
- ☐ Yes
- ☐ No
- D5. In the last twelve months, did you ever participate in group sex with other men?
- ☐ Yes (Display D6)
- ☐ No
- D6. During your most recent group sex experience, did you have any anal sex without a condom?
- ☐ Yes
- ☐ No
- D7. In the last twelve months, were you ever paid (with money or gifts) to have sex?
- ☐ Yes
- ☐ No (Skip to D9)
- D8. In the last twelve months, has your main source of income come from having sex with customers?
- ☐ Yes
- ☐ No
- D9. In the last twelve months, have you ever paid (with money or gifts) a man to have sex?
- ☐ Yes
- ☐ No

E. Sex Tourism (Q64-79)

The next set of questions will ask about leaving your city and/or China to purchase sex.

1 E1. Have you ever purchased sex (with money or gifts) while traveling outside of your city of
2 residence?

3 ☐ Yes

4 ☐ No (If "No" skip to End of block)

6 E2. Have you ever traveled outside of your city of residence with the primary purpose of
7 purchasing sex?

8 ☐ Yes

9 ☐ No

11 E3. When you traveled to purchase sex, did you travel within China or leave the country?

12 ☐ Within China (Display E4a)

13 ☐ Outside China (Display E4b)

14 ☐ Both (Display E4a and E4b)

16 E4a. Which city/cities in China did you travel to when you purchased sex? _____ (Text
17 Input)

19 E4b. Which country/countries and cities did you travel to when you purchased sex? _____ (Text
20 Input)

22 E5. How did you arrive at your destination?

23 ☐ Car

24 ☐ Train

25 ☐ Airplane

26 ☐ Ship

28 E6. Why did you decide to purchase sex while traveling?

29 ☐ I was afraid of seeing someone I know in my hometown

30 ☐ Sex is less expensive at the location I traveled to

31 ☐ There was less likelihood that I would have to use a condom if I purchase sex

32 ☐ I am unable to purchase sex in my hometown

33 ☐ I wanted to try sexual intercourse with another gender

34 ☐ I was drunk or using drugs, I did not plan it

36 E7. When you purchased sex while outside your city of residence, who did you purchase sex
37 from (select all that apply)?

38 ☐ Men

39 ☐ Women

40 ☐ Transgender

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2 E8a. When you purchased sex while outside your city of residence, have you ever had any
3 vaginal sex without a condom? (Display if “Women” or “TG” for E7)
4 ☐ Yes (Display E17)
5 ☐ No
6
7 E8b. When you purchased sex while outside your city of residence, have you ever had any anal
8 sex without a condom?
9 ☐ Yes (Display E17)
10 ☐ No
11
12
13 E9. Once you were at your travel destination (during your most recent trip abroad), how did you
14 find someone to purchase sex from (select all that apply)?
15 ☐ Mobile app portal
16 ☐ Online (not an app) portal
17 ☐ In-person proposition
18 ☐ Local establishment
19
20 E10. During your most recent experience when you purchased sex while abroad, approximately
21 how many sex partners did you purchase? (Please enter “0” partners if no partners of the
22 following type)
23 _____ male sex partners (*Number input*)
24 _____ female sex partners (*Number input*)
25 _____ transgender sex partners (*Number input*)
26
27 E11. During your most recent experience when you purchased sex while traveling,
28 approximately how much did you pay (RMB) for your last sex encounter?
29 _____ (*Text Input*)
30
31 E12. During your most recent experience when you purchased sex while traveling, of what
32 nationality was your last partner?
33 _____ (*Text Input*)
34
35
36 E13. During your most recent experience when you purchased sex while traveling, the reason(s)
37 you did not use a condom include (select all that apply):

- 1 ☐ I did not want to use one (e.g. personal preference, uncomfortable)
- 2 ☐ I did not want my partner to use one
- 3 ☐ Neither of us had a condom
- 4 ☐ My partner did not want to use one (e.g. personal preference, uncomfortable)
- 5 ☐ My partner did not want me to use one
- 6 ☐ The condom was of poor quality
- 7 ☐ I did not have time to use one
- 8 ☐ My partner did not have time to use one
- 9 ☐ I was drunk or high
- 10 ☐ My partner was drunk or high
- 11 ☐ I am HIV negative or I do not believe I am infected with HIV
- 12 ☐ My partner was HIV negative or I do not believe my partner was infected with HIV

E14. How strongly do you agree with the following statement: During my most recent experience purchasing sex while traveling, I behaved with less caution than I normally would while at home

- ☐ Strongly yes
- ☐ Yes
- ☐ The same
- ☐ No
- ☐ Strongly No

E15. Did you travel alone or with others?

- ☐ Alone
- ☐ With others

E16. During your most recent experience when you purchased sex while traveling, did you ask your partner about his/her HIV status before having sex?

- ☐ Yes
- ☐ No

F. Condom Behavior (Q80-96)

The next set of questions will ask about your practices and attitudes in regards to condom use.

F1. In the last three months, how often did you carry a condom with you when there was the possibility you may have sex later?

- ☐ Always
- ☐ Sometimes
- ☐ Hardly ever
- ☐ Never

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- F2. If you needed a condom, where is the first place you would go to find one?

☐ Pharmacy or drugstore

☐ Supermarket

☐ Health clinic

☐ Community event

☐ Restroom vending machine

☐ Friend

☐ Partner

☐ Other

F3. If I had sex and told my friends that I did not use a condom, they would be angry or disappointed.

☐ Strongly agree

☐ Agree

☐ Neutral

☐ Disagree

☐ Strongly disagree

F4. My friends talk a lot about "safer" sex.

☐ Strongly agree

☐ Agree

☐ Neutral

☐ Disagree

☐ Strongly disagree

F5. My friends and I encourage each other before dates to practice "safer" sex.

☐ Strongly agree

☐ Agree

☐ Neutral

☐ Disagree

☐ Strongly disagree

F6. If I thought that one of my friends had sex on a date, I would ask them if they used a condom.

☐ Strongly agree

☐ Agree

☐ Neutral

☐ Disagree

☐ Strongly disagree

1 F7. If a friend knew that I might have sex on a date, he/she would ask me if I was carrying a
2 condom.

- 3 ☐ Strongly agree
4 ☐ Agree
5 ☐ Neutral
6 ☐ Disagree
7 ☐ Strongly disagree

9 F8. When I think that one of my friends might have sex on a date, I would ask him/her if he/she
10 was carrying a condom.

- 11 ☐ Strongly agree
12 ☐ Agree
13 ☐ Neutral
14 ☐ Disagree
15 ☐ Strongly disagree

17 F9. If I might have sex on a date and I do not have a condom, I would make an effort to go out of
18 my way and get one.

- 19 ☐ Strongly agree
20 ☐ Agree
21 ☐ Neutral
22 ☐ Disagree
23 ☐ Strongly disagree

25 F10. I would feel comfortable discussing condom use with a potential partner before we engaged
26 in sex.

- 27 ☐ Strongly agree
28 ☐ Agree
29 ☐ Neutral
30 ☐ Disagree
31 ☐ Strongly disagree

33 F11. I would feel comfortable letting a primary partner know that I want to have sex with a
34 condom.

- 35 ☐ Strongly agree
36 ☐ Agree
37 ☐ Neutral
38 ☐ Disagree
39 ☐ Strongly disagree

F12. I would feel comfortable letting a casual partner know that I want to have sex with a condom.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

F13. I feel confident that I could refuse to have sex with a partner who did not want you to use a condom.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

F14. I feel confident in my ability to incorporate putting a condom on myself or my partner into foreplay.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

F15. I feel confident that I could use a condom with a partner without "breaking the mood."

- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly disagree

F16. In the last three months, did you ever **try** to convince a partner who did not want to use a condom to use one before having sex?

- ☐ Yes, and I was successful
- ☐ Yes, but I was unsuccessful
- ☐ No

F17. In the last three months, did your partner every **try** to convince you to use a condom when you did not want to use one before having sex?

- 1 ☐ Yes, and he was successful
2 ☐ Yes, but he was unsuccessful
3 ☐ No

G. HIV/STI Testing (Q97-132)

The next set of questions will ask about your HIV and STI testing and results. Self-testing refers to you administering the test yourself and interpreting results.

G1. Have you ever been tested for HIV?

- ☐ Yes
☐ No (Skip to G25)

G2. Have you ever given or received an HIV self-test?

- ☐ Yes
☐ No

G3. Have you ever self-tested for HIV?

- ☐ Yes
☐ No (Skip to G20) (Do not show G35)

G4. Did someone else force you to take an HIV self-test?

- ☐ Yes
☐ No

G5. Who was with you when you self-tested? (Can select multiple)

- ☐ No one, I was alone
☐ Partner
☐ Friend

G6. Was your HIV self-test the first time you ever tested for HIV?

- ☐ Yes
☐ No

G7. What happened to your HIV testing frequency after you first used a self-test?

- ☐ Increased
☐ Decreased
☐ No change

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- G8. Have you ever received a positive result with HIV self-testing?
- ☐ Yes
- ☐ No (Skip to G11)
- G9. Has using an HIV self-test caused you subsequent suicidal feelings?
- ☐ Yes
- ☐ No
- G10. Has using an HIV self-test led to a violent confrontation (physically hitting)?
- ☐ Yes
- ☐ No
- The next set of 4 questions will ask you to recall experiences specific to self-testing.*
- G11. Has using an HIV self-test has increased your desire to seek follow-up care, as opposed to other forms of HIV testing?
- ☐ Yes
- ☐ No
- G12. Self-testing for HIV gives me a sense of empowerment by allowing me to choose when I test.
- ☐ Strongly Agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly Disagree
- G13. Self-testing for HIV gives me a sense of empowerment by allowing me to choose where I test.
- ☐ Strongly Agree
- ☐ Agree
- ☐ Neutral
- ☐ Disagree
- ☐ Strongly Disagree
- G14. Self-testing for HIV gives me a sense of empowerment by allowing me to choose with whom I test.
- ☐ Strongly Agree
- ☐ Agree

- 1 1 ☐ Neutral
2 2 ☐ Disagree
3 3 ☐ Strongly Disagree
4 4
5 5 G15. Did you confirm your positive HIV self-test result at the CDC or hospital?
6 6 ☐ Yes
7 7 ☐ No
8 8
9 9 G16. Did you receive post-self test counseling?
10 10 ☐ Yes (show G17)
11 11 ☐ No
12 12
13 13 G17. What kind of post-test counseling did you receive?
14 14 ☐ online
15 15 ☐ telephone
16 16 ☐ in-person
17 17
18 18 G18. Where did you obtain your HIV self-test kit?
19 19 ☐ online
20 20 ☐ hospital
21 21 ☐ pharmacy
22 22 ☐ CBO
23 23 ☐ friend
24 24
25 25 G19. Was your HIV self-test oral or blood?
26 26 ☐ Oral
27 27 ☐ Blood
28 28
29 29 G20. In the last two years, how frequently did you get tested for HIV?
30 30 ☐ Less than once every two years
31 31 ☐ Once a year
32 32 ☐ Once every six months
33 33 ☐ Once every three months
34 34 ☐ Monthly
35 35
36 36 G21. What was the result of your most recent HIV test?
37 37 ☐ HIV positive/infected (Display G23)
38 38 ☐ HIV negative/uninfected
39 39 ☐ I never got my test results (Skip to G25)
40 40

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3 1 G22. Did you notify your primary male sex partner about your most recent HIV test result?
4 2 ☐ Yes
5 3 ☐ No
6 4 ☐ I do not have a regular partner (Do not display G25)
7
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10 6 G23. Have you ever taken anti-retroviral therapy (ART) for your HIV infection?
11 7 ☐ Yes – I have taken, and I am currently taking
12 8 ☐ Yes – I have taken, but I am currently not taking (Display G24)
13 9 ☐ No – I have never taken
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17 11 G24. Why did you stop taking ART? (Select all that apply)
18 12 ☐ It was too expensive
19 13 ☐ I didn't like the side effects
20 14 ☐ I didn't feel that it was working
21 15 ☐ I thought it was cumbersome (too much time, forgot to take, etc.)
22 16 ☐ Stigma
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27 18 G25. Has your primary male sex partner ever been tested for HIV? (Do not display if no to B8)
28 19 ☐ Yes
29 20 ☐ No (Skip to G27)
30
31 21
32 22 G26. What was the result of your primary male sex partner's most recent HIV test?
33 23 ☐ HIV positive/infected
34 24 ☐ HIV negative/uninfected
35 25 ☐ Never got test results
36 26 ☐ I don't know
37
38 27
39 28 G27. Have you ever had a male sex partner who tested HIV positive?
40 29 ☐ Yes
41 30 ☐ No (Skip to G30)
42 31 ☐ I don't know (Skip to G30)
43 32
44 33 G28. Did you ever have any anal sex without a condom with a HIV positive partner?
45 34 ☐ Yes
46 35 ☐ No
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50 37 G29. Approximately how many HIV positive male sex partners have you had?
51 38 _____ sex partners (*Number input*)
52
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G30. Have you ever been tested for syphilis?

☐ Yes

☐ No (Skip to G36)

G31. Have you ever used a self-testing kit for syphilis?

☐ Yes

☐ No (Skip to G36)

G32. Was your self-test the first time you ever tested for syphilis?

☐ Yes (Do not display G33)

☐ No

G33. What happened to your syphilis testing frequency after you first used a self-test?

☐ Increased

☐ Decreased

☐ No change

G34. Where did you obtain your syphilis self-test kit?

☐ online

☐ hospital

☐ pharmacy

☐ CBO

☐ Friend

G35. Have you ever performed syphilis and HIV self-testing together?

☐ Yes

☐ No

G36. In the last twelve months, which of the following services did you receive (Select all that apply):

☐ Condom distribution

☐ Lubricant distribution

☐ Peer Education

☐ STD Diagnosis or Treatment

☐ HIV counseling or Testing

☐ AIDS/STD Materials (pamphlets, etc.)

I. Community Engagement (Q133-143)

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3 1 *The next set of questions will ask you about your experiences with activities in your community*
4 2 *promoting sexual health.*
5
6 3
7 4 I1. In the last three weeks, have you viewed any videos promoting condom use among MSM?
8 5 ☐ Yes
9 6 ☐ No
10 7
11 8 I2. In the last three weeks, have you viewed any videos promoting HIV testing among MSM?
12 9 ☐ Yes
13 10 ☐ No
14 11
15 12 I3. Are you aware of any ongoing community events promoting sexual health among MSM?
16 13 ☐ Yes
17 14 ☐ No
18 15
19 16 I4. Have you ever helped organize a testing and/or awareness campaign (e.g. HIV, condom use,
20 17 etc.) that promoted sexual health among MSM?
21 18 ☐ Yes
22 19 ☐ No
23 20
24 21 I5. Have you ever volunteered at a health clinic or other location that provided sexual health
25 22 services among MSM?
26 23 ☐ Yes
27 24 ☐ No
28 25
29 26 I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually
30 27 transmitted disease?
31 28 ☐ Yes
32 29 ☐ No
33 30
34 31 I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV
35 32 and/or another sexually transmitted disease?
36 33 ☐ Yes
37 34 ☐ No
38 35
39 36 I8. How important to you is community engagement and participation in developing sexual
40 37 health campaigns (for your own community)?
41 38 ☐ Very important
42 39 ☐ Important
43 40 ☐ Neither important or not important
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☐ Slightly important

☐ Not important

I9. Have you ever participated in online forums or discussions on social media (ie. Weixin, Weibo, Twitter, or other on-line communities) about about sexual health, condom use, or HIV/STD testing or related services?

☐ Yes

☐ No

I10. Do you have a Weibo account?

☐ Yes (Display I11)

☐ No

I11. How many Weibo followers do you have?

☐ Less than 100

☐ 101-500

☐ 501-1000

☐ 1001-1500

☐ 1501-2000

☐ More than 2001

Video 1: Crowdsourcing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

Video 2: Social Marketing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

End of Survey

Please confirm your mobile phone number at this time to receive our reminder of the follow-up survey and reward. Please notice that only after you finish the 3 week follow up could you get the 100 top up reward.

☐ Mobile Phone #s: _____ (*Text Entry*) (must be 11 digits)

Follow-up Contact (Q144-145)

FUC1. Thank you for taking the time to complete our survey! Based on your responses to our questionnaire, we request that you to complete a follow-up survey in three weeks' time. Upon completion of this survey, you will receive an additional 50 RMB mobile phone recharge! When the time comes, we would like to send you a reminder to complete the survey via QQ. Will you agree to provide us your QQ number? If you agree, you will be contacted by the following user:

Number: 2663701478

Name: 赛思研究团队

- ☐ Agree (Display FUC2)
- ☐ Disagree

FUC2. Please input your QQ number:

☐ QQ number: _____

Referral (Q146)

R1. If you think any of your male friends would be interested in participating in our research survey, please share our study with them! Alternatively, you can provide us with either their mobile phone or QQ number, and we will send them a link to our survey. (Please enter as many unique numbers as you are willing in the spaces provided.)

If you provide a QQ number for referral, please notify your friend(s) that they will be contacted by 赛思研究团队 (#: 2663701478).

If you provide a mobile phone number for referral, please notify your friend(s) that they will be contacted by 18613067997.

- ☐ Mobile Phone #s: _____
- ☐ QQ numbers: _____



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<u>1</u>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<u>3</u>
	2b	All items from the World Health Organization Trial Registration Data Set	<u>1,14-15</u>
Protocol version	3	Date and version identifier	<u>1</u>
Funding	4	Sources and types of financial, material, and other support	<u>14</u>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<u>1,14</u>
	5b	Name and contact information for the trial sponsor	<u>14</u>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<u>15</u>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>N/A</u>

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>10</u>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>7</u>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>11</u>
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>11</u>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>11</u>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>N/A</u>
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>N/A</u>

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>10</u>
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>9</u>

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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
8				
9				
10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
11				
12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
13				
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15				
16	Methods: Monitoring			
17				
18	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
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23		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
24				
25				
26	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
27				
28				
29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12
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37				
38	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12
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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	23

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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Comparing the effectiveness of a crowdsourced video and a social marketing video in promoting condom use among Chinese men who have sex with men: A study protocol

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For peer review only

Comparing the effectiveness of a crowdsourced video and a social marketing video in promoting condom use among Chinese men who have sex with men: A study protocol

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Chuncheng Liu, Jessica Mao and Terrence Wong contributed equally to this work and are co-first authors.

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Version 1.0

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ABSTRACT

Introduction

Crowdsourcing has been used to spur innovation and increase community engagement in public health programs. Crowdsourcing is the process of giving individual tasks to a large group, often involving open contests and enabled through multi-sectoral partnerships. Here we describe a crowdsourced video intervention in which a video promoting condom use is produced through an open contest. The aim of this study is to determine whether a crowdsourced intervention is as effective as a social marketing intervention in promoting condom use among high-risk men who have sex with men (MSM) and transgender male-to-female (TG) in China.

Method

We held an open contest to develop a crowdsourced video and obtained a social marketing video from an advertising company. The crowdsourcing contest involved an open call for videos. Entries were judged on capacity to promote condom use, to be shareable or “go viral”, and to give value to the individual. 1170 participants will be recruited for the randomized controlled trial. Participants need to be MSM age 16 and over who have had condomless anal sex in the last 3 months. Recruitment will be through an online banner ad on a popular MSM webpage and other social media platforms. After completing an initial survey, participants will be randomly assigned to view either the social marketing video or the crowdsourcing video. Follow-up surveys will be completed at both 3 weeks and 3 months after initial intervention to evaluate condomless sex and related secondary outcomes. Secondary outcomes include condom social

1 norms, condom negotiation, condom self-efficacy, HIV/syphilis testing, frequency of sex acts
2 and incremental cost.

3 **Ethics and dissemination:**

4 Approval was obtained from the ethical review boards of the Guangdong Provincial Center for
5 Skin Diseases and STI control, the University of North Carolina at Chapel Hill, and the
6 University of California at San Francisco. The results of this trial will be made available through
7 publication in peer-reviewed journals.

8
9 **Trial registration number:** This trial was registered in ClinicalTrials.gov (NCT02516930).

10 11 12 13 **Strengths and Limitations of this study protocol:**

- 14 • This will be one of the few randomized controlled trials evaluating crowdsourcing
- 15 • The use of a large MSM platform will allow us to reach a large number of MSM who do
16 not disclose their sexual orientation to doctors or others
- 17 • No biomarker data will be collected and there are inherent limitations associated with
18 behavioural outcomes

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1 INTRODUCTION

2 Male Sexual Health

3 Male condoms have long been recognized as an effective method for reducing the risk of HIV
4 and other sexually transmitted diseases (STDs)[1, 2], but men who have sex with men (MSM)
5 infrequently use condoms in China[3-6]. The resulting high incidence of HIV and STDs among
6 MSM suggests the need for novel health promotion campaigns. One systematic review[7] and
7 one literature review among MSM[8] demonstrate that social marketing campaigns are effective
8 in promoting condom use, but the persistence of these behavioural changes over time is unclear.
9 We propose that crowdsourcing may substantially improve on existing methods for developing
10 condom promotion campaigns.

12 Crowdsourcing

13 Crowdsourcing is the process of giving individual tasks to a large group, often involving open
14 contests and enabled through multisectoral partnerships. While the process originated in the
15 private sector[9], intended to aid research, development and dissemination, it has since been
16 widely adopted. In 2010, the Executive Office of the President of the United States urged federal
17 agencies to utilize crowdsourcing as a method to develop innovative approaches to governmental
18 initiatives[10]. A crowdsourcing method differs from a social marketing method in several
19 ways[11]. Crowdsourcing is a bottom-up approach, utilizing the community for idea generation
20 through implementation rather than relying on the expertise of public health experts. This
21 ensures a higher degree of community engagement than approaches utilizing social marketing
22 do, which tends to be a top-down approach. Crowdsourcing promotes innovation because it
23 removes cognitive fixation, in which innovation is hampered due to new ideas being strongly

1 influenced by prior examples[12-16]. By engaging more people with less experience, this
2 phenomenon is avoidable and allows for a more creative process[17]. Our team has previously
3 used crowdsourcing successfully to develop an effective HIV testing promotion video and
4 images promoting sexual health.[18]

5 6 **OBJECTIVES**

7 *Aims and Hypotheses*

8 Specific Aim 1: To compare the effect of a crowdsourced one-minute video to a social marketing
9 one-minute video in promoting condom use among MSM and transgender male-to-female (TG)
10 in China. This will be evaluated using data from follow-up surveys at 3 weeks and 3 months
11 post-video.

12 Hypothesis 1: Crowdsourced videos are not inferior to social marketing videos to promote
13 condom use among MSM and TG in China.

15 Specific Aim 2: To compare the cost of using crowdsourcing compared to social marketing
16 methods for developing short videos focused on promoting condom use among MSM and TG
17 individuals in China.

18 Hypothesis 2: A crowdsourced video is cost saving compared to a social marketing video for
19 promoting condom use.

21 Specific Aim 3: To compare the effect of a crowdsourced one-minute video to a social marketing
22 one-minute video in changing condom use self-efficacy and self-reported behaviour among
23 MSM and TG individuals in China.

Hypothesis 3: Crowdsourced videos are not inferior to social marketing videos in changing condom use self-efficacy and self-reported behaviour among MSM and TG in China.

METHODS

Trial design

This study will be a pragmatic, non-inferiority, randomized controlled trial comparing two groups – MSM who watch a crowdsourced video and MSM who watch a social marketing video. Allocation to each arm will be done with a 1:1 ratio using a computer-based algorithm. The study is projected to run from November 2015 to February 2016.

Setting

This study survey will be made available to MSM across China through a popular online portal, Danlan and gay mobile dating app, Blued. Danlan.com is an online gay community that allows MSM to connect with each other for relationships, events, and communication. The website is maintained by a private corporation, Danlan, which also developed the for-profit app Blued. Blued has become very popular among the MSM population, recently reaching 15 million users[19]. User personal information is protected and secure. Studies have shown that the Internet has become a popular method for MSM to find partners, with a reported 28.3-88.4% of MSM using the Internet to seek sexual partners [20]. While Internet-based interventions have yet to be widely dispersed in mainland China, early studies show that such e-technology-based approaches would be well received[21].

1 Recruitment

2 Participants will be recruited using a banner link on a popular MSM app “Blued” (Danlan,
3 Beijing, China), as well as through announcements sent via Danlan’s social media (Weibo, a
4 microblogging platform, WeChat, a messaging platform, and QQ, a messaging platform). Blued
5 is China’s most popular social networking mobile application among MSM. Blued has 15
6 million followers with 24% (3.6 million people) daily activity rate[19]. Danlan has over 17,000
7 followers on social media platform Weibo and forwards news via WeChat and QQ to over
8 429,000 followers[22].

10 Eligibility

11 The survey is voluntary, and to be eligible, participants must state that they were born
12 biologically male, had anal sex with men at least once during their lifetime, have had condomless
13 anal/vaginal sex in the past three months, are at least 16 years of age, and able to complete an
14 online written survey in Chinese. All participants must agree to an online informed consent and
15 provide their cell mobile number. Participants who do not meet these criteria will not be allowed
16 to proceed with the survey.

18 Formative work

19 Prior to survey development, we will interview key informants specifically about conducting an
20 Internet survey among MSM in China. Survey development will be done drawing on previous
21 surveys and a review of existing literature, focusing on English and Chinese language studies.
22 The survey will be developed in both English and Chinese but conducted entirely in Chinese.
23 The Chinese version of the survey will be piloted online with 150 volunteers to gauge post-

1 intervention condom usage rates and to estimate the necessary sample size for the non-inferiority
2 study. The survey will also be piloted with Danlan to ensure there are no problems with
3 distribution. Feedback will be solicited online regarding question wording and interpretation.
4 Pilot data will not be included in the final analysis. The purpose of this extensive formative
5 research is to ensure that the online survey is simple and easy to complete. The CONSORT-
6 Ehealth checklist for online surveys[23] will be used to ensure completeness. The online survey
7 will be created using Qualtrics Survey Software (Qualtrics, Provo, Utah) and the videos will be
8 hosted on Tencent Video (Tencent, Shenzhen, China).

10 *Interventions*

11 The development of the crowdsourcing video was publicized via open contest. We posted a
12 public call on social media platforms (Weibo, WeChat) for videos promoting condom use
13 awareness. For further promotion, we hosted in-person events at several different college
14 campuses in Guangzhou, China and worked with local community-based organizations to
15 publicize the contest. In-person events included didactic sessions, interactive feedback sessions,
16 and community-driven events. Ten judges, including community health leaders, doctors,
17 business leaders, and researchers, evaluated the videos. Each judge scored the video entries on a
18 scale of 1-10 (10 the highest score) and a single winner was identified. The winning video will
19 be included in the survey as the intervention arm of the RCT. The one-minute video depicts a
20 group of men dressed as cartoon villains attempting and failing to break down a wall, followed
21 by an image of condoms. Our team will delay announcement of the contest winner to allow time
22 for adequate intervention implementation and comparison. The winning video will be announced
23 2 weeks after the intervention is evaluated using the 3-month follow-up survey.

1 The social marketing video was commissioned from a working group in Jinan. This one-minute
2 video contains audio of two men about to engage in intercourse, but stopping to discuss condom
3 use and sexual health as a symbol of love. Script of the video was written by experts in San
4 Francisco and modified by experts and the gay community in Jinan and Qingdao. The video was
5 shot by an advertising company based in Jinan.

6 7 *Data collection*

8 A survey will be developed using the Qualtrics survey tool. Participants will answer 150
9 questions on socio-demographic information, sexual behaviour, social norms, condom self-
10 efficacy, HIV testing, and community engagement. At the end of the survey, participants will be
11 randomly assigned to one of two intervention arms, the crowdsourcing video or social marketing
12 video, and will view the appropriate video. Participants will not be informed of the video options
13 upon randomization, and will not see the alternate intervention video. Participants will provide
14 mobile telephone numbers, and will receive text message reminders three weeks after initial
15 survey completion to complete the three-week follow-up survey. After completion of the three-
16 week survey, participants will be compensated for the first portion of the study (about \$15.87
17 USD). Three months after completion of the initial survey, participants will again receive a
18 mobile telephone reminder to complete the three-month survey. After completion participants
19 will receive the second portion of their compensation (about \$7.93 USD).

20
21 Participants will register for our survey using a mobile number. Following completion of data
22 collection, data entries will be screened for duplicate mobile numbers, and the second entry will
23 be excluded. Entries with invalid mobile numbers will also be excluded.

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A data monitoring committee will not be required as this study employs low risk behavioural interventions. All participants will provide consent prior to taking part in the study.

4

Measures

6

Data from survey items on socio-demographics and sexual behaviours will be collected using standardized survey instruments immediately before video watching, at three weeks after video watching, and at three months after video watching. Socio-demographic characteristics include participants' age, place of residence, highest level of education completed, annual income, marital status, sexual orientation, and sexual orientation disclosure. Behavioural variables include number of sex acts in the past three weeks, condomless sex with men, condomless sex with women, condom self-efficacy, and other secondary outcomes (See Supplemental File 1).

13

OUTCOMES

Primary Outcomes

16

The primary outcome will be any condomless vaginal or anal sex (with any sex partner) among MSM and TG individuals following the video intervention. A participant is counted as having had condomless sex if they participated in any act of sexual intercourse (vaginal or anal) that has taken place without use of a condom. Using a post-intervention survey, participants will be asked with what frequency they have used condoms since watching the video: all, most, some or none of the time (See Supplemental File 2). The three-week follow-up survey will ask about the three weeks following the intervention, and the three-month follow-up will cover the three months

1 following the intervention. Individuals who have not had sex in the interval will be classified as
2 having no condomless sex.

4 *Secondary Outcomes*

- 5 • Post-intervention sex acts
- 6 • Condom use social norms
- 7 • Condom self-efficacy
- 8 • Condom use negotiation
- 9 • HIV testing and self testing
- 10 • Syphilis testing and self testing
- 11 • Incremental cost of intervention associated with respective video interventions per
12 individual reporting increased condom use or no sex since intervention. Other cost-
13 related data from organizations involved in making the intervention videos will be
14 collected. Detailed information on incremental costs can be found in Table 1.

15 More detailed explanations of secondary outcomes can be found in Supplemental File 1.

Table 1. Incremental costs associated with social marketing and crowdsourced arms.

Phase	Financial costs	Economic costs
Contest development	<i>Inputs to be capture, can all directly be found in the project financial accounts, main challenge is to allocate across components and to allocate SESH overhead costs</i>	<i>Extra inputs not already captured by financial costs</i>
Video contest (including production)	Money paid for planning and implementation	<div>For social marketing arm:<ul style="list-style-type: none">• Personnel of CBOs/CDC (director of movie, actors, film editors)• Rental of professional video equipment (if applicable)• Building cost (office renting) for CBOs/CDC*• Equipment and software cost (if applicable) *<div>For crowdsourced arm:<ul style="list-style-type: none">• Personnel of SESH (although all volunteer)• Judging opportunity cost (volunteer)• Steering Committee planning meeting (three one-hour meetings)• Building cost (office renting)*• In-person promotion costs</div></div>
Survey start up	Money paid to launch the survey (start-up)	<ul style="list-style-type: none">• SESH personnel costs, to design and maintain the program• Equipment cost of SESH (computer and other items)*• Software (Qualtrics)*
Survey implementation and intervention	<div>Money paid to the participants (implementation)</div> <div>Money paid for the software used for follow up (implementation)</div>	<ul style="list-style-type: none">• SESH personnel costs
Testing		<ul style="list-style-type: none">• Cost for condoms (from CDC)

*The cost will be annualized and we will calculate a proportion of the cost to account for items only being used the study time frame. The key idea is that some of these phases are like capital goods, where they only need to be done once but have benefits for longer (thus requiring annualisation of costs), while the implementation phase has a life only as long as the survey is running.

Sample size calculation

Sample size for this non-inferiority trial was determined assuming an equal probability of reporting condomless sex in the crowdsourced video and social marketing video arms. Assuming a 50% probability of condomless sex in each arm, a one-sided significance level (α) of 2.5%, a non-inferiority limit of 10%, and loss to follow-up of 10%, a total sample size of 1170 individuals was required (585 in each arm) to have 90% power ($1-\beta$). The sample size was calculated using the formula [24]:

$$n = f(\alpha, \beta) \frac{[\pi_s (1 - \pi_s) + \pi_e (1 - \pi_e)]}{(\pi_s - \pi_e - d)^2}$$

where π_s and π_e are the true probabilities of reporting condomless sex in the social marketing video (standard) and crowdsourced video (experimental) intervention groups, respectively, d is the non-inferiority limit, and $f(\alpha, \beta) = [\Phi^{-1}(1-\alpha) + \Phi^{-1}(1-\beta)]^2$ where Φ denotes the cumulative distribution function of the standard normal distribution. More information on sample size calculation can be found in Table 2.

Table 2: Sample size for 90% power and one-sided 0.025 significance level

Probability of primary outcome in control group*	Probability of primary outcome in experimental group*	N evaluable per arm	Total sample size for RCT
0.50	0.50	526	1170
0.45	0.45	521	1158
0.40	0.40	505	1124
0.35	0.35	479	1066
0.30	0.30	442	984

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*Based on the pilot study, 9 of 25 participants (95% confidence interval: 18% to 57%) had condomless sex at least once in the three-week period immediately following the video intervention. According to a similar RCT we conducted in 2014, the loss to follow up rate was about 10%; adjustment for loss to follow up required $(N \text{ evaluable per arm}) / (1 - 0.1)$ to be enrolled. A non-inferiority limit of 0.1 was used for all calculations.

Randomization and allocation

Participants will be randomly assigned to one of the two intervention videos using an electronic randomizer tool available through Qualtrics. Randomization will occur independently of any other data collected, with participants allocated in a 1:1 ratio to one of the two arms. Participants will not be informed of which video (crowdsourcing or social marketing) they are assigned to.

DATA ANALYSIS

Primary analysis

The primary analysis will evaluate the non-inferiority hypothesis comparing the two interventions, as well as the superiority hypothesis. The difference in proportions having condomless sex (crowdsourced - social marketing) will be computed, with a corresponding two-sided 95% Wald confidence interval. The crowdsourced intervention will be declared non-inferior to social marketing if the upper confidence limit is below 10%. If the upper confidence limit is below 0%, then the crowdsourced intervention will be declared superior to social marketing. The recruitment methods, survey instrument, and video length will be the same between in the two study arms.

Effect modification analysis

Effect modification analyses will be undertaken based on prior exposure to the condom promotion video viewed by the participant to assess whether this exposure modified the effect of video intervention arm upon the primary condom use outcome. A linear probability model will be used to evaluate effect modification by testing for an interaction between intervention and prior video watching.

Missing data plan

If the primary outcome is missing for <11% of participants, then the primary analysis will use a complete-case approach. If the primary outcome is missing for 11 to <20% of participants, then a sensitivity analysis using multiple imputation based on the PROC MI procedure in SAS (Cary, NC) will also be used. If the primary outcome is missing for $\geq 20\%$ of participants, then multiple imputation will be used in the primary analysis.

Secondary analysis

Comparison will be made between the two trial arms with respect to each of the secondary outcomes enumerated above and in Supplemental File 1. Non-inferiority comparisons will also be made between study arms for the subset of individuals who reported sex during the follow-up period (3 weeks and 3 months respectively) and causal inference methods will be employed to account for post-randomization selection bias.

ETHICS AND DISSEMINATION

Ethical review

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1 IRB approval was obtained from the Guangdong Provincial Center for Skin Diseases and STI
2 Control, University of North Carolina at Chapel Hill, and University of California San Francisco.

4 *Informed Consent*

5 All participants will be provided an online consent form immediately prior to survey
6 commencement. This online informed consent describes personal data to be collected, explaining
7 that data will be used for research purposes. Contact information is provided to participants to
8 address further questions. Participants will be required to sign the consent and provide a mobile
9 telephone number as agreement to proceed with the survey.

11 *Confidentiality*

12 Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted
13 securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured
14 Qualtrics server in the United States. The server is configured with redundant hard drive array to
15 ensure reliability. Access to the data will be password protected within the server's firewall.
16 Survey responses will be kept separately from participants' email addresses; the two files will be
17 linked with a non-descript, unique, randomly generated identifier.

19 Participants will provide mobile telephone numbers, which will be kept separately from data
20 containing answers to survey items. These telephone numbers will be accessible only to two
21 researchers solely for the means of sending reminders, follow-up surveys and mobile top-up
22 incentives.

2 The results of this study will be prepared and submitted for publication in a peer-reviewed
3 journal. Study findings will also be shared through conference abstracts and presentations,
4 workshops, and to our partnering organizations.

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Contributors

CW and JT conceived the study, CL, JM, TW, WT, LT ST, WZ, YQ, KM, MG, CW and JT contributed to study design. WT, ST, KM, and MG helped with statistical support and endpoints. CW, JM and TW designed data collection tools. JT, WT, CL and JM drafted and revised the manuscript. All authors contributed critical intellectual input and approved the final manuscript.

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Competing Interests

None of the authors declare any conflicts of interest.

Ethics Approval

Ethical approval has been obtained from the ethical review boards of the Guangdong Provincial Center for Skin Diseases and STI control, the University of North Carolina at Chapel Hill, and the University of California at San Francisco.

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1 **Appendix 1. Secondary outcomes measured as part of this RCT.**

Secondary Outcome	Definition
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective video interventions (development, start-up, implementation, condom use, intervention – see Table 2 for details) per individual who reported no sex or sex with a condom during the follow-up period.
<i>Female condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with a woman divided by the total number of men who viewed the video in that arm.
<i>Male condomless sex</i>	Frequency of men, defined as number of men who reported condomless anal sex with a man divided by the total number of men who viewed the video in that arm
<i>Post-video condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with any partner immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>Frequency of sex acts</i>	Frequency of men, defined as the number of men who had decreased total number of sex acts in the three weeks following the intervention compared to the three weeks immediately preceding the intervention in that arm
<i>Condom use social norms</i>	Frequency of men, defined as number of men who report higher levels of social norms when comparing their pre-intervention and post-intervention condom use norms*
<i>Condom self-efficacy</i>	Frequency of men, defined as number of men who had an increase in self-efficacy when comparing their pre-intervention and post-intervention self-efficacy**
<i>Condom negotiation</i>	Frequency of men, defined as the number of men who attempted to convince an unwilling partner to use a condom immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>HIV testing</i>	Frequency of men, defined as the number of men who reported being tested for HIV during the interval between watching the video and following up compared to the number of men who followed up
<i>STI testing</i>	Frequency of men, defined as the number of men who reported being tested for STIs (excluding HIV) during the interval between watching the video and following up compared to the number of men who followed up

*Condom use social norms will be measured using six survey items that are each on a five point Likert scale. Increased condom use social norms will be defined as having an increase from baseline in any two of these six survey items and dichotomized accordingly. The condom use social norm outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

**Self-efficacy will be measured using seven survey items that are each on a five point Likert scale. Increased self-efficacy will be defined as having an increase from baseline in any two of

these seven survey items and dichotomized accordingly. The self-efficacy outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

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Supplementary File: Online Survey
Men’s Heath Study (Final)

About this Study:

You are being asked to take part in a research study that will help us better understand sexual behavior and condom use among men in China. Your participation in this project will allow us to develop better interventions to promote condom use and to improve sexual health among men across China.

What’s Involved?

If you participate in this study, you will be asked to complete an online questionnaire and a subset of participants will be asked watch a one minute video. A subset of participants will also be asked to complete up to two additional follow-up questionnaires. The questionnaires will ask you to provide sociodemographic information and information about your sexual behaviors. In order to ensure that your privacy is protected, all of your online responses will be encrypted and securely transferred to our data servers.

Upon completion of this study and a 3-week follow up survey, **you will receive 100 RMB credit** to your mobile phone. Eligible participants who also complete the follow-up questionnaires can **receive up to 150 RMB credit** to their mobile phone.

If you have any questions about the research or your participation in the study, feel free to contact

A. Basic Information (Eligibility Survey) (Q1-5)

A1. Were you born biologically male or female?

- ☐ Male
- ☐ Female (Not eligible to take this survey – Skip to End of Survey)

A2. What is your date of birth?

- ☐ dd.mm.yyy (*Calendar input*) (Not eligible to take this survey if year is greater than Launch day + 1999 or < 16 y/o – Skip to End of Survey)

A3. In your lifetime have you ever had anal sex with another man?

- ☐ Yes
- ☐ No (Not eligible to take this survey – Skip to End of Survey)

A4. In the last three months, did you have any anal and /or vaginal sex without a condom with any sex partner?

- ☐ Yes
- ☐ No (Not eligible to take this survey – Skip to End of Survey)

A5. Will you agree to provide us your Chinese mobile phone number? (Answering this question is required to participate in the survey and to receive your reward for participating. We will not distribute your number to any agency or individual. Thank you for your cooperation.)

- ☐ Agree
- ☐ Decline (Not eligible to take this survey – Skip to End of Survey)

Which carrier are you using right now?

- ☐ China Mobile
- ☐ China Unicom
- ☐ China Telecom

Online Consent Form

Title of Study: Men's Health Study

IRB study number: 15-1522

Principal Investigator: Dr. Joseph Tucker
Dr. Joseph D. Tucker, UNC Project-China, Number 2 Lujing Road, Guangzhou, China,

What are some general things you should know about research studies? You are being asked to participate in a research study. To join this research study is voluntary. You may for whatever reason refuse to join or withdraw your consent to be in the study at any time, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about joining this research study.

What is the purpose of this study? Innovative approaches to condom promotion campaigns are urgently needed. The current strategy to developing many of these campaigns is to repackage old ideas rather than create new ones. The purpose of this research study is to understand how crowdsourcing can be used to leverage both the high Internet use and willingness to participate in online forums of young MSM (men who have sex with men) to transform the design and implementation of condom promotion campaigns. Crowdsourcing is the process of taking a task traditionally performed by a single individual or organization, and instead outsourcing the task to a large group to complete in the form of a contest or open call, often enabled by the Internet.

How many people will take part in this study? If you decide to participate in this research study, you will be one of approximately 1170 individuals recruited across China.

What will happen if you take part in the study? Your part in this research study will last approximately 20 minutes. During this study, you will be asked to first complete an online questionnaire, and depending on your responses, you may be asked to watch a one minute video afterwards. Upon completion of this initial questionnaire, you will be asked to input your mobile phone number as a means for the research team to prevent duplicate responses, to send reminders, and to distribute rewards for participation. Additionally, some participant will be asked to complete up to two additional follow-up questionnaires after three-week and twelve-week's times. If you do not respond to the initial follow-up request, you will receive a message reminder. To do this, we will also ask you to provide your QQ number. The study questionnaires will ask you to provide sociodemographic information as well as details about your sexual health and sexual activity.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. The proposed study will make important contributions to the sexual health literature. The field of condom interventions among young MSM in resource-limited settings is in its infancy. The results from this study will help the research team develop a MSM targeted, community-level intervention that will be fielded and evaluated in the Chinese setting. Your participation will also help design better interventions to promote condom use among MSM in China.

What are the possible risks or discomforts involved from being in this study? We will ask participants to provide sensitive information about their sexual partners and practices. Participants may feel embarrassed, anxious, or otherwise distressed by providing information of such a personal nature. Participants may also experience fatigue in response to the proposed evaluations (e.g. from looking at a computer screen). Some participants might fear that refusal to participate in the study might jeopardize their sexual orientation identity – especially if the participant has not come “out” to him or herself and/or the community). Other participants may fear that the research staff might “out” them or discuss their private details with other (MSM and non-MSM) members in their community. While the risk is minimal, there is still the possibility for breaches of confidentiality.

How will your privacy be protected? All data are directly entered into computers as participants complete the questionnaires. Programs to ensure accuracy, completeness, and internal consistency are automated. 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 providers 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. For example, if a hacker could crack a standard 40-bit SSL session in a day, it is estimated that it would take well beyond a trillion years to accomplish the same thing against a 128-bit SSL session. A dedicated server, which eliminates security issues involved with shared hosting environments where hundreds of websites and users reside on one shared web server as well as ensuring both physical and network security, will be used to house the data. 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. Survey responses will be kept separately from participants’ email addresses; the two files will be linked with a non-descript, unique, randomly generated identifier. Only the PI and a designated senior staff member will have the password to access to the “key” that links the nondescript identifier to personally identifiable information. Cookies will not be used in any way to track participant activity.

What if you want to stop before your part in the study is complete? If at any point in the study you do not want to answer a question or no longer want to participate, you can stop and withdraw from this study without penalty. The investigators also have the right to stop your participation if you have an unexpected reaction, have failed to follow instructions, etc.

Will you receive anything for being in this study? Will it cost anything? Participants who are asked to watch a one-minute video will have the opportunity to earn up to 150 RMB credit on their mobile phone – this credit will be distributed as two separate 100 and 50 RMB mobile phone recharges. Participants will receive a 100 RMB phone recharge upon completion of the first questionnaire and 3-week follow up survey, and 50 RMB for the 3-month follow up survey if that they are eligible for. There are no costs associated with participating in this research study.

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What if you have questions about this study? If you have any questions, complaints, or concerns about the research or your participation in the study, feel free to contact

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns, or if you would like to obtain information or offer input, please contact the UNC Institutional Review Board at 1-919-966-3113 or by email to IRB_subjects@unc.edu. You may also contact the Guangdong Provincial Skin Diseases & STI Control Center IRB at 020 – 83027652 or by email to sesh@seshglobal.org.

If you understand and agree to participate in this research study, please select “Agree” from the options below. We thank you for your participation!

- ☐ Agree
- ☐ Decline (Skip to End of Survey)

Survey Access (Q6-7)

6. How did you find out about our research study?

- ☐ Blued's banner ad
- ☐ Danlan webpage banner ad (www.danlan.org)
- ☐ Weibo banner ad
- ☐ Weixin banner ad
- ☐ Friend referral
- ☐ SESH referred me through QQ
- ☐ SESH referred me through SMS

7. What device are you using to access our research study?

- ☐ Desktop or laptop computer
- ☐ Mobile phone
- ☐ Tablet device

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A. Sociodemographics (Q8-15)
The next set of questions will ask you to provide some information about yourself.

A6. What province or province-level city do you currently live in?

- ☐ Beijing
- ☐ Tianjin
- ☐ Hebei
- ☐ Shanxi
- ☐ Inner Mongolia
- ☐ Liaoning
- ☐ Jilin
- ☐ Heilong Jiang
- ☐ Shanghai
- ☐ Jiangsu
- ☐ Zhejiang
- ☐ Anhui
- ☐ Fujian
- ☐ Jiangxi
- ☐ Shandong
- ☐ Henan
- ☐ Hubei
- ☐ Hunan
- ☐ Guangdong
- ☐ Guangxi
- ☐ Hainan
- ☐ Chongqing
- ☐ Sichuan
- ☐ Guizhou
- ☐ Yun An
- ☐ Xizang (Tibet)
- ☐ Shaanxi
- ☐ Gansu
- ☐ Qinghai
- ☐ Ningxia
- ☐ Xinjiang
- ☐ Hong Kong
- ☐ Aomen

A7. What city do you currently live in? _____ (Text input) (Do not display if answered
北京, 上海, 重庆, 天津, 香港, 澳门 to A6)

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6 2 A8. What is your current legal marital status (referring to women)?
7 3 ☐ Not married
8 4 ☐ Engaged or Married
9 5 ☐ Separated or Divorced
10 6 ☐ Widowed
11 7

12 8 A9. Are you currently enrolled as either a full-time or part-time student?
13 9 ☐ Yes
14 10 ☐ No
15 11

16 12 A10. What is the highest level of education that you have **completed**?
17 13 ☐ High school or below (including Zhongzhuan)
18 14 ☐ Some college (Dazhuan)
19 15 ☐ College/Bachelors
20 16 ☐ Masters/PhD
21 17

22 18 A11. What is your total individual **monthly** income from all sources?
23 19 ☐ Less than 1500 RMB
24 20 ☐ Between 1500 and 3000 RMB
25 21 ☐ Between 3001 and 5000 RMB
26 22 ☐ Between 5001 and 8000 RMB
27 23 ☐ Greater than 8000 RMB
28 24

29 25 A12. What do you primarily consider yourself to be?
30 26 ☐ Gay
31 27 ☐ Bisexual
32 28 ☐ Straight/Heterosexual
33 29 ☐ Transgender
34 30 ☐ Unsure/Other
35 31

36 32 A13. Have you spoken with a physician or other health professional (e.g. HIV testing counselor,
37 33 pharmacist) about your sexuality or sexual history with men?
38 34 ☐ Yes
39 35 ☐ No
40 36

41 37 **B. MSM Basic Situation (Q16-38)**
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45 38 *The next set of questions will ask you about your sexual behaviors with other men.*
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3 1 *A “primary partner” is someone who you have sex with regularly and/or have an emotional*
4 2 *commitment to. A “casual partner” is someone who you have sex with and do not have an*
5 3 *emotional commitment to.*
6 4
7 5
8 6
9 6 B1. How old were you during your first insertive sexual encounter?
10
11 7 _____years old (*Number input*)
12 8
13 9 B2. Was your first insertive sexual encounter with a male or female?
14
15 10 ☐ Male (Skip to B4)
16 11 ☐ Female
17 12 ☐ Other
18
19
20 13
21 14 B3. How old were you when you had sex with another man for the first time?
22
23 15 _____years old (*Number input*)
24 16
25 17 B4. Were you insertive (1) or receptive (0) during your first sexual encounter with another man?
26
27 18 ☐ Insertive (1)
28 19 ☐ Receptive (0)
29 20 ☐ Both insertive (1) and receptive (0)
30
31 21
32 22 B5. Did you use a condom during your first sexual encounter with another man?
33
34 23 ☐ Yes
35 24 ☐ No
36 25
37
38 26 B6. In general, where do you usually go to meet your sex partners (Select all that apply)?
39
40 27 ☐ Pub, disco, tearoom, or club
41 28 ☐ Spa or bath house, sauna, foot or body massage parlor
42 29 ☐ Park, public restroom, public lawn
43 30 ☐ Internet
44 31 ☐ Other
45
46 32
47 33 B7. In the last three months, approximately how many male sex partners have you had?
48
49 34 _____male sex partners (*Number input*) (If answer <1, skip to end of section)
50 35
51
52 36 B8. Of the men you have had sex with in the last three months, would you consider one of them
53 37 to be a primary sex partner?
54
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1 ☐ Yes
2 ☐ No (Skip to B16)
3
4 B9. In the last three months, approximately how many times per week did you have anal sex
5 with your primary partner?
6 _____ sex encounters per week
7

8 B10. How long have you and your primary sex partner been in a relationship?

- 9 ☐ Less than three months
10 ☐ Between three and six months
11 ☐ Between six and twelve months
12 ☐ Between one and two years
13 ☐ More than two years
14

15 B11. In the last three months, when you had anal sex with your primary partner, what role did
16 you assume?

- 17 ☐ Always insertive (always 1) (Do not display B15)
18 ☐ Mostly insertive (mostly 1)
19 ☐ Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)
20 ☐ Mostly receptive (mostly 0)
21 ☐ Always receptive (always 0) (Do not display B14)
22 ☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B14 and B15)
23

24 B12. In the last three months, when you had sex with your primary partner, how frequently did
25 you or your partner use condoms? (Do not display if “No anal sex, only oral sex” to B11)

- 26 ☐ Never used (Skip to B14)
27 ☐ Sometimes used
28 ☐ Mostly used
29 ☐ Always used (Do not display B14, B15)
30

31 B13. In the last three months, when you had sex with your primary partner did a condom ever
32 slip off, tear, or otherwise fail?

- 33 ☐ Yes
34 ☐ No
35

36 B14. When you are insertive, the reason(s) you do not use a condom with your primary partner
37 include (select all that apply):

- 38 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
39 ☐ Neither of us has a condom

- For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

- 1 ☐ Mostly receptive (mostly 0)
- 2 ☐ Always receptive (always 0) (Do not display B21)
- 3 ☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B21 and B22)

4

5 B19. In the last three months, when you had sex with a casual partner, how frequently did you or

6 your partner use condoms? (Do not display if B17 is "0" or B18 is "无肛交, 只有口交 (既不

7 是 1 也不是 0)")

- 8 ☐ Never used (Skip to B21)
- 9 ☐ Sometimes used
- 10 ☐ Mostly used
- 11 ☐ Always used (Do not display B21, B22)

12

13 B20. In the last three months, when you had sex with a casual partner did a condom ever slip off,

14 tear, or otherwise fail? (Do not display if answer to B19 is "Never used")

- 15 ☐ Yes
- 16 ☐ No

17

18 B21. When you are insertive, the reason(s) you do not use a condom with a casual partner

19 include (select all that apply):

- 20 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
- 21 ☐ Neither of us has a condom
- 22 ☐ My partner does not want me to use one
- 23 ☐ The condom is of poor quality
- 24 ☐ I do not have time to use one
- 25 ☐ I am drunk or high
- 26 ☐ I am HIV negative or I do not believe I am infected with HIV
- 27 ☐ My partner is HIV negative or I do not believe he is infected with HIV
- 28 ☐ Other

29

30 B22. When you are receptive, the reason(s) your casual partner does not use a condom with you

31 include (select all that apply):

- 32 ☐ He does not want to use one (e.g. personal preference, uncomfortable)
- 33 ☐ Neither of us has a condom
- 34 ☐ I do not want him to use one
- 35 ☐ The condom is of poor quality
- 36 ☐ He does not have time to use one
- 37 ☐ He is drunk or high

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- ☐ He is HIV negative or he does not believe he is infected with HIV

☐ I am HIV negative or he does not believe I am infected with HIV

☐ Other
- B23. In the last month, did you have any anal sex without a condom with any male partner? (Do not display if answer “1” to B7 and “Always” to B19)
- ☐ Yes

☐ No

16 10 **C. Heterosexual Sex Situation (Q39-54)**

17 11 *The next set of questions will ask about your sexual behaviors with women.*

18 12
19 13 *A “primary female partner” is someone who you have sex with regularly, have an emotional commitment to, and/or have married or engaged to be married. A “casual female partner” is someone who you have had sex with but do not have an emotional commitment to.*

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- C1. Have you ever had vaginal, anal, and/or oral sex with a female partner?
- ☐ Yes

☐ No (Skip to End of Section)
- C2. In the last six months, did you have any vaginal and/or anal sex with a female partner?
- ☐ Yes

☐ No (Skip to End of Section)
- C3. In the last six months, approximately how many female sex partners have you had?
- _____ female sex partners (*Number input*) (If answer <1 then skip to End of Section)
- C4. In the last six months, have you had a primary female sex partner?
- ☐ Yes

☐ No (Skip to C9)
- C5. In the last six months, approximately how many times per week did you have vaginal and/or anal sex with your primary female partner?
- _____ sex encounters per week
- C6. In the last six months, when you had sex with your primary female partner, how frequently did you or your partner use condoms?
- ☐ Never used (Skip to C8)

☐ Sometimes used

- 1
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3 1 ☐ Mostly used
4 2 ☐ Always used (Do not display C8)
5
6 3
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8 4 C7. In the last six months, when you had sex with your primary female partner did a condom
9 5 ever slip off, tear, or otherwise fail?
10 6 ☐ Yes
11 7 ☐ No
12 8
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14 9 C8. The reason(s) you do not use a condom with your primary female partner include (select all
15 10 that apply):
16 11 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
17 12 ☐ Neither of us has a condom
18 13 ☐ My partner does not want me to use one
19 14 ☐ The condom is of poor quality
20 15 ☐ I do not have time to use one
21 16 ☐ I believe that my partner is loyal to me
22 17 ☐ I am loyal to my partner
23 18 ☐ I am drunk or high
24 19 ☐ I am HIV negative or I do not believe I am infected with HIV
25 20 ☐ My partner is HIV negative or I do not believe she is infected with HIV
26 21 ☐ Other
27 22
28 23 C9. In the last six months, have you had sex with another woman who was not your primary
29 24 partner?
30 25 ☐ Yes
31 26 ☐ No (Skip to End of Section if “Always” to C6; otherwise Skip to C14 – Should not answer
32 27 “No” to C4 and C9)
33 28
34 29 C10. In the last six months, approximately how many times per week did you have vaginal
35 30 and/or anal sex (all casual sex partners combined)?
36 31 _____ sex encounters per week
37 32
38 33 C11. In the last six months, when you had sex with a casual female partner, how frequently did
39 34 you or your partner use condoms?
40 35 ☐ Never used (Skip to C13)
41 36 ☐ Sometimes used
42 37 ☐ Mostly used
43 38 ☐ Always used (Do not display C13; Skip to End of Section if “Always” to C6)
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5 2 C12. In the last six months, when you had sex with a casual female partner did a condom ever
6 3 slip off, tear, or otherwise fail?
7 4 ☐ Yes
8 5 ☐ No
9 6
10 7 C13. The reason(s) you do not use a condom with a casual female partner include (select all that
11 8 apply):
12 9 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
13 10 ☐ Neither of us has a condom
14 11 ☐ My partner does not want me to use one
15 12 ☐ The condom is of poor quality
16 13 ☐ I do not have time to use one
17 14 ☐ I am drunk or high
18 15 ☐ I am HIV negative or I do not believe I am infected with HIV
19 16 ☐ My partner is HIV negative or I do not believe she is infected with HIV
20 17 ☐ Other
21 18
22 19
23 20 C14. In the last month, did you have sex without a condom with any female partner? (Do not
24 21 display if answer “1” to B7 and “Always” to B19)
25 22
26 23 ☐ Yes
27 24 ☐ No
28 25
29 26
30 27 **D. Sexual Behavior (Q55-63)**
31 28 *The next set of questions will ask about any “risky” sexual behaviors that you may or may not*
32 29 *have engaged in with other men and/or women.*
33 30
34 31 D1. In the last three months, did you ever have sex while you were drunk (from drinking
35 32 alcohol)?
36 33 ☐ Yes
37 34 ☐ No
38 35
39 36 D2. In the last three months, was you partner ever drunk (from drinking alcohol) while you had
40 37 sex?
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- 1 ☐ Yes
- 2 ☐ No (Skip to D4 if “No” for D1 and D2)
- 3
- 4 D3. In the last three months, how often did you have sex while you and/or your partner was
- 5 drunk?
- 6 ☐ Never
- 7 ☐ Rarely
- 8 ☐ Occasionally/Sometimes
- 9 ☐ Very often
- 10 ☐ Always
- 11
- 12 D4. In the last twelve months, did you ever use “meth” before or during sex?
- 13 ☐ Yes
- 14 ☐ No
- 15
- 16 D5. In the last twelve months, did you ever participate in group sex with other men?
- 17 ☐ Yes (Display D6)
- 18 ☐ No
- 19
- 20 D6. During your most recent group sex experience, did you have any anal sex without a
- 21 condom?
- 22 ☐ Yes
- 23 ☐ No
- 24
- 25 D7. In the last twelve months, were you ever paid (with money or gifts) to have sex?
- 26 ☐ Yes
- 27 ☐ No (Skip to D9)
- 28
- 29 D8. In the last twelve months, has your main source of income come from having sex with
- 30 customers?
- 31 ☐ Yes
- 32 ☐ No
- 33
- 34 D9. In the last twelve months, have you ever paid (with money or gifts) a man to have sex?
- 35 ☐ Yes
- 36 ☐ No
- 37

E. Sex Tourism (Q64-79)

The next set of questions will ask about leaving your city and/or China to purchase sex.

E1. Have you ever purchased sex (with money or gifts) while traveling outside of your city of residence?

- ☐ Yes
- ☐ No (If “No” skip to End of block)

E2. Have you ever traveled outside of your city of residence with the primary purpose of purchasing sex?

- ☐ Yes
- ☐ No

E3. When you traveled to purchase sex, did you travel within China or leave the country?

- ☐ Within China (Display E4a)
- ☐ Outside China (Display E4b)
- ☐ Both (Display E4a and E4b)

E4a. Which city/cities in China did you travel to when you purchased sex? _____ (Text Input)

E4b. Which country/countries and cities did you travel to when you purchased sex? _____ (Text Input)

E5. How did you arrive at your destination?

- ☐ Car
- ☐ Train
- ☐ Airplane
- ☐ Ship

E6. Why did you decide to purchase sex while traveling?

- ☐ I was afraid of seeing someone I know in my hometown
- ☐ Sex is less expensive at the location I traveled to
- ☐ There was less likelihood that I would have to use a condom if I purchase sex
- ☐ I am unable to purchase sex in my hometown
- ☐ I wanted to try sexual intercourse with another gender
- ☐ I was drunk or using drugs, I did not plan it

E7. When you purchased sex while outside your city of residence, who did you purchase sex from (select all that apply)?

- 1 ☐ Men
2 ☐ Women
3 ☐ Transgender

4
5 E8a. When you purchased sex while outside your city of residence, have you ever had any
6 vaginal sex without a condom? (Display if “Women” or “TG” for E7)
7 ☐ Yes (Display E17)
8 ☐ No

9
10 E8b. When you purchased sex while outside your city of residence, have you ever had any anal
11 sex without a condom?
12 ☐ Yes (Display E17)
13 ☐ No

14
15
16 E9. Once you were at your travel destination (during your most recent trip abroad), how did you
17 find someone to purchase sex from (select all that apply)?
18 ☐ Mobile app portal
19 ☐ Online (not an app) portal
20 ☐ In-person proposition
21 ☐ Local establishment

22
23 E10. During your most recent experience when you purchased sex while abroad, approximately
24 how many sex partners did you purchase? (Please enter “0” partners if no partners of the
25 following type)

26 _____ male sex partners (*Number input*)
27 _____ female sex partners (*Number input*)
28 _____ transgender sex partners (*Number input*)

29
30 E11. During your most recent experience when you purchased sex while traveling,
31 approximately how much did you pay (RMB) for your last sex encounter?
32 _____ (*Text Input*)

33
34 E12. During your most recent experience when you purchased sex while traveling, of what
35 nationality was your last partner?
36 _____ (*Text Input*)

E13. During your most recent experience when you purchased sex while traveling, the reason(s) you did not use a condom include (select all that apply):

- ☐ I did not want to use one (e.g. personal preference, uncomfortable)
- ☐ I did not want my partner to use one
- ☐ Neither of us had a condom
- ☐ My partner did not want to use one (e.g. personal preference, uncomfortable)
- ☐ My partner did not want me to use one
- ☐ The condom was of poor quality
- ☐ I did not have time to use one
- ☐ My partner did not have time to use one
- ☐ I was drunk or high
- ☐ My partner was drunk or high
- ☐ I am HIV negative or I do not believe I am infected with HIV
- ☐ My partner was HIV negative or I do not believe my partner was infected with HIV

E14. How strongly do you agree with the following statement: During my most recent experience purchasing sex while traveling, I behaved with less caution than I normally would while at home

- ☐ Strongly yes
- ☐ Yes
- ☐ The same
- ☐ No
- ☐ Strongly No

E15. Did you travel alone or with others?

- ☐ Alone
- ☐ With others

E16. During your most recent experience when you purchased sex while traveling, did you ask your partner about his/her HIV status before having sex?

- ☐ Yes
- ☐ No

F. Condom Behavior (Q80-96)

The next set of questions will ask about your practices and attitudes in regards to condom use.

F1. In the last three months, how often did you carry a condom with you when there was the possibility you may have sex later?

1 ☐ Always

2 ☐ Sometimes

3 ☐ Hardly ever

4 ☐ Never

5
6 F2. If you needed a condom, where is the first place you would go to find one?

7 ☐ Pharmacy or drugstore

8 ☐ Supermarket

9 ☐ Health clinic

10 ☐ Community event

11 ☐ Restroom vending machine

12 ☐ Friend

13 ☐ Partner

14 ☐ Other

15
16 F3. If I had sex and told my friends that I did not use a condom, they would be angry or
17 disappointed.

18 ☐ Strongly agree

19 ☐ Agree

20 ☐ Neutral

21 ☐ Disagree

22 ☐ Strongly disagree

23
24 F4. My friends talk a lot about "safer" sex.

25 ☐ Strongly agree

26 ☐ Agree

27 ☐ Neutral

28 ☐ Disagree

29 ☐ Strongly disagree

30
31 F5. My friends and I encourage each other before dates to practice "safer" sex.

32 ☐ Strongly agree

33 ☐ Agree

34 ☐ Neutral

35 ☐ Disagree

36 ☐ Strongly disagree

37
38 F6. If I thought that one of my friends had sex on a date, I would ask them if they used a
39 condom.

40 ☐ Strongly agree

- I agree
- If I think that one of my friends might have sex on a date, I would ask him/her to use a condom.
- I agree
- If I have sex on a date and I do not have a condom, I would make an effort to get one.
- I agree
- I feel comfortable discussing condom use with a potential partner before having sex.
- I agree

- 1 ☐ Agree
 2 ☐ Neutral
 3 ☐ Disagree
 4 ☐ Strongly disagree
 5
 6 F12. I would feel comfortable letting a casual partner know that I want to have sex with a
 7 condom.
 8 ☐ Strongly agree
 9 ☐ Agree
 10 ☐ Neutral
 11 ☐ Disagree
 12 ☐ Strongly disagree
 13
 14 F13. I feel confident that I could refuse to have sex with a partner who did not want you to use a
 15 condom.
 16 ☐ Strongly agree
 17 ☐ Agree
 18 ☐ Neutral
 19 ☐ Disagree
 20 ☐ Strongly disagree
 21
 22 F14. I feel confident in my ability to incorporate putting a condom on myself or my partner into
 23 foreplay.
 24 ☐ Strongly agree
 25 ☐ Agree
 26 ☐ Neutral
 27 ☐ Disagree
 28 ☐ Strongly disagree
 29
 30 F15. I feel confident that I could use a condom with a partner without "breaking the mood."
 31 ☐ Strongly agree
 32 ☐ Agree
 33 ☐ Neutral
 34 ☐ Disagree
 35 ☐ Strongly disagree
 36
 37 F16. In the last three months, did you ever **try** to convince a partner who did not want to use a
 38 condom to use one before having sex?
 39 ☐ Yes, and I was successful
 40 ☐ Yes, but I was unsuccessful
 41 ☐ No

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- 2 F17. In the last three months, did your partner every **try** to convince you to use a condom when
- 3 you did not want to use one before having sex?
- 4 ☐ Yes, and he was successful
- 5 ☐ Yes, but he was unsuccessful
- 6 ☐ No

7

8

9 **G. HIV/STI Testing (Q97-132)**

10 *The next set of questions will ask about your HIV and STI testing and results. Self-testing refers*

11 *to you administering the test yourself and interpreting results.*

- 12
- 13 G1. Have you ever been tested for HIV?
- 14 ☐ Yes
- 15 ☐ No (Skip to G25)
- 16
- 17 G2. Have you ever given or received an HIV self-test?
- 18 ☐ Yes
- 19 ☐ No
- 20
- 21 G3. Have you ever self-tested for HIV?
- 22 ☐ Yes
- 23 ☐ No (Skip to G20) (Do not show G35)
- 24
- 25 G4. Did someone else force you to take an HIV self-test?
- 26 ☐ Yes
- 27 ☐ No
- 28
- 29 G5. Who was with you when you self-tested? (Can select multiple)
- 30 ☐ No one, I was alone
- 31 ☐ Partner
- 32 ☐ Friend
- 33
- 34 G6. Was your HIV self-test the first time you ever tested for HIV?
- 35 ☐ Yes
- 36 ☐ No
- 37
- 38 G7. What happened to your HIV testing frequency after you first used a self-test?

- 1 ☐ Increased
2 ☐ Decreased
3 ☐ No change

4
5 G8. Have you ever received a positive result with HIV self-testing?

- 6 ☐ Yes
7 ☐ No (Skip to G11)

8
9
10 G9. Has using an HIV self-test caused you subsequent suicidal feelings?

- 11 ☐ Yes
12 ☐ No

13
14 G10. Has using an HIV self-test led to a violent confrontation (physically hitting)?

- 15 ☐ Yes
16 ☐ No

17
18 *The next set of 4 questions will ask you to recall experiences specific to self-testing.*

19
20 G11. Has using an HIV self-test has increased your desire to seek follow-up care, as opposed to
21 other forms of HIV testing?

- 22 ☐ Yes
23 ☐ No

24
25 G12. Self-testing for HIV gives me a sense of empowerment by allowing me to choose when I
26 test.

- 27 ☐ Strongly Agree
28 ☐ Agree
29 ☐ Neutral
30 ☐ Disagree
31 ☐ Strongly Disagree

32
33 G13. Self-testing for HIV gives me a sense of empowerment by allowing me to choose where I
34 test.

- 35 ☐ Strongly Agree
36 ☐ Agree
37 ☐ Neutral
38 ☐ Disagree
39 ☐ Strongly Disagree

☐ Strongly Disagree

☐ No

☐ No

- in-person

○ friend

○ Blood

☐ Monthly

1 G21. What was the result of your most recent HIV test?

- 2 ☐ HIV positive/infected (Display G23)
3 ☐ HIV negative/uninfected
4 ☐ I never got my test results (Skip to G25)

6 G22. Did you notify your primary male sex partner about your most recent HIV test result?

- 7 ☐ Yes
8 ☐ No
9 ☐ I do not have a regular partner (Do not display G25)

11 G23. Have you ever taken anti-retroviral therapy (ART) for your HIV infection?

- 12 ☐ Yes – I have taken, and I am currently taking
13 ☐ Yes – I have taken, but I am currently not taking (Display G24)
14 ☐ No – I have never taken

16 G24. Why did you stop taking ART? (Select all that apply)

- 17 ☐ It was too expensive
18 ☐ I didn't like the side effects
19 ☐ I didn't feel that it was working
20 ☐ I thought it was cumbersome (too much time, forgot to take, etc.)
21 ☐ Stigma

23 G25. Has your primary male sex partner ever been tested for HIV? (Do not display if no to B8)

- 24 ☐ Yes
25 ☐ No (Skip to G27)

27 G26. What was the result of your primary male sex partner's most recent HIV test?

- 28 ☐ HIV positive/infected
29 ☐ HIV negative/uninfected
30 ☐ Never got test results
31 ☐ I don't know

33 G27. Have you ever had a male sex partner who tested HIV positive?

- 34 ☐ Yes
35 ☐ No (Skip to G30)
36 ☐ I don't know (Skip to G30)

38 G28. Did you ever have any anal sex without a condom with a HIV positive partner?

☐ Yes

☐ No

G29. Approximately how many HIV positive male sex partners have you had?

sex partners (*Number input*)

G30. Have you ever been tested for syphilis?

☐ Yes

- No (Skip to G36)

G31. Have you ever used a self-testing kit for syphilis?

☐ Yes

○ No (Skip to G36)

G32. Was your self-test the first time you ever tested for syphilis?

☐ Yes (Do not display G33)

☐ No

G33. What happened to your syphilis testing frequency after you first used a self-test?

○ Increased

○ Decreased

☐ No change

G34. Where did you obtain your syphilis self-test kit?

☐ online

○ hospital

○ pharmacy

○ CBO

○ Friend

G35. Have you ever performed syphilis and HIV self-testing together?

☐ Yes

☐ No

G36. In the last twelve months, which of the following services did you receive (Select all that apply):

- ☐ Condom distribution
- ☐ Lubricant distribution
- ☐ Peer Education
- ☐ STD Diagnosis or Treatment
- ☐ HIV counseling or Testing
- ☐ AIDS/STD Materials (pamphlets, etc.)

I. Community Engagement (Q133-143)

The next set of questions will ask you about your experiences with activities in your community promoting sexual health.

I1. In the last three weeks, have you viewed any videos promoting condom use among MSM?

- ☐ Yes
- ☐ No

I2. In the last three weeks, have you viewed any videos promoting HIV testing among MSM?

- ☐ Yes
- ☐ No

I3. Are you aware of any ongoing community events promoting sexual health among MSM?

- ☐ Yes
- ☐ No

I4. Have you ever helped organize a testing and/or awareness campaign (e.g. HIV, condom use, etc.) that promoted sexual health among MSM?

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☐ Yes
- 2

☐ No
- 3
- 4

I5. Have you ever volunteered at a health clinic or other location that provided sexual health
- 5

services among MSM?
- 6

☐ Yes
- 7

☐ No
- 8
- 9

I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually
- 10

transmitted disease?
- 11

☐ Yes
- 12

☐ No
- 13
- 14

I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV
- 15

and/or another sexually transmitted disease?
- 16

☐ Yes
- 17

☐ No
- 18
- 19

I8. How important to you is community engagement and participation in developing sexual
- 20

health campaigns (for your own community)?
- 21

☐ Very important
- 22

☐ Important
- 23

☐ Neither important or not important

☐ Slightly important

☐ Not important

I9. Have you ever participated in online forums or discussions on social media (ie. Weixin, Weibo, Twitter, or other on-line communities) about about sexual health, condom use, or HIV/STD testing or related services?

☐ Yes

☐ No

I10. Do you have a Weibo account?

☐ Yes (Display I11)

☐ No

I11. How many Weibo followers do you have?

☐ Less than 100

☐ 101-500

☐ 501-1000

☐ 1001-1500

☐ 1501-2000

☐ More than 2001

Video 1: Crowdsourcing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

Video 2: Social Marketing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

End of Survey

Please confirm your mobile phone number at this time to receive our reminder of the follow-up survey and reward. Please notice that only after you finish the 3 week follow up could you get the 100 top up reward.

☐ Mobile Phone #s: _____ (*Text Entry*) (must be 11 digits)

Follow-up Contact (Q144-145)

FUC1. Thank you for taking the time to complete our survey! Based on your responses to our questionnaire, we request that you to complete a follow-up survey in three weeks' time. Upon completion of this survey, you will receive an additional 50 RMB mobile phone recharge! When the time comes, we would like to send you a reminder to complete the survey via QQ. Will you agree to provide us your QQ number? If you agree, you will be contacted by the following user:

Number: 2663701478

Name: 赛思研究团队

- ☐ Agree (Display FUC2)
☐ Disagree

FUC2. Please input your QQ number:

☐ QQ number: _____

Referral (Q146)

R1. If you think any of your male friends would be interested in participating in our research survey, please share our study with them! Alternatively, you can provide us with either their mobile phone or QQ number, and we will send them a link to our survey. (Please enter as many unique numbers as you are willing in the spaces provided.)

If you provide a QQ number for referral, please notify your friend(s) that they will be contacted by 赛思研究团队 (#: 2663701478).

If you provide a mobile phone number for referral, please notify your friend(s) that they will be contacted by 18613067997.

- ☐ Mobile Phone #s: _____
☐ QQ numbers: _____



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<u>1</u>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<u>3</u>
	2b	All items from the World Health Organization Trial Registration Data Set	<u>1,14-15</u>
Protocol version	3	Date and version identifier	<u>1</u>
Funding	4	Sources and types of financial, material, and other support	<u>14</u>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<u>1,14</u>
	5b	Name and contact information for the trial sponsor	<u>14</u>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<u>15</u>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>N/A</u>

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>10</u>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>7</u>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>11</u>
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>11</u>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>11</u>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>N/A</u>
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>N/A</u>

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>10</u>
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>9</u>

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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
11				
12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
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16	Methods: Monitoring			
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18	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
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23		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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26	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
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29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12
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38	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12
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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	23

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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Comparing the effectiveness of a crowdsourced video and a social marketing video in promoting condom use among Chinese men who have sex with men: A study protocol

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Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, SOCIAL MEDICINE

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Manuscripts

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Comparing the effectiveness of a crowdsourced video and a social marketing video in promoting condom use among Chinese men who have sex with men: A study protocol

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Version 1.0

ABSTRACT

Introduction

Crowdsourcing has been used to spur innovation and increase community engagement in public health programs. Crowdsourcing is the process of giving individual tasks to a large group, often involving open contests and enabled through multi-sectoral partnerships. Here we describe one crowdsourced video intervention in which a video promoting condom use is produced through an open contest. The aim of this study is to determine whether a crowdsourced intervention is as effective as a social marketing intervention in promoting condom use among high-risk men who have sex with men (MSM) and transgender male-to-female (TG) in China.

Method

We evaluate videos developed by crowdsourcing and social marketing, respectively. The crowdsourcing contest involved an open call for videos. Entries were judged on capacity to promote condom use, to be shareable or “go viral”, and to give value to the individual. 1170 participants will be recruited for the randomized controlled trial. Participants need to be MSM age 16 and over who have had condomless anal sex in the last 3 months. Recruitment will be through an online banner ad on a popular MSM webpage and other social media platforms. After completing an initial survey, participants will be randomly assigned to view either the social marketing video or the crowdsourcing video. Follow-up surveys will be completed at both 3 weeks and 3 months after initial intervention to evaluate condomless sex and related secondary outcomes. Secondary outcomes include condom social norms, condom negotiation, condom self-efficacy, HIV/syphilis testing, frequency of sex acts and incremental cost.

Ethics and dissemination:

Approval was obtained from the ethical review boards of the Guangdong Provincial Center for Skin Diseases and STI Control, UNC, and UCSF. The results of this trial will be made available through publication in peer-reviewed journals.

Trial registration number: This trial was registered in ClinicalTrials.gov (NCT02516930).

Strengths and Limitations of this study protocol:

- This will be one of the few randomized controlled trials evaluating crowdsourcing
- The use of a large MSM platform will allow us to reach a large number of MSM who do not disclose their sexual orientation to doctors or others
- No biomarker data will be collected and there are inherent limitations associated with behavioural outcomes

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1 INTRODUCTION

2 Male Sexual Health

3 Male condoms have long been recognized as an effective method for reducing the risk of HIV
4 and other sexually transmitted diseases (STDs)[1, 2], but men who have sex with men (MSM)
5 infrequently use condoms in China[3-6]. The resulting high incidence of HIV and STDs among
6 MSM suggests the need for novel health promotion campaigns. One systematic review[7] and
7 one literature review among MSM[8] demonstrate that social marketing campaigns are effective
8 in promoting condom use, but the persistence of these behavioural changes over time is unclear.
9 We propose that crowdsourcing may substantially improve on existing methods for developing
10 condom promotion campaigns.

12 Crowdsourcing

13 Crowdsourcing is the process of giving individual tasks to a large group, often involving open
14 contests and enabled through multisectoral partnerships. While the process originated in the
15 private sector[9], intended to aid research, development and dissemination, it has since been
16 widely adopted. In 2010, the Executive Office of the President of the United States urged federal
17 agencies to utilize crowdsourcing as a method to develop innovative approaches to governmental
18 initiatives[10]. A crowdsourcing method differs from a social marketing method in several
19 ways[11]. Crowdsourcing is a bottom-up approach, utilizing the community for idea generation
20 through implementation rather than relying on the expertise of public health experts. This
21 ensures a higher degree of community engagement than approaches utilizing social marketing
22 do, which tends to be a top-down approach. Crowdsourcing promotes innovation because it
23 removes cognitive fixation, in which innovation is hampered due to new ideas being strongly

influenced by prior examples[12-16]. By engaging more people with less experience, this phenomenon is avoidable and allows for a more creative process[17]. Our team has previously used crowdsourcing successfully to develop an effective HIV testing promotion video and images promoting sexual health.[18]

OBJECTIVES

Aims and Hypotheses

Specific Aim 1: To compare the effect of a crowdsourced one-minute video to a social marketing one-minute video in promoting condom use among MSM and transgender male-to-female (TG) in China. This will be evaluated using data from follow-up surveys at 3 weeks and 3 months post-video.

Hypothesis 1: Crowdsourced videos are not inferior to social marketing videos to promote condom use among MSM and TG in China.

Specific Aim 2: To compare the cost of using crowdsourcing compared to social marketing methods for developing short videos focused on promoting condom use among MSM and TG individuals in China.

Hypothesis 2: A crowdsourced video is cost saving compared to a social marketing video for promoting condom use.

Specific Aim 3: To compare the effect of a crowdsourced one-minute video to a social marketing one-minute video in changing condom use self-efficacy and self-reported behaviour among MSM and TG individuals in China.

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1 Hypothesis 3: Crowdsourced videos are not inferior to social marketing videos in changing
2 condom use self-efficacy and self-reported behaviour among MSM and TG in China.

4 **METHODS**

5 *Trial design*

6 This study will be a pragmatic, non-inferiority, randomized controlled trial comparing two
7 groups – MSM who watch a crowdsourced video and MSM who watch a social marketing video.
8 Allocation to each arm will be done with a 1:1 ratio using a computer-based algorithm. The
9 study is projected to run from November 2015 to February 2016.

11 *Setting*

12 This study survey will be made available to MSM across China through a popular online portal,
13 Danlan and gay mobile dating app, Blued. Danlan.com is an online gay community that allows
14 MSM to connect with each other for relationships, events, and communication. The website is
15 maintained by a private corporation, Danlan, which also developed the for-profit app Blued.
16 Blued has become very popular among the MSM population, recently reaching 15 million
17 users[19]. User personal information is protected and secure. Studies have shown that the
18 Internet has become a popular method for MSM to find partners, with a reported 28.3-88.4% of
19 MSM using the Internet to seek sexual partners [20]. While Internet-based interventions have yet
20 to be widely dispersed in mainland China, early studies show that such e-technology-based
21 approaches would be well received[21].

1 Recruitment

2 Participants will be recruited using a banner link on a popular MSM app “Blued” (Danlan,
3 Beijing, China), as well as through announcements sent via Danlan’s social media (Weibo, a
4 microblogging platform, WeChat, a messaging platform, and QQ, a messaging platform). Blued
5 is China’s most popular social networking mobile application among MSM. Blued has 15
6 million followers with 24% (3.6 million people) daily activity rate[19]. Danlan has over 17,000
7 followers on social media platform Weibo and forwards news via WeChat and QQ to over
8 429,000 followers[22].

10 Eligibility

11 The survey is voluntary, and to be eligible, participants must state that they were born
12 biologically male, had anal sex with men at least once during their lifetime, have had condomless
13 anal/vaginal sex in the past three months, are at least 16 years of age, and able to complete an
14 online written survey in Chinese. All participants must agree to an online informed consent and
15 provide their cell mobile number. Participants who do not meet these criteria will not be allowed
16 to proceed with the survey.

18 Formative work

19 Prior to survey development, we will interview key informants specifically about conducting an
20 Internet survey among MSM in China. Survey development will be done drawing on previous
21 surveys and a review of existing literature, focusing on English and Chinese language studies.
22 The survey will be developed in both English and Chinese but conducted entirely in Chinese.
23 The Chinese version of the survey will be piloted online with 150 volunteers to gauge post-

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1 intervention condom usage rates and to estimate the necessary sample size for the non-inferiority
2 study. The survey will also be piloted with Danlan to ensure there are no problems with
3 distribution. Feedback will be solicited online regarding question wording and interpretation.
4 Pilot data will not be included in the final analysis. The purpose of this extensive formative
5 research is to ensure that the online survey is simple and easy to complete. The CONSORT-
6 Ehealth checklist for online surveys[23] will be used to ensure completeness. The online survey
7 will be created using Qualtrics Survey Software (Qualtrics, Provo, Utah) and the videos will be
8 hosted on Tencent Video (Tencent, Shenzhen, China).

10 *Interventions*

11 The development of the crowdsourcing video was publicized via open contest. We posted a
12 public call on social media platforms (Weibo, WeChat) for videos promoting condom use
13 awareness. For further promotion, we hosted in-person events at several different college
14 campuses in Guangzhou, China and worked with local community-based organizations to
15 publicize the contest. In-person events included didactic sessions, interactive feedback sessions,
16 and community-driven events. Ten judges, including community health leaders, doctors,
17 business leaders, and researchers, evaluated the videos. Each judge scored the video entries on a
18 scale of 1-10 (10 the highest score) and a single winner was identified. The winning video will
19 be included in the survey as the intervention arm of the RCT. The one-minute video depicts a
20 group of men dressed as cartoon villains attempting and failing to break down a wall, followed
21 by an image of condoms. Our team will delay public announcement of the contest winner to
22 allow time for adequate intervention implementation and comparison. The winning video will be

publicly announced 2 weeks after the intervention is evaluated using the 3-month follow-up survey.

The social marketing video was commissioned from a working group in Jinan. This one-minute video contains audio of two men about to engage in intercourse, but stopping to discuss condom use and sexual health as a symbol of love. Script of the video was written by experts in San Francisco and modified by experts and the gay community in Jinan and Qingdao. The video was shot by an advertising company based in Jinan.

Data collection

A survey will be developed using the Qualtrics survey tool. Participants will answer 150 questions on socio-demographic information, sexual behaviour, social norms, condom self-efficacy, HIV testing, and community engagement. At the end of the survey, participants will be randomly assigned to one of two intervention arms, the crowdsourcing video or social marketing video, and will view the appropriate video. Participants will not be informed of the video options upon randomization, and will not see the alternate intervention video. Participants will provide mobile telephone numbers, and will receive text message reminders three weeks after initial survey completion to complete the three-week follow-up survey. After completion of the three-week survey, participants will be compensated for the first portion of the study (about \$15.87 USD). Three months after completion of the initial survey, participants will again receive a mobile telephone reminder to complete the three-month survey. After completion participants will receive the second portion of their compensation (about \$7.93 USD).

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3 1 Participants will register for our survey using a mobile number. Following completion of data
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5 2 collection, data entries will be screened for duplicate mobile numbers, and the second entry will
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7 3 be excluded. Entries with invalid mobile numbers will also be excluded.
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12 5 A data monitoring committee will not be required as this study employs low risk behavioural
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14 6 interventions. All participants will provide consent prior to taking part in the study.
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20 8 *Measures*

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22 9 Data from survey items on socio-demographics and sexual behaviours will be collected using
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24 10 standardized survey instruments immediately before video watching, at three weeks after video
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26 11 watching, and at three months after video watching. Socio-demographic characteristics include
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28 12 participants' age, place of residence, highest level of education completed, annual income,
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30 13 marital status, sexual orientation, and sexual orientation disclosure. Behavioural variables
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32 14 include number of sex acts in the past three weeks, condomless sex with men, condomless sex
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34 15 with women, condom self-efficacy, and other secondary outcomes (See Supplemental File 1).
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41 17 **OUTCOMES**

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43 18 *Primary Outcomes*

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46 19 The primary outcome will be any condomless vaginal or anal sex (with any sex partner) among
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48 20 MSM and TG individuals following the video intervention. A participant is counted as having
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50 21 had condomless sex if they participated in any act of sexual intercourse (vaginal or anal) that has
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52 22 taken place without use of a condom. Using a post-intervention survey, participants will be asked
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54 23 with what frequency they have used condoms since watching the video: all, most, some or none
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of the time (See Supplemental File 2). The three-week follow-up survey will ask about the three weeks following the intervention, and the three-month follow-up will cover the three months following the intervention. Individuals who have not had sex in the interval will be classified as having no condomless sex.

Secondary Outcomes

- Post-intervention sex acts
- Condom use social norms
- Condom self-efficacy
- Condom use negotiation
- HIV testing and self testing
- Syphilis testing and self testing
- Incremental cost of intervention associated with respective video interventions per individual reporting increased condom use or no sex since intervention. Other cost-related data from organizations involved in making the intervention videos will be collected. Detailed information on incremental costs can be found in Table 1.

More detailed explanations of secondary outcomes can be found in Supplemental File 1.

Table 1. Incremental costs associated with social marketing and crowdsourced arms.

Phase	Financial costs	Economic costs
Contest development	<i>Inputs to be capture, can all directly be found in the project financial accounts, main challenge is to allocate across components and to allocate SESH overhead costs</i>	<i>Extra inputs not already captured by financial costs</i>
Video contest (including production)	Money paid for planning and implementation	<div>For social marketing arm:<ul style="list-style-type: none">• Personnel of CBOs/CDC (director of movie, actors, film editors)• Rental of professional video equipment (if applicable)• Building cost (office renting) for CBOs/CDC*• Equipment and software cost (if applicable) *<div>For crowdsourced arm:<ul style="list-style-type: none">• Personnel of SESH (although all volunteer)• Judging opportunity cost (volunteer)• Steering Committee planning meeting (three one-hour meetings)• Building cost (office renting)*• In-person promotion costs</div></div>
Survey start up	Money paid to launch the survey (start-up)	<ul style="list-style-type: none">• SESH personnel costs, to design and maintain the program• Equipment cost of SESH (computer and other items)*• Software (Qualtrics)*
Survey implementation and intervention	<div>Money paid to the participants (implementation)</div> <div>Money paid for the software used for follow up (implementation)</div>	<ul style="list-style-type: none">• SESH personnel costs
Testing		<ul style="list-style-type: none">• Cost for condoms (from CDC)

*The cost will be annualized and we will calculate a proportion of the cost to account for items only being used the study time frame. The key idea is that some of these phases are like capital goods, where they only need to be done once but have benefits for longer (thus requiring annualisation of costs), while the implementation phase has a life only as long as the survey is running.

Sample size calculation

Sample size for this non-inferiority trial was determined assuming an equal probability of reporting condomless sex in the crowdsourced video and social marketing video arms. Assuming a 50% probability of condomless sex in each arm, a one-sided significance level (α) of 2.5%, a non-inferiority limit of 10%, and loss to follow-up of 10%, a total sample size of 1170 individuals was required (585 in each arm) to have 90% power ($1-\beta$). The sample size was calculated using the formula [24]:

$$n = f(\alpha, \beta) \frac{[\pi_s (1 - \pi_s) + \pi_e (1 - \pi_e)]}{(\pi_s - \pi_e - d)^2}$$

where π_s and π_e are the true probabilities of reporting condomless sex in the social marketing video (standard) and crowdsourced video (experimental) intervention groups, respectively, d is the non-inferiority limit, and $f(\alpha, \beta) = [\Phi^{-1}(1-\alpha) + \Phi^{-1}(1-\beta)]^2$ where Φ denotes the cumulative distribution function of the standard normal distribution. More information on sample size calculation can be found in Table 2.

Table 2: Sample size for 90% power and one-sided 0.025 significance level

Probability of primary outcome in control group*	Probability of primary outcome in experimental group*	N evaluable per arm	Total sample size for RCT
0.50	0.50	526	1170
0.45	0.45	521	1158
0.40	0.40	505	1124
0.35	0.35	479	1066
0.30	0.30	442	984

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*Based on the pilot study, 9 of 25 participants (95% confidence interval: 18% to 57%) had condomless sex at least once in the three-week period immediately following the video intervention. According to a similar RCT we conducted in 2014, the loss to follow up rate was about 10%; adjustment for loss to follow up required $(N \text{ evaluable per arm})/(1 - 0.1)$ to be enrolled. A non-inferiority limit of 0.1 was used for all calculations.

Randomization and allocation

Participants will be randomly assigned to one of the two intervention videos using an electronic randomizer tool available through Qualtrics. Randomization will occur independently of any other data collected, with participants allocated in a 1:1 ratio to one of the two arms. Participants will not be informed of which video (crowdsourcing or social marketing) they are assigned to.

DATA ANALYSIS

Primary analysis

The primary analysis will evaluate the non-inferiority hypothesis comparing the two interventions, as well as the superiority hypothesis. The difference in proportions having condomless sex (crowdsourced - social marketing) will be computed, with a corresponding two-sided 95% Wald confidence interval. The crowdsourced intervention will be declared non-inferior to social marketing if the upper confidence limit is below 10%. If the upper confidence limit is below 0%, then the crowdsourced intervention will be declared superior to social marketing. The recruitment methods, survey instrument, and video length will be the same between in the two study arms.

Effect modification analysis

Effect modification analyses will be undertaken based on prior exposure to the condom promotion video viewed by the participant to assess whether this exposure modified the effect of video intervention arm upon the primary condom use outcome. A linear probability model will be used to evaluate effect modification by testing for an interaction between intervention and prior video watching.

Missing data plan

If the primary outcome is missing for <11% of participants, then the primary analysis will use a complete-case approach. If the primary outcome is missing for 11 to <20% of participants, then a sensitivity analysis using multiple imputation based on the PROC MI procedure in SAS (Cary, NC) will also be used. If the primary outcome is missing for $\geq 20\%$ of participants, then multiple imputation will be used in the primary analysis.

Secondary analysis

Comparison will be made between the two trial arms with respect to each of the secondary outcomes enumerated above and in Supplemental File 1. Non-inferiority comparisons will also be made between study arms for the subset of individuals who reported sex during the follow-up period (3 weeks and 3 months respectively) and causal inference methods will be employed to account for post-randomization selection bias.

ETHICS AND DISSEMINATION

Ethical review

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1 IRB approval was obtained from the Guangdong Provincial Center for Skin Diseases and STI
2 Control, University of North Carolina at Chapel Hill, and University of California San Francisco.

3
4 *Informed Consent*

5 All participants will be provided an online consent form immediately prior to survey
6 commencement. This online informed consent describes personal data to be collected, explaining
7 that data will be used for research purposes. Contact information is provided to participants to
8 address further questions. Participants will be required to sign the consent and provide a mobile
9 telephone number as agreement to proceed with the survey.

10
11 *Confidentiality*

12 Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted
13 securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured
14 Qualtrics server in the United States. The server is configured with redundant hard drive array to
15 ensure reliability. Access to the data will be password protected within the server's firewall.
16 Survey responses will be kept separately from participants' email addresses; the two files will be
17 linked with a non-descript, unique, randomly generated identifier.

18
19 Participants will provide mobile telephone numbers, which will be kept separately from data
20 containing answers to survey items. These telephone numbers will be accessible only to two
21 researchers solely for the means of sending reminders, follow-up surveys and mobile top-up
22 incentives.

23

1 Dissemination

2 The results of this study will be prepared and submitted for publication in a peer-reviewed
3 journal. Study findings will also be shared through conference abstracts and presentations,
4 workshops, and to our partnering organizations.

For peer review only

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Contributors

CW and JT conceived the study, CL, JM, TW, WT, LT ST, WZ, YQ, KM, MG, CW and JT contributed to study design. WT, ST, KM, and MG helped with statistical support and endpoints. CW, JM and TW designed data collection tools. JT, WT, CL and JM drafted and revised the manuscript. All authors contributed critical intellectual input and approved the final manuscript.

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Guangzhou, China. The funding source had no role in the design of the study and will not have any role during its execution, analyses, interpretation of data, or decision to submit results.

Competing Interests

None of the authors declare any conflicts of interest.

Ethics Approval

Ethical approval has been obtained from the ethical review boards of the Guangdong Provincial Center for Skin Diseases and STI control, the University of North Carolina at Chapel Hill, and the University of California at San Francisco.

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1 **Appendix 1. Secondary outcomes measured as part of this RCT.**

Secondary Outcome	Definition
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective video interventions (development, start-up, implementation, condom use, intervention – see Table 2 for details) per individual who reported no sex or sex with a condom during the follow-up period.
<i>Female condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with a woman divided by the total number of men who viewed the video in that arm.
<i>Male condomless sex</i>	Frequency of men, defined as number of men who reported condomless anal sex with a man divided by the total number of men who viewed the video in that arm
<i>Post-video condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with any partner immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>Frequency of sex acts</i>	Frequency of men, defined as the number of men who had decreased total number of sex acts in the three weeks following the intervention compared to the three weeks immediately preceding the intervention in that arm
<i>Condom use social norms</i>	Frequency of men, defined as number of men who report higher levels of social norms when comparing their pre-intervention and post-intervention condom use norms*
<i>Condom self-efficacy</i>	Frequency of men, defined as number of men who had an increase in self-efficacy when comparing their pre-intervention and post-intervention self-efficacy**
<i>Condom negotiation</i>	Frequency of men, defined as the number of men who attempted to convince an unwilling partner to use a condom immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>HIV testing</i>	Frequency of men, defined as the number of men who reported being tested for HIV during the interval between watching the video and following up compared to the number of men who followed up
<i>STI testing</i>	Frequency of men, defined as the number of men who reported being tested for STIs (excluding HIV) during the interval between watching the video and following up compared to the number of men who followed up

*Condom use social norms will be measured using six survey items that are each on a five point Likert scale. Increased condom use social norms will be defined as having an increase from baseline in any two of these six survey items and dichotomized accordingly. The condom use social norm outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

**Self-efficacy will be measured using seven survey items that are each on a five point Likert scale. Increased self-efficacy will be defined as having an increase from baseline in any two of

these seven survey items and dichotomized accordingly. The self-efficacy outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends.

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Supplementary File: Online Survey

Men's Heath Study (Final)

About this Study:

You are being asked to take part in a research study that will help us better understand sexual behavior and condom use among men in China. Your participation in this project will allow us to develop better interventions to promote condom use and to improve sexual health among men across China.

What's Involved?

If you participate in this study, you will be asked to complete an online questionnaire and a subset of participants will be asked watch a one minute video. A subset of participants will also be asked to complete up to two additional follow-up questionnaires. The questionnaires will ask you to provide sociodemographic information and information about your sexual behaviors. In order to ensure that your privacy is protected, all of your online responses will be encrypted and securely transferred to our data servers.

Upon completion of this study and a 3-week follow up survey, **you will receive 100 RMB credit** to your mobile phone. Eligible participants who also complete the follow-up questionnaires can **receive up to 150 RMB credit** to their mobile phone.

If you have any questions about the research or your participation in the study, feel free to contact

A. Basic Information (Eligibility Survey) (Q1-5)

A1. Were you born biologically male or female?

- ☐ Male
- ☐ Female (Not eligible to take this survey – Skip to End of Survey)

A2. What is your date of birth?

- ☐ dd.mm.yyy (*Calendar input*) (Not eligible to take this survey if year is greater than Launch day + 1999 or < 16 y/o – Skip to End of Survey)

A3. In your lifetime have you ever had anal sex with another man?

- ☐ Yes
- ☐ No (Not eligible to take this survey – Skip to End of Survey)

A4. In the last three months, did you have any anal and /or vaginal sex without a condom with any sex partner?

- ☐ Yes
- ☐ No (Not eligible to take this survey – Skip to End of Survey)

A5. Will you agree to provide us your Chinese mobile phone number? (Answering this question is required to participate in the survey and to receive your reward for participating. We will not distribute your number to any agency or individual. Thank you for your cooperation.)

- ☐ Agree
- ☐ Decline (Not eligible to take this survey – Skip to End of Survey)

Which carrier are you using right now?

- ☐ China Mobile
- ☐ China Unicom
- ☐ China Telecom

Online Consent Form

Title of Study: Men's Health Study

IRB study number: 15-1522

Principal Investigator: Dr. Joseph Tucker

Dr. Joseph D. Tucker, UNC Project-China, Number 2 Lujing Road, Guangzhou, China,

What are some general things you should know about research studies? You are being asked to participate in a research study. To join this research study is voluntary. You may for whatever reason refuse to join or withdraw your consent to be in the study at any time, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about joining this research study.

What is the purpose of this study? Innovative approaches to condom promotion campaigns are urgently needed. The current strategy to developing many of these campaigns is to repackage old ideas rather than create new ones. The purpose of this research study is to understand how crowdsourcing can be used to leverage both the high Internet use and willingness to participate in online forums of young MSM (men who have sex with men) to transform the design and implementation of condom promotion campaigns. Crowdsourcing is the process of taking a task traditionally performed by a single individual or organization, and instead outsourcing the task to a large group to complete in the form of a contest or open call, often enabled by the Internet.

How many people will take part in this study? If you decide to participate in this research study, you will be one of approximately 1170 individuals recruited across China.

What will happen if you take part in the study? Your part in this research study will last approximately 20 minutes. During this study, you will be asked to first complete an online questionnaire, and depending on your responses, you may be asked to watch a one minute video afterwards. Upon completion of this initial questionnaire, you will be asked to input your mobile phone number as a means for the research team to prevent duplicate responses, to send reminders, and to distribute rewards for participation. Additionally, some participant will be asked to complete up to two additional follow-up questionnaires after three-week and twelve-week's times. If you do not respond to the initial follow-up request, you will receive a message reminder. To do this, we will also ask you to provide your QQ number. The study questionnaires will ask you to provide sociodemographic information as well as details about your sexual health and sexual activity.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. The proposed study will make important contributions to the sexual health literature. The field of condom interventions among young MSM in resource-limited settings is in its infancy. The results from this study will help the research team develop a MSM targeted, community-level intervention that will be fielded and evaluated in the Chinese setting. Your participation will also help design better interventions to promote condom use among MSM in China.

What are the possible risks or discomforts involved from being in this study? We will ask participants to provide sensitive information about their sexual partners and practices. Participants may feel embarrassed, anxious, or otherwise distressed by providing information of such a personal nature. Participants may also experience fatigue in response to the proposed evaluations (e.g. from looking at a computer screen). Some participants might fear that refusal to participate in the study might jeopardize their sexual orientation identity – especially if the participant has not come “out” to him or herself and/or the community). Other participants may fear that the research staff might “out” them or discuss their private details with other (MSM and non-MSM) members in their community. While the risk is minimal, there is still the possibility for breaches of confidentiality.

How will your privacy be protected? All data are directly entered into computers as participants complete the questionnaires. Programs to ensure accuracy, completeness, and internal consistency are automated. 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 providers 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. For example, if a hacker could crack a standard 40-bit SSL session in a day, it is estimated that it would take well beyond a trillion years to accomplish the same thing against a 128-bit SSL session. A dedicated server, which eliminates security issues involved with shared hosting environments where hundreds of websites and users reside on one shared web server as well as ensuring both physical and network security, will be used to house the data. 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. Survey responses will be kept separately from participants’ email addresses; the two files will be linked with a non-descript, unique, randomly generated identifier. Only the PI and a designated senior staff member will have the password to access to the “key” that links the nondescript identifier to personally identifiable information. Cookies will not be used in any way to track participant activity.

What if you want to stop before your part in the study is complete? If at any point in the study you do not want to answer a question or no longer want to participate, you can stop and withdraw from this study without penalty. The investigators also have the right to stop your participation if you have an unexpected reaction, have failed to follow instructions, etc.

Will you receive anything for being in this study? Will it cost anything? Participants who are asked to watch a one-minute video will have the opportunity to earn up to 150 RMB credit on their mobile phone – this credit will be distributed as two separate 100 and 50 RMB mobile phone recharges. Participants will receive a 100 RMB phone recharge upon completion of the first questionnaire and 3-week follow up survey, and 50 RMB for the 3-month follow up survey if that they are eligible for. There are no costs associated with participating in this research study.

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What if you have questions about this study? If you have any questions, complaints, or concerns about the research or your participation in the study, feel free to contact

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns, or if you would like to obtain information or offer input, please contact the UNC Institutional Review Board at 1-919-966-3113 or by email to IRB_subjects@unc.edu. You may also contact the Guangdong Provincial Skin Diseases & STI Control Center IRB at 020 – 83027652 or by email to sesh@seshglobal.org.

If you understand and agree to participate in this research study, please select “Agree” from the options below. We thank you for your participation!

- ☐ Agree
- ☐ Decline (Skip to End of Survey)

Survey Access (Q6-7)

6. How did you find out about our research study?

- ☐ Blued's banner ad
- ☐ Danlan webpage banner ad (www.danlan.org)
- ☐ Weibo banner ad
- ☐ Weixin banner ad
- ☐ Friend referral
- ☐ SESH referred me through QQ
- ☐ SESH referred me through SMS

7. What device are you using to access our research study?

- ☐ Desktop or laptop computer
- ☐ Mobile phone
- ☐ Tablet device

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A. Sociodemographics (Q8-15)
The next set of questions will ask you to provide some information about yourself.

A6. What province or province-level city do you currently live in?

- ☐ Beijing
- ☐ Tianjin
- ☐ Hebei
- ☐ Shanxi
- ☐ Inner Mongolia
- ☐ Liaoning
- ☐ Jilin
- ☐ Heilong Jiang
- ☐ Shanghai
- ☐ Jiangsu
- ☐ Zhejiang
- ☐ Anhui
- ☐ Fujian
- ☐ Jiangxi
- ☐ Shandong
- ☐ Henan
- ☐ Hubei
- ☐ Hunan
- ☐ Guangdong
- ☐ Guangxi
- ☐ Hainan
- ☐ Chongqing
- ☐ Sichuan
- ☐ Guizhou
- ☐ Yun An
- ☐ Xizang (Tibet)
- ☐ Shaanxi
- ☐ Gansu
- ☐ Qinghai
- ☐ Ningxia
- ☐ Xinjiang
- ☐ Hong Kong
- ☐ Aomen

A7. What city do you currently live in? _____ (Text input) (Do not display if answered
北京, 上海, 重庆, 天津, 香港, 澳门 to A6)

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☐ Not married

☐ Engaged or Married

☐ Separated or Divorced

☐ Widowed

A9. Are you currently enrolled as either a full-time or part-time student?

☐ Yes

☐ No

A10. What is the highest level of education that you have **completed**?

☐ High school or below (including Zhongzhuan)

☐ Some college (Dazhuan)

☐ College/Bachelors

☐ Masters/PhD

A11. What is your total individual **monthly** income from all sources?

☐ Less than 1500 RMB

☐ Between 1500 and 3000 RMB

☐ Between 3001 and 5000 RMB

☐ Between 5001 and 8000 RMB

☐ Greater than 8000 RMB

A12. What do you primarily consider yourself to be?

☐ Gay

☐ Bisexual

☐ Straight/Heterosexual

☐ Transgender

☐ Unsure/Other

A13. Have you spoken with a physician or other health professional (e.g. HIV testing counselor, pharmacist) about your sexuality or sexual history with men?

☐ Yes

☐ No

B. MSM Basic Situation (Q16-38)

The next set of questions will ask you about your sexual behaviors with other men.

1
2
3 1 *A “primary partner” is someone who you have sex with regularly and/or have an emotional*
4 2 *commitment to. A “casual partner” is someone who you have sex with and do not have an*
5 3 *emotional commitment to.*
6 4
7 5
8 6
9 6 B1. How old were you during your first insertive sexual encounter?
10 7
11 7 _____years old (*Number input*)
12 8
13 9 B2. Was your first insertive sexual encounter with a male or female?
14 10 ☐ Male (Skip to B4)
15 11 ☐ Female
16 12 ☐ Other
17 13
18 14 B3. How old were you when you had sex with another man for the first time?
19 15
20 15 _____years old (*Number input*)
21 16
22 17 B4. Were you insertive (1) or receptive (0) during your first sexual encounter with another man?
23 18 ☐ Insertive (1)
24 19 ☐ Receptive (0)
25 20 ☐ Both insertive (1) and receptive (0)
26 21
27 22 B5. Did you use a condom during your first sexual encounter with another man?
28 23 ☐ Yes
29 24 ☐ No
30 25
31 26 B6. In general, where do you usually go to meet your sex partners (Select all that apply)?
32 27 ☐ Pub, disco, tearoom, or club
33 28 ☐ Spa or bath house, sauna, foot or body massage parlor
34 29 ☐ Park, public restroom, public lawn
35 30 ☐ Internet
36 31 ☐ Other
37 32
38 33 B7. In the last three months, approximately how many male sex partners have you had?
39 34
40 34 _____male sex partners (*Number input*) (If answer <1, skip to end of section)
41 35
42 36
43 36 B8. Of the men you have had sex with in the last three months, would you consider one of them
44 37 to be a primary sex partner?
45
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1 ☐ Yes
2 ☐ No (Skip to B16)
3
4 B9. In the last three months, approximately how many times per week did you have anal sex
5 with your primary partner?
6 _____ sex encounters per week
7

8 B10. How long have you and your primary sex partner been in a relationship?

- 9 ☐ Less than three months
10 ☐ Between three and six months
11 ☐ Between six and twelve months
12 ☐ Between one and two years
13 ☐ More than two years
14

15 B11. In the last three months, when you had anal sex with your primary partner, what role did
16 you assume?

- 17 ☐ Always insertive (always 1) (Do not display B15)
18 ☐ Mostly insertive (mostly 1)
19 ☐ Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)
20 ☐ Mostly receptive (mostly 0)
21 ☐ Always receptive (always 0) (Do not display B14)
22 ☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B14 and B15)
23

24 B12. In the last three months, when you had sex with your primary partner, how frequently did
25 you or your partner use condoms? (Do not display if "No anal sex, only oral sex" to B11)

- 26 ☐ Never used (Skip to B14)
27 ☐ Sometimes used
28 ☐ Mostly used
29 ☐ Always used (Do not display B14, B15)
30

31 B13. In the last three months, when you had sex with your primary partner did a condom ever
32 slip off, tear, or otherwise fail?

- 33 ☐ Yes
34 ☐ No
35

36 B14. When you are insertive, the reason(s) you do not use a condom with your primary partner
37 include (select all that apply):

- 38 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
39 ☐ Neither of us has a condom

- For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

- 1 ☐ Mostly receptive (mostly 0)
- 2 ☐ Always receptive (always 0) (Do not display B21)
- 3 ☐ No anal sex, only oral sex (Neither 1 nor 0) (Do not display B21 and B22)

4

5 B19. In the last three months, when you had sex with a casual partner, how frequently did you or

6 your partner use condoms? (Do not display if B17 is "0" or B18 is "无肛交, 只有口交 (既不

7 是 1 也不是 0)")

- 8 ☐ Never used (Skip to B21)
- 9 ☐ Sometimes used
- 10 ☐ Mostly used
- 11 ☐ Always used (Do not display B21, B22)

12

13 B20. In the last three months, when you had sex with a casual partner did a condom ever slip off,

14 tear, or otherwise fail? (Do not display if answer to B19 is "Never used")

- 15 ☐ Yes
- 16 ☐ No

17

18 B21. When you are insertive, the reason(s) you do not use a condom with a casual partner

19 include (select all that apply):

- 20 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
- 21 ☐ Neither of us has a condom
- 22 ☐ My partner does not want me to use one
- 23 ☐ The condom is of poor quality
- 24 ☐ I do not have time to use one
- 25 ☐ I am drunk or high
- 26 ☐ I am HIV negative or I do not believe I am infected with HIV
- 27 ☐ My partner is HIV negative or I do not believe he is infected with HIV
- 28 ☐ Other

29

30 B22. When you are receptive, the reason(s) your casual partner does not use a condom with you

31 include (select all that apply):

- 32 ☐ He does not want to use one (e.g. personal preference, uncomfortable)
- 33 ☐ Neither of us has a condom
- 34 ☐ I do not want him to use one
- 35 ☐ The condom is of poor quality
- 36 ☐ He does not have time to use one
- 37 ☐ He is drunk or high

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- ☐ He is HIV negative or he does not believe he is infected with HIV

☐ I am HIV negative or he does not believe I am infected with HIV

☐ Other
- B23. In the last month, did you have any anal sex without a condom with any male partner? (Do not display if answer “1” to B7 and “Always” to B19)
- ☐ Yes

☐ No

16 10 **C. Heterosexual Sex Situation (Q39-54)**

17 11 *The next set of questions will ask about your sexual behaviors with women.*

18 12
19 13 *A “primary female partner” is someone who you have sex with regularly, have an emotional commitment to, and/or have married or engaged to be married. A “casual female partner” is someone who you have had sex with but do not have an emotional commitment to.*

20 14
21 15
22 16
23 17 C1. Have you ever had vaginal, anal, and/or oral sex with a female partner?

- 24 18 ☐ Yes
- 25 19 ☐ No (Skip to End of Section)

26 20
27 21 C2. In the last six months, did you have any vaginal and/or anal sex with a female partner?

- 28 22 ☐ Yes
- 29 23 ☐ No (Skip to End of Section)

30 24
31 25 C3. In the last six months, approximately how many female sex partners have you had?
32 26 _____ female sex partners (*Number input*) (If answer <1 then skip to End of Section)

33 27
34 28 C4. In the last six months, have you had a primary female sex partner?

- 35 29 ☐ Yes
- 36 30 ☐ No (Skip to C9)

37 31
38 32 C5. In the last six months, approximately how many times per week did you have vaginal and/or
39 33 anal sex with your primary female partner?
40 34 _____ sex encounters per week

41 35
42 36 C6. In the last six months, when you had sex with your primary female partner, how frequently
43 37 did you or your partner use condoms?

- 44 38 ☐ Never used (Skip to C8)
- 45 39 ☐ Sometimes used

- 1 ☐ Mostly used
- 2 ☐ Always used (Do not display C8)
- 3
- 4 C7. In the last six months, when you had sex with your primary female partner did a condom
- 5 ever slip off, tear, or otherwise fail?
- 6 ☐ Yes
- 7 ☐ No
- 8
- 9 C8. The reason(s) you do not use a condom with your primary female partner include (select all
- 10 that apply):
- 11 ☐ I do not want to use one (e.g. personal preference, uncomfortable)
- 12 ☐ Neither of us has a condom
- 13 ☐ My partner does not want me to use one
- 14 ☐ The condom is of poor quality
- 15 ☐ I do not have time to use one
- 16 ☐ I believe that my partner is loyal to me
- 17 ☐ I am loyal to my partner
- 18 ☐ I am drunk or high
- 19 ☐ I am HIV negative or I do not believe I am infected with HIV
- 20 ☐ My partner is HIV negative or I do not believe she is infected with HIV
- 21 ☐ Other
- 22
- 23 C9. In the last six months, have you had sex with another woman who was not your primary
- 24 partner?
- 25 ☐ Yes
- 26 ☐ No (Skip to End of Section if “Always” to C6; otherwise Skip to C14 – Should not answer
- 27 “No” to C4 and C9)
- 28
- 29 C10. In the last six months, approximately how many times per week did you have vaginal
- 30 and/or anal sex (all casual sex partners combined)?
- 31 _____ sex encounters per week
- 32
- 33 C11. In the last six months, when you had sex with a casual female partner, how frequently did
- 34 you or your partner use condoms?
- 35 ☐ Never used (Skip to C13)
- 36 ☐ Sometimes used
- 37 ☐ Mostly used
- 38 ☐ Always used (Do not display C13; Skip to End of Section if “Always” to C6)

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- C12. In the last six months, when you had sex with a casual female partner did a condom ever slip off, tear, or otherwise fail?

☐ Yes

☐ No

C13. The reason(s) you do not use a condom with a casual female partner include (select all that apply):

☐ I do not want to use one (e.g. personal preference, uncomfortable)

☐ Neither of us has a condom

☐ My partner does not want me to use one

☐ The condom is of poor quality

☐ I do not have time to use one

☐ I am drunk or high

☐ I am HIV negative or I do not believe I am infected with HIV

☐ My partner is HIV negative or I do not believe she is infected with HIV

☐ Other

C14. In the last month, did you have sex without a condom with any female partner? (Do not display if answer “1” to B7 and “Always” to B19)

☐ Yes

☐ No

D. Sexual Behavior (Q55-63)

The next set of questions will ask about any “risky” sexual behaviors that you may or may not have engaged in with other men and/or women.

D1. In the last three months, did you ever have sex while you were drunk (from drinking alcohol)?

☐ Yes

☐ No

D2. In the last three months, was you partner ever drunk (from drinking alcohol) while you had sex?

- 1 ☐ Yes
- 2 ☐ No (Skip to D4 if “No” for D1 and D2)
- 3
- 4 D3. In the last three months, how often did you have sex while you and/or your partner was
- 5 drunk?
- 6 ☐ Never
- 7 ☐ Rarely
- 8 ☐ Occasionally/Sometimes
- 9 ☐ Very often
- 10 ☐ Always
- 11
- 12 D4. In the last twelve months, did you ever use “meth” before or during sex?
- 13 ☐ Yes
- 14 ☐ No
- 15
- 16 D5. In the last twelve months, did you ever participate in group sex with other men?
- 17 ☐ Yes (Display D6)
- 18 ☐ No
- 19
- 20 D6. During your most recent group sex experience, did you have any anal sex without a
- 21 condom?
- 22 ☐ Yes
- 23 ☐ No
- 24
- 25 D7. In the last twelve months, were you ever paid (with money or gifts) to have sex?
- 26 ☐ Yes
- 27 ☐ No (Skip to D9)
- 28
- 29 D8. In the last twelve months, has your main source of income come from having sex with
- 30 customers?
- 31 ☐ Yes
- 32 ☐ No
- 33
- 34 D9. In the last twelve months, have you ever paid (with money or gifts) a man to have sex?
- 35 ☐ Yes
- 36 ☐ No
- 37

E. Sex Tourism (Q64-79)

The next set of questions will ask about leaving your city and/or China to purchase sex.

E1. Have you ever purchased sex (with money or gifts) while traveling outside of your city of residence?

- ☐ Yes
- ☐ No (If “No” skip to End of block)

E2. Have you ever traveled outside of your city of residence with the primary purpose of purchasing sex?

- ☐ Yes
- ☐ No

E3. When you traveled to purchase sex, did you travel within China or leave the country?

- ☐ Within China (Display E4a)
- ☐ Outside China (Display E4b)
- ☐ Both (Display E4a and E4b)

E4a. Which city/cities in China did you travel to when you purchased sex? _____ (Text Input)

E4b. Which country/countries and cities did you travel to when you purchased sex? _____ (Text Input)

E5. How did you arrive at your destination?

- ☐ Car
- ☐ Train
- ☐ Airplane
- ☐ Ship

E6. Why did you decide to purchase sex while traveling?

- ☐ I was afraid of seeing someone I know in my hometown
- ☐ Sex is less expensive at the location I traveled to
- ☐ There was less likelihood that I would have to use a condom if I purchase sex
- ☐ I am unable to purchase sex in my hometown
- ☐ I wanted to try sexual intercourse with another gender
- ☐ I was drunk or using drugs, I did not plan it

E7. When you purchased sex while outside your city of residence, who did you purchase sex from (select all that apply)?

- 1 ☐ Men
2 ☐ Women
3 ☐ Transgender

4
5 E8a. When you purchased sex while outside your city of residence, have you ever had any
6 vaginal sex without a condom? (Display if “Women” or “TG” for E7)
7 ☐ Yes (Display E17)
8 ☐ No

9
10 E8b. When you purchased sex while outside your city of residence, have you ever had any anal
11 sex without a condom?
12 ☐ Yes (Display E17)
13 ☐ No

14
15
16 E9. Once you were at your travel destination (during your most recent trip abroad), how did you
17 find someone to purchase sex from (select all that apply)?
18 ☐ Mobile app portal
19 ☐ Online (not an app) portal
20 ☐ In-person proposition
21 ☐ Local establishment

22
23 E10. During your most recent experience when you purchased sex while abroad, approximately
24 how many sex partners did you purchase? (Please enter “0” partners if no partners of the
25 following type)

26 _____ male sex partners (*Number input*)
27 _____ female sex partners (*Number input*)
28 _____ transgender sex partners (*Number input*)

29
30 E11. During your most recent experience when you purchased sex while traveling,
31 approximately how much did you pay (RMB) for your last sex encounter?
32 _____ (*Text Input*)

33
34 E12. During your most recent experience when you purchased sex while traveling, of what
35 nationality was your last partner?
36 _____ (*Text Input*)

E13. During your most recent experience when you purchased sex while traveling, the reason(s) you did not use a condom include (select all that apply):

- ☐ I did not want to use one (e.g. personal preference, uncomfortable)
- ☐ I did not want my partner to use one
- ☐ Neither of us had a condom
- ☐ My partner did not want to use one (e.g. personal preference, uncomfortable)
- ☐ My partner did not want me to use one
- ☐ The condom was of poor quality
- ☐ I did not have time to use one
- ☐ My partner did not have time to use one
- ☐ I was drunk or high
- ☐ My partner was drunk or high
- ☐ I am HIV negative or I do not believe I am infected with HIV
- ☐ My partner was HIV negative or I do not believe my partner was infected with HIV

E14. How strongly do you agree with the following statement: During my most recent experience purchasing sex while traveling, I behaved with less caution than I normally would while at home

- ☐ Strongly yes
- ☐ Yes
- ☐ The same
- ☐ No
- ☐ Strongly No

E15. Did you travel alone or with others?

- ☐ Alone
- ☐ With others

E16. During your most recent experience when you purchased sex while traveling, did you ask your partner about his/her HIV status before having sex?

- ☐ Yes
- ☐ No

F. Condom Behavior (Q80-96)

The next set of questions will ask about your practices and attitudes in regards to condom use.

F1. In the last three months, how often did you carry a condom with you when there was the possibility you may have sex later?

1 ○ Always

2 ○ Sometimes

3 ○ Hardly ever

4 ○ Never

5
6 F2. If you needed a condom, where is the first place you would go to find one?

7 ○ Pharmacy or drugstore

8 ○ Supermarket

9 ○ Health clinic

10 ○ Community event

11 ○ Restroom vending machine

12 ○ Friend

13 ○ Partner

14 ○ Other

15
16 F3. If I had sex and told my friends that I did not use a condom, they would be angry or
17 disappointed.

18 ○ Strongly agree

19 ○ Agree

20 ○ Neutral

21 ○ Disagree

22 ○ Strongly disagree

23
24 F4. My friends talk a lot about "safer" sex.

25 ○ Strongly agree

26 ○ Agree

27 ○ Neutral

28 ○ Disagree

29 ○ Strongly disagree

30
31 F5. My friends and I encourage each other before dates to practice "safer" sex.

32 ○ Strongly agree

33 ○ Agree

34 ○ Neutral

35 ○ Disagree

36 ○ Strongly disagree

37
38 F6. If I thought that one of my friends had sex on a date, I would ask them if they used a
39 condom.

40 ○ Strongly agree

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- 1

☐ Agree
- 2

☐ Neutral
- 3

☐ Disagree
- 4

☐ Strongly disagree
- 5
- 6

F7. If a friend knew that I might have sex on a date, he/she would ask me if I was carrying a condom.
- 7
- 8

☐ Strongly agree
- 9

☐ Agree
- 10

☐ Neutral
- 11

☐ Disagree
- 12

☐ Strongly disagree
- 13
- 14

F8. When I think that one of my friends might have sex on a date, I would ask him/her if he/she was carrying a condom.
- 15
- 16

☐ Strongly agree
- 17

☐ Agree
- 18

☐ Neutral
- 19

☐ Disagree
- 20

☐ Strongly disagree
- 21
- 22

F9. If I might have sex on a date and I do not have a condom, I would make an effort to go out of my way and get one.
- 23
- 24

☐ Strongly agree
- 25

☐ Agree
- 26

☐ Neutral
- 27

☐ Disagree
- 28

☐ Strongly disagree
- 29
- 30

F10. I would feel comfortable discussing condom use with a potential partner before we engaged in sex.
- 31
- 32

☐ Strongly agree
- 33

☐ Agree
- 34

☐ Neutral
- 35

☐ Disagree
- 36

☐ Strongly disagree
- 37
- 38

F11. I would feel comfortable letting a primary partner know that I want to have sex with a condom.
- 39
- 40

☐ Strongly agree

- 1 ○ Agree
 2 ○ Neutral
 3 ○ Disagree
 4 ○ Strongly disagree
 5
- 6 F12. I would feel comfortable letting a casual partner know that I want to have sex with a
 7 condom.
 8 ○ Strongly agree
 9 ○ Agree
 10 ○ Neutral
 11 ○ Disagree
 12 ○ Strongly disagree
 13
- 14 F13. I feel confident that I could refuse to have sex with a partner who did not want you to use a
 15 condom.
 16 ○ Strongly agree
 17 ○ Agree
 18 ○ Neutral
 19 ○ Disagree
 20 ○ Strongly disagree
 21
- 22 F14. I feel confident in my ability to incorporate putting a condom on myself or my partner into
 23 foreplay.
 24 ○ Strongly agree
 25 ○ Agree
 26 ○ Neutral
 27 ○ Disagree
 28 ○ Strongly disagree
 29
- 30 F15. I feel confident that I could use a condom with a partner without "breaking the mood."
 31 ○ Strongly agree
 32 ○ Agree
 33 ○ Neutral
 34 ○ Disagree
 35 ○ Strongly disagree
 36
- 37 F16. In the last three months, did you ever **try** to convince a partner who did not want to use a
 38 condom to use one before having sex?
 39 ○ Yes, and I was successful
 40 ○ Yes, but I was unsuccessful
 41 ○ No
 42

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5 2 F17. In the last three months, did your partner every **try** to convince you to use a condom when
6 3 you did not want to use one before having sex?
7 4 ☐ Yes, and he was successful
8 5 ☐ Yes, but he was unsuccessful
9 6 ☐ No
10 7
11 8
12 9

13
14
15 9 **G. HIV/STI Testing (Q97-132)**

16
17 10 *The next set of questions will ask about your HIV and STI testing and results. Self-testing refers*
18 11 *to you administering the test yourself and interpreting results.*
19 12

- 20
21 13 G1. Have you ever been tested for HIV?
22 14 ☐ Yes
23 15 ☐ No (Skip to G25)
24 16
25 17 G2. Have you ever given or received an HIV self-test?
26 18 ☐ Yes
27 19 ☐ No
28 20
29 21 G3. Have you ever self-tested for HIV?
30 22 ☐ Yes
31 23 ☐ No (Skip to G20) (Do not show G35)
32 24
33 25 G4. Did someone else force you to take an HIV self-test?
34 26 ☐ Yes
35 27 ☐ No
36 28
37 29 G5. Who was with you when you self-tested? (Can select multiple)
38 30 ☐ No one, I was alone
39 31 ☐ Partner
40 32 ☐ Friend
41 33
42 34 G6. Was your HIV self-test the first time you ever tested for HIV?
43 35 ☐ Yes
44 36 ☐ No
45 37
46 38 G7. What happened to your HIV testing frequency after you first used a self-test?
47
48
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- 1 ☐ Increased
2 ☐ Decreased
3 ☐ No change

4
5 G8. Have you ever received a positive result with HIV self-testing?

- 6 ☐ Yes
7 ☐ No (Skip to G11)

8
9
10 G9. Has using an HIV self-test caused you subsequent suicidal feelings?

- 11 ☐ Yes
12 ☐ No

13
14 G10. Has using an HIV self-test led to a violent confrontation (physically hitting)?

- 15 ☐ Yes
16 ☐ No

17
18 *The next set of 4 questions will ask you to recall experiences specific to self-testing.*

19
20 G11. Has using an HIV self-test has increased your desire to seek follow-up care, as opposed to
21 other forms of HIV testing?

- 22 ☐ Yes
23 ☐ No

24
25 G12. Self-testing for HIV gives me a sense of empowerment by allowing me to choose when I
26 test.

- 27 ☐ Strongly Agree
28 ☐ Agree
29 ☐ Neutral
30 ☐ Disagree
31 ☐ Strongly Disagree

32
33 G13. Self-testing for HIV gives me a sense of empowerment by allowing me to choose where I
34 test.

- 35 ☐ Strongly Agree
36 ☐ Agree
37 ☐ Neutral
38 ☐ Disagree
39 ☐ Strongly Disagree

☐ Strongly Disagree

☐ No

☐ No

- in-person

○ friend

○ Blood

☐ Monthly

1 G21. What was the result of your most recent HIV test?

- 2 ☐ HIV positive/infected (Display G23)
3 ☐ HIV negative/uninfected
4 ☐ I never got my test results (Skip to G25)

6 G22. Did you notify your primary male sex partner about your most recent HIV test result?

- 7 ☐ Yes
8 ☐ No
9 ☐ I do not have a regular partner (Do not display G25)

11 G23. Have you ever taken anti-retroviral therapy (ART) for your HIV infection?

- 12 ☐ Yes – I have taken, and I am currently taking
13 ☐ Yes – I have taken, but I am currently not taking (Display G24)
14 ☐ No – I have never taken

16 G24. Why did you stop taking ART? (Select all that apply)

- 17 ☐ It was too expensive
18 ☐ I didn't like the side effects
19 ☐ I didn't feel that it was working
20 ☐ I thought it was cumbersome (too much time, forgot to take, etc.)
21 ☐ Stigma

23 G25. Has your primary male sex partner ever been tested for HIV? (Do not display if no to B8)

- 24 ☐ Yes
25 ☐ No (Skip to G27)

27 G26. What was the result of your primary male sex partner's most recent HIV test?

- 28 ☐ HIV positive/infected
29 ☐ HIV negative/uninfected
30 ☐ Never got test results
31 ☐ I don't know

33 G27. Have you ever had a male sex partner who tested HIV positive?

- 34 ☐ Yes
35 ☐ No (Skip to G30)
36 ☐ I don't know (Skip to G30)

38 G28. Did you ever have any anal sex without a condom with a HIV positive partner?

- ☐ Condom distribution
- ☐ Lubricant distribution
- ☐ Peer Education
- ☐ STD Diagnosis or Treatment
- ☐ HIV counseling or Testing
- ☐ AIDS/STD Materials (pamphlets, etc.)

I. Community Engagement (Q133-143)

The next set of questions will ask you about your experiences with activities in your community promoting sexual health.

I1. In the last three weeks, have you viewed any videos promoting condom use among MSM?

- ☐ Yes
- ☐ No

I2. In the last three weeks, have you viewed any videos promoting HIV testing among MSM?

- ☐ Yes
- ☐ No

I3. Are you aware of any ongoing community events promoting sexual health among MSM?

- ☐ Yes
- ☐ No

I4. Have you ever helped organize a testing and/or awareness campaign (e.g. HIV, condom use, etc.) that promoted sexual health among MSM?

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☐ Yes
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☐ No
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I5. Have you ever volunteered at a health clinic or other location that provided sexual health
- 5

services among MSM?
- 6

☐ Yes
- 7

☐ No
- 8
- 9

I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually
- 10

transmitted disease?
- 11

☐ Yes
- 12

☐ No
- 13
- 14

I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV
- 15

and/or another sexually transmitted disease?
- 16

☐ Yes
- 17

☐ No
- 18
- 19

I8. How important to you is community engagement and participation in developing sexual
- 20

health campaigns (for your own community)?
- 21

☐ Very important
- 22

☐ Important
- 23

☐ Neither important or not important

☐ Slightly important

☐ Not important

I9. Have you ever participated in online forums or discussions on social media (ie. Weixin, Weibo, Twitter, or other on-line communities) about about sexual health, condom use, or HIV/STD testing or related services?

☐ Yes

☐ No

I10. Do you have a Weibo account?

☐ Yes (Display I11)

☐ No

I11. How many Weibo followers do you have?

☐ Less than 100

☐ 101-500

☐ 501-1000

☐ 1001-1500

☐ 1501-2000

☐ More than 2001

Video 1: Crowdsourcing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

Video 2: Social Marketing

We would now like you to watch a short-one minute video. Please make sure to view the entire video before closing the window. The video may take up to a minute to load, thank you for your patience.

End of Survey

Please confirm your mobile phone number at this time to receive our reminder of the follow-up survey and reward. Please notice that only after you finish the 3 week follow up could you get the 100 top up reward.

☐ Mobile Phone #s: _____ (Text Entry) (must be 11 digits)

Follow-up Contact (Q144-145)

FUC1. Thank you for taking the time to complete our survey! Based on your responses to our questionnaire, we request that you to complete a follow-up survey in three weeks' time. Upon completion of this survey, you will receive an additional 50 RMB mobile phone recharge! When the time comes, we would like to send you a reminder to complete the survey via QQ. Will you agree to provide us your QQ number? If you agree, you will be contacted by the following user:

Number: 2663701478

Name: 赛思研究团队

- ☐ Agree (Display FUC2)
☐ Disagree

FUC2. Please input your QQ number:

☐ QQ number: _____

Referral (Q146)

R1. If you think any of your male friends would be interested in participating in our research survey, please share our study with them! Alternatively, you can provide us with either their mobile phone or QQ number, and we will send them a link to our survey. (Please enter as many unique numbers as you are willing in the spaces provided.)

If you provide a QQ number for referral, please notify your friend(s) that they will be contacted by 赛思研究团队 (#: 2663701478).

If you provide a mobile phone number for referral, please notify your friend(s) that they will be contacted by 18613067997.

- ☐ Mobile Phone #s: _____
☐ QQ numbers: _____



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<u>1</u>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<u>3</u>
	2b	All items from the World Health Organization Trial Registration Data Set	<u>1,14-15</u>
Protocol version	3	Date and version identifier	<u>1</u>
Funding	4	Sources and types of financial, material, and other support	<u>14</u>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<u>1,14</u>
	5b	Name and contact information for the trial sponsor	<u>14</u>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<u>15</u>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>N/A</u>

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Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12

Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations 10

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 7

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions 11

Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned 11

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions 11

Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A

Methods: Data collection, management, and analysis

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol 10

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols 9

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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
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12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
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16	Methods: Monitoring			
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18	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
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23		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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26	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
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29	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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33	Ethics and dissemination			
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35	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12
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38	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12
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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	23

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.