# 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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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
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
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, the University of North Carolina at Chapel Hill, and the University of California at San Francisco. 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 study protocol was prospectively registered
- This study will be a pragmatic, non-inferiority, randomised controlled trial
- Participants will be self-selecting
INTRODUCTION

Male Sexual Health

Male condoms have long been recognized as an effective method for reducing the risk of HIV and other sexually transmitted diseases (STDs)\(^1\,^2\), but men who have sex with men (MSM) infrequently use condoms in China\(^3\,^6\). The resulting high incidence of HIV and STDs among MSM suggests the need for novel health promotion campaigns. One systematic review\(^7\) and one literature review among MSM\(^8\) demonstrate that social marketing campaigns are effective in promoting condom use, but the persistence of these behavioural changes over time is unclear.

We propose that crowdsourcing may substantially improve on existing methods for developing condom promotion campaigns.

Crowdsourcing

Crowdsourcing is the process of giving individual tasks to a large group, often involving open contests and enabled through multisectoral partnerships. While the process originated in the private sector\(^9\), intended to aid research, development and dissemination, it has since been widely adopted. In 2010, the Executive Office of the President of the United States urged federal agencies to utilize crowdsourcing as a method to develop innovative approaches to governmental initiatives\(^10\). A crowdsourcing method differs from a social marketing method in several ways\(^11\).

Crowdsourcing is a bottom-up approach, utilizing the community for idea generation through implementation rather than relying on the expertise of public health experts. This ensures a higher degree of community engagement than approaches utilizing social marketing do, which tends to be a top-down approach. Crowdsourcing promotes innovation because it removes cognitive fixation, in which innovation is hampered due to new ideas being strongly influenced
by prior examples\textsuperscript{12-16}. By engaging more people with less experience, this phenomenon is
avoidable and allows for a more creative process\textsuperscript{17}. Our team has previously used crowdsourcing
successfully to develop an effective HIV testing promotion video and images promoting sexual
health.\textsuperscript{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.
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. 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. 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.
Recruitment

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

Eligibility

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

Formative work

Prior to survey development, we will interview key informants specifically about conducting an Internet survey among MSM in China. Survey development will be done drawing on previous surveys and a review of existing literature, focusing on English and Chinese language studies. The survey will be developed in both English and Chinese. The Chinese version of the survey will be piloted online with 150 volunteers to gauge post-intervention condom usage rates and to 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 surveys\(^{23}\) 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.
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).

A data monitoring committee will not be required as this study employs low risk behavioural interventions.
Measures

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 Appendix 1).

OUTCOMES

Primary Outcomes

The primary outcome will be any condomless vaginal or anal sex (with any sex partner) among MSM and TG individuals following the video intervention. 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. Individuals who have not had sex in the interval will be classified as having no condomless sex. Condomless vaginal or anal sex will be defined as condomless sex of any frequency (e.g. using a condom none, some or most of the time).

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.

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-β). The sample size was calculated using the formula:

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

where \(\pi_s\) and \(\pi_e\) 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 \(\Phi\) denotes the cumulative distribution function of the standard normal distribution.
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.

Effect modification analysis

Effect modification analyses will be under taken 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 ≥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
address further questions. Participants will be required to sign the consent and provide a mobile telephone number as agreement to proceed with the survey.

Confidentiality

Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured Qualtrics server in the United States. The server is 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.

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

Dissemination

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

We thank the staff at the Guangdong Provincial Center for Skin Diseases and STI Control, University of North Carolina at Chapel Hill, University of California San Francisco, London School of Hygiene and Tropical Medicine, Shandong University, Shandong Provincial Centers for Disease Control and Prevention. Thanks to John Best for his help in developing the study. Thanks also to Lisa Hightow-Weidman, Rosanna Peeling, Fern Terris-Prestholt, Peter Vickerman, Kate Mitchell, and Baoli Ma. Special thanks to all those who contributed to this contest and those who served as judges.

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

<table>
<thead>
<tr>
<th>Probability of primary outcome in control group</th>
<th>Probability of primary outcome in experimental group</th>
<th>N evaluable per arm</th>
<th>Total sample size for RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.50</td>
<td>0.50</td>
<td>526</td>
<td>1170</td>
</tr>
<tr>
<td>0.45</td>
<td>0.45</td>
<td>521</td>
<td>1158</td>
</tr>
<tr>
<td>0.40</td>
<td>0.40</td>
<td>505</td>
<td>1124</td>
</tr>
<tr>
<td>0.35</td>
<td>0.35</td>
<td>479</td>
<td>1066</td>
</tr>
<tr>
<td>0.30</td>
<td>0.30</td>
<td>442</td>
<td>984</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Financial costs</th>
<th>Economic costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contest development</td>
<td><em>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</em></td>
<td><em>Extra inputs not already captured by financial costs</em></td>
</tr>
<tr>
<td>Video contest (including production)</td>
<td>Money paid for planning and implementation</td>
<td>For social marketing arm:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Personnel of CBOs/CDC (director of movie, actors, film editors)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Rental of professional video equipment (if applicable)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Building cost (office renting) for CBOs/CDC*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Equipment and software cost (if applicable)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For crowdsourced arm:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Personnel of SESH (although all volunteer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Judging opportunity cost (volunteer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Steering Committee planning meeting (three one-hour meetings)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Building cost (office renting)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- In-person promotion costs</td>
</tr>
<tr>
<td>Survey start up</td>
<td>Money paid to launch the survey (start-up)</td>
<td>- SESH personnel costs, to design and maintain the program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Equipment cost of SESH (computer and other items)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Software (Qualtrics)*</td>
</tr>
<tr>
<td>Survey implementation and intervention</td>
<td>Money paid to the participants (implementation)</td>
<td>- SESH personnel costs</td>
</tr>
<tr>
<td></td>
<td>Money paid for the software used for follow up (implementation)</td>
<td></td>
</tr>
<tr>
<td>Testing</td>
<td></td>
<td>- Cost for condoms (from CDC)</td>
</tr>
</tbody>
</table>

*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.
<table>
<thead>
<tr>
<th>Secondary Outcome</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incremental cost</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Female condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Male condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Post-video condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Frequency of sex acts</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Condom use social norms</strong></td>
<td>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*.</td>
</tr>
<tr>
<td><strong>Condom self-efficacy</strong></td>
<td>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**.</td>
</tr>
<tr>
<td><strong>Condom negotiation</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>HIV testing</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Syphilis testing</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

*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
- [x] 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
- [x] 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
- [x] 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
- [x] 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
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 provides users with the assurance of access to a valid, “non-spoofed” site, and prevents data interception or tampering with sensitive information. The SSL certificate that will be used for this project will use 128-bit encryption, the preferred security level of government and financial institutions. 128-bit encryption offers protection that is virtually unbreakable. 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 generally 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)
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
- Heilongjiang
- Shanghai
- Jiangsu
- Zhejiang
- Anhui
- Fujian
- Jiangxi
- Shandong
- Henan
- Hubei
- Hunan
- Guangdong
- Guangxi
- Hainan
- Chongqing
- Sichuan
- Guizhou
- Yunnan
- 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)
A8. What is your current legal marital status (referring to women)?
- 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.
A “primary partner” is someone who you have sex with regularly and/or have an emotional commitment to. A “casual partner” is someone who you have sex with and do not have an emotional commitment to.

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

_______ years old (Number input)

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

- Male (Skip to B4)
- Female
- Other

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

_______ years old (Number input)

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

- Insertive (1)
- Receptive (0)
- Both insertive (1) and receptive (0)

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

- Yes
- No

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

- Pub, disco, tearoom, or club
- Spa or bath house, sauna, foot or body massage parlor
- Park, public restroom, public lawn
- Internet
- Other

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

_______ male sex partners (Number input) (If answer <1, skip to end of section)

B8. Of the men you have had sex with in the last three months, would you consider one of them to be a primary sex partner?
B9. In the last three months, approximately how many times per week did you have anal sex with your primary partner?

__________________________________________________________________________________________

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
B15. When you are receptive, the reason(s) your primary partner does not use a condom with you include (select all that apply):

- My partner does not want me to use one
- The condom is of poor quality
- I do not have time to use one
- I believe that my partner is loyal to me
- I am loyal to my partner
- 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

B16. In the last three months, have you had sex with another man who was not your primary partner?

- Yes
- No (Skip to B23, Should not say “No” to B8 and B16)

B17. In the last three months, approximately how many times per week did you have anal sex (all casual sex partners combined)?

_________ sex encounters per week

B18. In the last three months, when you had anal sex with a casual partner, what role did you assume?

- Always insertive (always 1) (Do not display B22)
- Mostly insertive (mostly 1)
- Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)
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**
I am HIV negative or he does not believe I am infected with HIV

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

C. Heterosexual Sex Situation (Q39-54)
The next set of questions will ask about your sexual behaviors with women.

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.

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
Mostly used
C7. In the last six months, when you had sex with your primary female partner did a condom ever slip off, tear, or otherwise fail?

- Yes
- No

C8. The reason(s) you do not use a condom with your primary 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 believe that my partner is loyal to me
- I am loyal to my partner
- 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

C9. In the last six months, have you had sex with another woman who was not your primary partner?

- Yes
- No (Skip to End of Section if “Always” to C6; otherwise Skip to C14 – Should not answer “No” to C4 and C9)

C10. In the last six months, approximately how many times per week did you have vaginal and/or anal sex (all casual sex partners combined)?

_______ sex encounters per week

C11. In the last six months, when you had sex with a casual female partner, how frequently did you or your partner use condoms?

- Never used (Skip to C13)
- Sometimes used
- 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 your partner ever drunk (from drinking alcohol) while you had
sex?
☐ Yes
☐ No (Skip to D4 if “No” for D1 and D2)
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.
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)?
   - Men
   - Women
   - Transgender
E8a. When you purchased sex while outside your city of residence, have you ever had any vaginal sex without a condom? (Display if "Women" or "TG" for E7)
- Yes (Display E17)
- No

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

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

E10. During your most recent experience when you purchased sex while abroad, approximately how many sex partners did you purchase? (Please enter “0” partners if no partners of the following type)
- _______ male sex partners (Number input)
- _______ female sex partners (Number input)
- _______ transgender sex partners (Number input)

E11. During your most recent experience when you purchased sex while traveling, approximately how much did you pay (RMB) for your last sex encounter?
- _______ (Text Input)

E12. During your most recent experience when you purchased sex while traveling, of what nationality was your last partner?
- _______ (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?

Always
Sometimes
Hardly ever
Never
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
F7. If a friend knew that I might have sex on a date, he/she would ask me if I was carrying a condom.

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

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.

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

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.

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

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

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

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

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree
F12. I would feel comfortable letting a casual partner know that I want to have sex with a condom.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. 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.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

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

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

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

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. 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?

1. Yes, and I was successful
2. Yes, but I was unsuccessful
3. 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?
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
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
G15. Did you confirm your positive HIV self-test result at the CDC or hospital?

- Yes
- No

G16. Did you receive post-self test counseling?

- Yes (show G17)
- No

G17. What kind of post-test counseling did you receive?

- Online
- Telephone
- In-person

G18. Where did you obtain your HIV self-test kit?

- Online
- Hospital
- Pharmacy
- CBO
- Friend

G19. Was your HIV self-test oral or blood?

- Oral
- Blood

G20. In the last two years, how frequently did you get tested for HIV?

- Less than once every two years
- Once a year
- Once every six months
- Once every three months
- Monthly

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

- HIV positive/infected (Display G23)
- HIV negative/uninfected
- I never got my test results (Skip to G25)
G22. Did you notify your primary male sex partner about your most recent HIV test result?

- Yes
- No
- I do not have a regular partner (Do not display G25)

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

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

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

- It was too expensive
- I didn’t like the side effects
- I didn’t feel that it was working
- I thought it was cumbersome (too much time, forgot to take, etc.)
- Stigma

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

- Yes
- No (Skip to G27)

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

- HIV positive/infected
- HIV negative/uninfected
- Never got test results
- I don’t know

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

- Yes
- No (Skip to G30)
- I don’t know (Skip to G30)

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?
- Yes
- No

I5. Have you ever volunteered at a health clinic or other location that provided sexual health services among MSM?
- Yes
- No

I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually transmitted disease?
- Yes
- No

I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV and/or another sexually transmitted disease?
- Yes
- No

I8. How important to you is community engagement and participation in developing sexual health campaigns (for your own community)?
- Very important
- Important
- Neither important or not important
I9. Have you ever participated in online forums or discussions on social media (ie. Weixin, Weibo, Twitter, or other online communities) 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 #:_________ (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*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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<tr>
<td>Title</td>
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<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
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<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>3</td>
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<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>1,14-15</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
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<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
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<td>Roles and</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1,14</td>
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<tr>
<td>responsibilities</td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
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<td></td>
<td>5c</td>
<td>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</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
## 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

6b Explanation for choice of comparators

**Objectives**

7 Specific objectives or hypotheses

**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)

## 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

**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)

**Interventions**

11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

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)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

**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

**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)
### Sample size

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

**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

Strategies for achieving adequate participant enrolment to reach target sample size

**Recruitment**

15

**Strategies for achieving adequate participant enrolment to reach target sample size**

7

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

**Sequence generation**

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

**Sequence generation**

16a

11

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

11

**Allocation concealment mechanism**

Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

**Allocation concealment mechanism**

16b

11

**Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned**

11

**Implementation**

Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

**Implementation**

16c

11

**Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions**

11

**Blinding (masking)**

Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how

**Blinding (masking)**

17a

N/A

**Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how**

N/A

If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

**17b**

N/A

### Methods: Data collection, management, and analysis

#### Data collection methods

Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., 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

**Data collection methods**

18a

10

**Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., 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

**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
<table>
<thead>
<tr>
<th>Section</th>
<th>Reference</th>
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<td>Data management</td>
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<tr>
<td>Methods: Monitoring</td>
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<td>Data monitoring</td>
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<tr>
<td>Harms</td>
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<tr>
<td>Auditing</td>
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<td>Ethics and dissemination</td>
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<td>Research ethics approval</td>
<td>12</td>
</tr>
<tr>
<td>Protocol amendments</td>
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</tr>
</tbody>
</table>

### Data management

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.

### 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.
- 20b Methods for any additional analyses (eg, subgroup and adjusted analyses)
- 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)

### Methods: 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.
- 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

### Harms

Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

### Auditing

Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>13</td>
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<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
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<td>27</td>
<td>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</td>
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<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>16</td>
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<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>14</td>
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<tr>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
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<tr>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>14</td>
</tr>
<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
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<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
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**Appendices**

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<th>Item</th>
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<tr>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
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<tr>
<td>33</td>
<td>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</td>
<td>23</td>
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</table>

*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” license.*
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

<table>
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<th>BMJ Open</th>
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<tr>
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<td>Protocol</td>
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<td>Date Submitted by the Author:</td>
<td>17-Mar-2016</td>
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<tbody>
<tr>
<td>Liu, Chuncheng; UNC Project China</td>
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<td>Mao, Jessica; UNC Project China</td>
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<td>Wong, Terrence; UNC Project China</td>
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<td>Tso, Lai Sze; UNC Project China</td>
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<td>Zhang, Ye; UNC Project China; Guangdong Provincial Center for Skin Diseases and Sexually Transmitted Infections Control</td>
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<td>Zhang, Wei; UNC Project China</td>
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<td>Qin, Yilu; UNC Project China</td>
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<tr>
<td>Chen, Zhihuang; Danlan Ma, Wei; Shandong University School of Public Health</td>
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<td>Mollan, Katie; University of North Carolina at Chapel Hill</td>
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<tr>
<td>Wei, Chongyi; University of California - San Francisco, Department of Epidemiology and Biostatistics &amp; Global Health Sciences</td>
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<tr>
<td>Tucker, Joseph; UNC Project China</td>
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**Primary Subject Heading**: Public health

**Secondary Subject Heading**: HIV/AIDS, Infectious diseases, Research methods

**Keywords**: PUBLIC HEALTH, HIV & AIDS < INFECTIOUS DISEASES, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
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

Chuncheng Liu¹*, Jessica Mao¹*, Terrence Wong¹*, Weiming Tang¹, Lai Sze Tso¹, Songyuan Tang¹, Ye Zhang¹,⁶, Wei Zhang¹, Yilu Qin¹, Zihuang Chen², Wei Ma³, Dianming Kang⁴, Haochu Li¹,³, Meizhen Liao⁴, Katie Mollan⁵, Michael Hudgens⁵, Barry Bayus⁵, Shujie Huang⁶, Bin Yang⁶, Chongyi Wei⁷, Joseph D. Tucker¹,#

¹University of North Carolina Chapel Hill Project-China
²Danlan Welfare
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⁴Shandong Center for Disease Prevention and Control
⁵University of North Carolina at Chapel Hill
⁶Guangdong Provincial Center for Skin Diseases and Sexually Transmitted Infections Control
⁷University of California, San Francisco

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

#Corresponding Author: jdtucker@med.unc.edu

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 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
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, the University of North Carolina at Chapel Hill, and the University of California at San Francisco. 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
INTRODUCTION

Male Sexual Health

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

Crowdsourcing

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

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

Eligibility

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

Formative work

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

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

**Measures**

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).

**OUTCOMES**

**Primary Outcomes**

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
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
dividual 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.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Financial costs</th>
<th>Economic costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contest development</td>
<td>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</td>
<td>Extra inputs not already captured by financial costs</td>
</tr>
<tr>
<td>Video contest</td>
<td>Money paid for planning and implementation</td>
<td>For social marketing arm:</td>
</tr>
<tr>
<td>including production</td>
<td></td>
<td>• Personnel of CBOs/CDC (director of movie, actors, film editors)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Rental of professional video equipment (if applicable)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Building cost (office renting) for CBOs/CDC*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Equipment and software cost (if applicable) *</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For crowdsourced arm:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Personnel of SESH (although all volunteer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Judging opportunity cost (volunteer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Steering Committee planning meeting (three one-hour meetings)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Building cost (office renting)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• In-person promotion costs</td>
</tr>
<tr>
<td>Survey start up</td>
<td>Money paid to launch the survey (start-up)</td>
<td>SESH personnel costs, to design and maintain the program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equipment cost of SESH (computer and other items)*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Software (Qualtrics)*</td>
</tr>
<tr>
<td>Survey implementation</td>
<td>Money paid to the participants (implementation)</td>
<td>SESH personnel costs</td>
</tr>
<tr>
<td>and intervention</td>
<td>Money paid for the software used for follow up (implementation)</td>
<td></td>
</tr>
<tr>
<td>Testing</td>
<td></td>
<td>Cost for condoms (from CDC)</td>
</tr>
</tbody>
</table>

*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 ($\alpha$) 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 $\pi_s$ and $\pi_e$ 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 $\Phi$ 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

<table>
<thead>
<tr>
<th>Probability of primary outcome in control group</th>
<th>Probability of primary outcome in experimental group</th>
<th>N evaluable per arm</th>
<th>Total sample size for RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.50</td>
<td>0.50</td>
<td>526</td>
<td>1170</td>
</tr>
<tr>
<td>0.45</td>
<td>0.45</td>
<td>521</td>
<td>1158</td>
</tr>
<tr>
<td>0.40</td>
<td>0.40</td>
<td>505</td>
<td>1124</td>
</tr>
<tr>
<td>0.35</td>
<td>0.35</td>
<td>479</td>
<td>1066</td>
</tr>
<tr>
<td>0.30</td>
<td>0.30</td>
<td>442</td>
<td>984</td>
</tr>
</tbody>
</table>
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 ≥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**
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 address further questions. Participants will be required to sign the consent and provide a mobile telephone number as agreement to proceed with the survey.

**Confidentiality**

Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured Qualtrics server in the United States. The server is 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.

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

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

We thank the staff at the Guangdong Provincial Center for Skin Diseases and STI Control, University of North Carolina at Chapel Hill, University of California San Francisco, London School of Hygiene and Tropical Medicine, Shandong University, Shandong Provincial Centers for Disease Control and Prevention. Thanks to John Best for his help in developing the study.

Thanks also to Lisa Hightow-Weidman, Rosanna Peeling, Fern Terris-Prestholdt, Peter Vickerman, Kate Mitchell, and Baoli Ma. Special thanks to all those who contributed to this contest and those who served as judges.

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

<table>
<thead>
<tr>
<th>Secondary Outcome</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incremental cost</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Female condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Male condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Post-video condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Frequency of sex acts</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Condom use social norms</strong></td>
<td>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*</td>
</tr>
<tr>
<td><strong>Condom self-efficacy</strong></td>
<td>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**</td>
</tr>
<tr>
<td><strong>Condom negotiation</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>HIV testing</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>STI testing</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

*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 to 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 )

1. **A1. Were you born biologically male or female?**
   - Male
   - Female (Not eligible to take this survey – Skip to End of Survey)

2. **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)

3. **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)

4. **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)

5. **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-descriptive, unique, randomly generally 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
- Xizang (Tibet)
- Shaanxi
- Gansu
- Qinghai
- Ningxia
- Xinjiang
- Hong Kong
- Aomen
- Beijing, Shanghai, Chongqing, Tianjin, Hong Kong, Macao (not displayed if answered to A6)

A7. What city do you currently live in? ____________ (Text input) (Do not display if answered to A6)
A8. What is your current legal marital status (referring to women)?
- 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 Zhongzhuang)
- 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.
A “primary partner” is someone who you have sex with regularly and/or have an emotional commitment to. A “casual partner” is someone who you have sex with and do not have an emotional commitment to.

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

______years old (Number input)

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

- Male (Skip to B4)
- Female
- Other

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

______ years old (Number input)

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

- Insertive (1)
- Receptive (0)
- Both insertive (1) and receptive (0)

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

- Yes
- No

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

- Pub, disco, tearoom, or club
- Spa or bath house, sauna, foot or body massage parlor
- Park, public restroom, public lawn
- Internet
- Other

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

______ male sex partners (Number input) (If answer <1, skip to end of section)

B8. Of the men you have had sex with in the last three months, would you consider one of them to be a primary sex partner?
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
My partner does not want me to use one

The condom is of poor quality

I do not have time to use one

I believe that my partner is loyal to me

I am loyal to my partner

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

B15. When you are receptive, the reason(s) your primary 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

I believe that my partner is loyal to me

He believes that I am loyal to him

He is drunk or high

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

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

Other

B16. In the last three months, have you had sex with another man who was not your primary partner?

Yes

No (Skip to B23, Should not say “No” to B8 and B16)

B17. In the last three months, approximately how many times per week did you have anal sex (all casual sex partners combined)?

_________ sex encounters per week

B18. In the last three months, when you had anal sex with a casual partner, what role did you assume?

Always insertive (always 1) (Do not display B22)

Mostly insertive (mostly 1)

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

- 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)

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
1. He is HIV negative or he does not believe he is infected with HIV
2. I am HIV negative or he does not believe I am infected with HIV
3. 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)

1. Yes
2. No

C. Heterosexual Sex Situation (Q39-54)
The next set of questions will ask about your sexual behaviors with women.

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.

C1. Have you ever had vaginal, anal, and/or oral sex with a female partner?
1. Yes
2. 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?
1. Yes
2. 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?
1. Yes
2. 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?
1. Never used (Skip to C8)
2. Sometimes used
C7. In the last six months, when you had sex with your primary female partner did a condom ever slip off, tear, or otherwise fail?

- Yes
- No

C8. The reason(s) you do not use a condom with your primary 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 believe that my partner is loyal to me
- I am loyal to my partner
- 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

C9. In the last six months, have you had sex with another woman who was not your primary partner?

- Yes
- No (Skip to End of Section if “Always” to C6; otherwise Skip to C14 – Should not answer “No” to C4 and C9)

C10. In the last six months, approximately how many times per week did you have vaginal and/or anal sex (all casual sex partners combined)?

________ sex encounters per week

C11. In the last six months, when you had sex with a casual female partner, how frequently did you or your partner use condoms?

- Never used (Skip to C13)
- Sometimes used
- 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 your partner ever drunk (from drinking alcohol) while you had sex?
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.

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

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

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

E10. During your most recent experience when you purchased sex while abroad, approximately how many sex partners did you purchase? (Please enter “0” partners if no partners of the following type)
- _______ male sex partners (Number input)
- _______ female sex partners (Number input)
- _______ transgender sex partners (Number input)

E11. During your most recent experience when you purchased sex while traveling, approximately how much did you pay (RMB) for your last sex encounter?
- _______ (Text Input)

E12. During your most recent experience when you purchased sex while traveling, of what nationality was your last partner?
- _______ (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?
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
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**F7.** If a friend knew that I might have sex on a date, he/she would ask me if I was carrying a condom.

- 1 Agree
- 2 Neutral
- 3 Disagree
- 4 Strongly disagree

**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.

- 1 Agree
- 2 Neutral
- 3 Disagree
- 4 Strongly disagree

**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.

- 1 Agree
- 2 Neutral
- 3 Disagree
- 4 Strongly disagree

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

- 1 Agree
- 2 Neutral
- 3 Disagree
- 4 Strongly disagree

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

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

- 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 ever **try** to convince you to use a condom when you did not want to use one before having sex?

- Yes, and he was successful
- Yes, but he was unsuccessful
- 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?
1. Increased
2. Decreased
3. No change

G8. Have you ever received a positive result with HIV self-testing?
4. Yes
5. No (Skip to G11)

G9. Has using an HIV self-test caused you subsequent suicidal feelings?
6. Yes
7. No

G10. Has using an HIV self-test led to a violent confrontation (physically hitting)?
8. Yes
9. 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?
10. Yes
11. No

G12. Self-testing for HIV gives me a sense of empowerment by allowing me to choose when I test.
12. Strongly Agree
13. Agree
14. Neutral
15. Disagree
16. Strongly Disagree

G13. Self-testing for HIV gives me a sense of empowerment by allowing me to choose where I test.
17. Strongly Agree
18. Agree
19. Neutral
20. Disagree
21. 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
- Neutral
- Disagree
- Strongly Disagree

G15. Did you confirm your positive HIV self-test result at the CDC or hospital?
- Yes
- No

G16. Did you receive post-self test counseling?
- Yes (show G17)
- No

G17. What kind of post-test counseling did you receive?
- online
- telephone
- in-person

G18. Where did you obtain your HIV self-test kit?
- online
- hospital
- pharmacy
- CBO
- friend

G19. Was your HIV self-test oral or blood?
- Oral
- Blood

G20. In the last two years, how frequently did you get tested for HIV?
- Less than once every two years
- Once a year
- Once every six months
- Once every three months
- Monthly
G21. What was the result of your most recent HIV test?
1. HIV positive/infected (Display G23)
2. HIV negative/uninfected
3. I never got my test results (Skip to G25)

G22. Did you notify your primary male sex partner about your most recent HIV test result?
1. Yes
2. No
3. I do not have a regular partner (Do not display G25)

G23. Have you ever taken anti-retroviral therapy (ART) for your HIV infection?
1. Yes – I have taken, and I am currently taking
2. Yes – I have taken, but I am currently not taking (Display G24)
3. No – I have never taken

G24. Why did you stop taking ART? (Select all that apply)
1. It was too expensive
2. I didn’t like the side effects
3. I didn’t feel that it was working
4. I thought it was cumbersome (too much time, forgot to take, etc.)
5. Stigma

G25. Has your primary male sex partner ever been tested for HIV? (Do not display if no to B8)
1. Yes
2. No (Skip to G27)

G26. What was the result of your primary male sex partner’s most recent HIV test?
1. HIV positive/infected
2. HIV negative/uninfected
3. Never got test results
4. I don’t know

G27. Have you ever had a male sex partner who tested HIV positive?
1. Yes
2. No (Skip to G30)
3. I don’t know (Skip to G30)

G28. Did you ever have any anal sex without a condom with a HIV positive partner?
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):
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?
I5. Have you ever volunteered at a health clinic or other location that provided sexual health services among MSM?

- Yes
- No

I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually transmitted disease?

- Yes
- No

I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV and/or another sexually transmitted disease?

- Yes
- No

I8. How important to you is community engagement and participation in developing sexual health campaigns (for your own community)?

- Very important
- Important
- Neither important or 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 #:_________ (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 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:_________
<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
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</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
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<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
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<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>1,14-15</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>14</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1,14</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th>Sample size</th>
<th>14</th>
<th>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
</tr>
<tr>
<td><strong>Methods: Assignment of interventions (for controlled trials)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>16a</td>
<td>Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</td>
</tr>
<tr>
<td>Allocation concealment mechanism</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</td>
</tr>
<tr>
<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>17a</td>
<td>Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial</td>
</tr>
<tr>
<td><strong>Methods: Data collection, management, and analysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data collection methods</td>
<td>18a</td>
<td>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., 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</td>
</tr>
<tr>
<td></td>
<td>18b</td>
<td>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</td>
</tr>
</tbody>
</table>
### Data management

19. Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

### 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

20b. Methods for any additional analyses (e.g., subgroup and adjusted analyses)

20c. Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)

### Methods: 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

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

### 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

### Auditing

23. Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

### Ethics and dissemination

24. Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

25. Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>13</td>
</tr>
<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>27</td>
<td>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</td>
<td>13</td>
</tr>
<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>16</td>
</tr>
<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>14</td>
</tr>
<tr>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>N/A</td>
</tr>
<tr>
<td>31a</td>
<td>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</td>
<td>14</td>
</tr>
<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>N/A</td>
</tr>
<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>N/A</td>
</tr>
<tr>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
<td>25</td>
</tr>
<tr>
<td>33</td>
<td>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</td>
<td>23</td>
</tr>
</tbody>
</table>

*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" license.*
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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<td>Protocol</td>
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<tr>
<td>Date Submitted by the Author:</td>
<td>04-May-2016</td>
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</table>
| Complete List of Authors: | Liu, Chuncheng; UNC Project China
Mao, Jessica; UNC Project China
Wong, Terrence; UNC Project China
Tang, Weiming; UNC Project China
Tso, Lai Sze; UNC Project China
Tang, Songyuan; UNC Project China
Zhang, Ye; UNC Project China; Guangdong Provincial Center for Skin Diseases and Sexually Transmitted Infections Control
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Yang, Bin; Guangdong Provincial Center for Skin Diseases and Sexually Transmitted Infections Control
Wei, Chongyi; University of California - San Francisco, Department of Epidemiology and Biostatistics & Global Health Sciences
Tucker, Joseph; UNC Project China |
| Primary Subject Heading: | Public health |
| Secondary Subject Heading: | HIV/AIDS, Infectious diseases, Research methods |
| Keywords: | HIV & AIDS < INFECTIOUS DISEASES, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, SOCIAL MEDICINE |
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

Chuncheng Liu¹*, Jessica Mao¹*, Terrence Wong¹*, Weiming Tang¹, Lai Sze Tso¹, Songyuan Tang¹, Ye Zhang¹, Wei Zhang¹, Yilu Qin¹, Zihuang Chen², Wei Ma³, Dianming Kang⁴, Haochu Li¹,², Meizhen Liao⁴, Katie Mollan⁵, Michael Hudgens⁵, Barry Bayus⁵, Shujie Huang⁶, Bin Yang⁶, Chongyang Wei⁷, Joseph D. Tucker¹#

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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
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
INTRODUCTION

Male Sexual Health

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

Crowdsourcing

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

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

Eligibility

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

Formative work

Prior to survey development, we will interview key informants specifically about conducting an Internet survey among MSM in China. Survey development will be done drawing on previous surveys and a review of existing literature, focusing on English and Chinese language studies. The survey will be developed in both English and Chinese but conducted entirely in Chinese. The Chinese version of the survey will be piloted online with 150 volunteers to gauge post-
intervention condom usage rates and to 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 surveys[23] 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 public announcement of the contest winner to 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).
Participants will register for our survey using a mobile number. Following completion of data collection, data entries will be screened for duplicate mobile numbers, and the second entry will be excluded. Entries with invalid mobile numbers will also be excluded.

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.

Measures

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).

OUTCOMES

Primary Outcomes

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
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.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Financial costs</th>
<th>Economic costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contest development</td>
<td><em>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</em></td>
<td><em>Extra inputs not already captured by financial costs</em></td>
</tr>
</tbody>
</table>
| Video contest (including production) | Money paid for planning and implementation | For social marketing arm:  
  - 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:  
  - 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)                                     | 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) | SESH personnel costs  
  Money paid for the software used for follow up (implementation)  
  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 ($\alpha$) 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 $\pi_s$ and $\pi_e$ 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 $\Phi$ denotes the cumulative distribution function of the standard normal distribution. More information on sample size calculation can be found in Table 2.

<table>
<thead>
<tr>
<th>Probability of primary outcome in control group*</th>
<th>Probability of primary outcome in experimental group*</th>
<th>N evaluable per arm</th>
<th>Total sample size for RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.50</td>
<td>0.50</td>
<td>526</td>
<td>1170</td>
</tr>
<tr>
<td>0.45</td>
<td>0.45</td>
<td>521</td>
<td>1158</td>
</tr>
<tr>
<td>0.40</td>
<td>0.40</td>
<td>505</td>
<td>1124</td>
</tr>
<tr>
<td>0.35</td>
<td>0.35</td>
<td>479</td>
<td>1066</td>
</tr>
<tr>
<td>0.30</td>
<td>0.30</td>
<td>442</td>
<td>984</td>
</tr>
</tbody>
</table>
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 \( \frac{\text{N evaluable per arm}}{1 - 0.1} \) 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 ≥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**
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 address further questions. Participants will be required to sign the consent and provide a mobile telephone number as agreement to proceed with the survey.

Confidentiality

Data will be collected through the Qualtrics survey tool (Provo, Utah). Data will be transmitted securely using SSL (TLS) 128 bit encryption across the Internet (HTTP) and located in a secured Qualtrics server in the United States. The server is 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.

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

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

We thank the staff at the Guangdong Provincial Center for Skin Diseases and STI Control, University of North Carolina at Chapel Hill, University of California San Francisco, London School of Hygiene and Tropical Medicine, Shandong University, Shandong Provincial Centers for Disease Control and Prevention. Thanks to John Best for his help in developing the study. Thanks also to Lisa Hightow-Weidman, Rosanna Peeling, Fern Terris-Prestholdt, Peter Vickerman, Kate Mitchell, and Baoli Ma. Special thanks to all those who contributed to this contest and those who served as judges.

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.
References


7. Sweat MD, Denison J, Kennedy C, Tedrow V, O’Reilly K. Effects of condom social marketing on condom use in developing countries: a systematic review and meta-analysis,


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

<table>
<thead>
<tr>
<th>Secondary Outcome</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incremental cost</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Female condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Male condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Post-video condomless sex</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Frequency of sex acts</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Condom use social norms</strong></td>
<td>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*</td>
</tr>
<tr>
<td><strong>Condom self-efficacy</strong></td>
<td>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**</td>
</tr>
<tr>
<td><strong>Condom negotiation</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>HIV testing</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>STI testing</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

*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.
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 to 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
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-descriptive, unique, randomly generally 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
- 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 in previous question)
A8. What is your current legal marital status (referring to women)?
- 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.
A “primary partner” is someone who you have sex with regularly and/or have an emotional commitment to. A “casual partner” is someone who you have sex with and do not have an emotional commitment to.

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

_______ years old (Number input)

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

☒ Male (Skip to B4)
☒ Female
☒ Other

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

_______ years old (Number input)

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

☒ Insertive (1)
☒ Receptive (0)
☒ Both insertive (1) and receptive (0)

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

☒ Yes
☒ No

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

☒ Pub, disco, tearoom, or club
☒ Spa or bath house, sauna, foot or body massage parlor
☒ Park, public restroom, public lawn
☒ Internet
☒ Other

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

_______ male sex partners (Number input) (If answer <1, skip to end of section)

B8. Of the men you have had sex with in the last three months, would you consider one of them to be a primary sex partner?
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. My partner does not want me to use one
2. The condom is of poor quality
3. I do not have time to use one
4. I believe that my partner is loyal to me
5. I am loyal to my partner
6. I am drunk or high
7. I am HIV negative or I do not believe I am infected with HIV
8. My partner is HIV negative or I do not believe he is infected with HIV
9. Other

B15. When you are receptive, the reason(s) your primary partner does not use a condom with you include (select all that apply):

10. He does not want to use one (e.g. personal preference, uncomfortable)
11. Neither of us has a condom
12. I do not want him to use one
13. The condom is of poor quality
14. He does not have time to use one
15. I believe that my partner is loyal to me
16. He believes that I am loyal to him
17. He is drunk or high
18. He is HIV negative or does not believe he is infected with HIV
19. I am HIV negative or does not believe I am infected with HIV
20. Other

B16. In the last three months, have you had sex with another man who was not your primary partner?

21. Yes
22. No (Skip to B23, Should not say “No” to B8 and B16)

B17. In the last three months, approximately how many times per week did you have anal sex (all casual sex partners combined)?

23. ________ sex encounters per week

B18. In the last three months, when you had anal sex with a casual partner, what role did you assume?

24. Always insertive (always 1) (Do not display B22)
25. Mostly insertive (mostly 1)
26. Both insertive and receptive in similar amounts (Both 1 and 0 in similar amounts)
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)"

- 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)

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"

- Never used (Skip to B21)
- Sometimes used
- Mostly used
- Always used (Do not display B21, B22)

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
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

C. Heterosexual Sex Situation (Q39-54)

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

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.

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
C7. In the last six months, when you had sex with your primary female partner did a condom ever slip off, tear, or otherwise fail?

- Yes
- No

C8. The reason(s) you do not use a condom with your primary 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 believe that my partner is loyal to me
- I am loyal to my partner
- 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

C9. In the last six months, have you had sex with another woman who was not your primary partner?

- Yes
- No (Skip to End of Section if “Always” to C6; otherwise Skip to C14 – Should not answer “No” to C4 and C9)

C10. In the last six months, approximately how many times per week did you have vaginal and/or anal sex (all casual sex partners combined)?

_________sex encounters per week

C11. In the last six months, when you had sex with a casual female partner, how frequently did you or your partner use condoms?

- Never used (Skip to C13)
- Sometimes used
- 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?
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.

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)?
E8a. When you purchased sex while outside your city of residence, have you ever had any vaginal sex without a condom? (Display if “Women” or “TG” for E7)

- Yes (Display E17)
- No

E8b. When you purchased sex while outside your city of residence, have you ever had any anal sex without a condom?

- Yes (Display E17)
- No

E9. Once you were at your travel destination (during your most recent trip abroad), how did you find someone to purchase sex from (select all that apply)?

- Mobile app portal
- Online (not an app) portal
- In-person proposition
- Local establishment

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

- _______ male sex partners (Number input)
- _______ female sex partners (Number input)
- _______ transgender sex partners (Number input)

E11. During your most recent experience when you purchased sex while traveling, approximately how much did you pay (RMB) for your last sex encounter?

- _______ (Text Input)

E12. During your most recent experience when you purchased sex while traveling, of what nationality was your last partner?

- _______ (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. F2. If you needed a condom, where is the first place you would go to find one?
6. Pharmacy or drugstore
7. Supermarket
8. Health clinic
9. Community event
10. Restroom vending machine
11. Friend
12. Partner
13. Other

14. F3. If I had sex and told my friends that I did not use a condom, they would be angry or disappointed.
15. Strongly agree
16. Agree
17. Neutral
18. Disagree
19. Strongly disagree

21. Strongly agree
22. Agree
23. Neutral
24. Disagree
25. Strongly disagree

26. F5. My friends and I encourage each other before dates to practice "safer" sex.
27. Strongly agree
28. Agree
29. Neutral
30. Disagree
31. Strongly disagree

32. F6. If I thought that one of my friends had sex on a date, I would ask them if they used a condom.
33. Strongly agree
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F7. If a friend knew that I might have sex on a date, he/she would ask me if I was carrying a condom.

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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.

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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.

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

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

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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 ever try to convince you to use a condom when you did not want to use one before having sex?
   ○ Yes, and he was successful
   ○ Yes, but he was unsuccessful
   ○ 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?
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
- Neutral
- Disagree
- Strongly Disagree

G15. Did you confirm your positive HIV self-test result at the CDC or hospital?

- Yes
- No

G16. Did you receive post-self test counseling?

- Yes (show G17)
- No

G17. What kind of post-test counseling did you receive?

- online
- telephone
- in-person

G18. Where did you obtain your HIV self-test kit?

- online
- hospital
- pharmacy
- CBO
- friend

G19. Was your HIV self-test oral or blood?

- Oral
- Blood

G20. In the last two years, how frequently did you get tested for HIV?

- Less than once every two years
- Once a year
- Once every six months
- Once every three months
- Monthly
G21. What was the result of your most recent HIV test?

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

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

4. Yes
5. No
6. I do not have a regular partner (Do not display G25)

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

7. Yes – I have taken, and I am currently taking
8. Yes – I have taken, but I am currently not taking (Display G24)
9. No – I have never taken

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

10. It was too expensive
11. I didn’t like the side effects
12. I didn’t feel that it was working
13. I thought it was cumbersome (too much time, forgot to take, etc.)
14. Stigma

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

15. Yes
16. No (Skip to G27)

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

17. HIV positive/infected
18. HIV negative/uninfected
19. Never got test results
20. I don’t know

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

21. Yes
22. No (Skip to G30)
23. I don’t know (Skip to G30)

G28. Did you ever have any anal sex without a condom with a HIV positive partner?
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):
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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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I5. Have you ever volunteered at a health clinic or other location that provided sexual health services among MSM?

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<td>O No</td>
</tr>
</tbody>
</table>

I6. Have you ever encouraged someone else to get tested for HIV and/or another sexually transmitted disease?

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>6</td>
<td></td>
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<tr>
<td>7</td>
<td>O Yes</td>
</tr>
<tr>
<td>8</td>
<td>O No</td>
</tr>
</tbody>
</table>

I7. Have you ever accompanied a friend or partner to a testing facility to get tested for HIV and/or another sexually transmitted disease?

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>9</td>
<td></td>
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<tr>
<td>10</td>
<td>O Yes</td>
</tr>
<tr>
<td>11</td>
<td>O No</td>
</tr>
</tbody>
</table>

I8. How important to you is community engagement and participation in developing sexual health campaigns (for your own community)?

<p>| | |</p>
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<tbody>
<tr>
<td>12</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>O Very important</td>
</tr>
<tr>
<td>14</td>
<td>O Important</td>
</tr>
<tr>
<td>15</td>
<td>O Neither important or not important</td>
</tr>
</tbody>
</table>

I9. Have you ever participated in online forums or discussions on social media (ie. Weixin, Weibo, Twitter, or other on-line communities) 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 #:_________ *(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 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*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>1,14-15</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>14</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1,14</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
## 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

### Objectives
7 Specific objectives or hypotheses

### Trial design
8 Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)

## Methods: Participants, interventions, and outcomes

### Study setting
9 Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

### Eligibility criteria
10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)

### Interventions
11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

### Outcomes
12 Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

### 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)
| Sample size | 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 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 |

### Methods: Assignment of interventions (for controlled trials)

**Allocation:**

| Sequence generation | Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 11 |
| Allocation concealment mechanism | Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 11 |
| Implementation | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 11 |

**Blinding (masking):**

| Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how | N/A |
| 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

<p>| Data collection methods | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., 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 |
| 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 |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management</td>
<td>19</td>
<td>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</td>
<td>14</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>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</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
<td>12</td>
</tr>
<tr>
<td>Methods: Monitoring</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>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.</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>21b</td>
<td>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</td>
<td>N/A</td>
</tr>
<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
<td>N/A</td>
</tr>
<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethics and dissemination</td>
<td></td>
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<tr>
<td>Research ethics approval</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
<td>12</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>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)</td>
<td>12</td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Score</td>
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<td></td>
</tr>
<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>N/A</td>
<td></td>
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<tr>
<td>27</td>
<td>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</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>16</td>
<td></td>
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<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>14</td>
<td></td>
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<tr>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>31a</td>
<td>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</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>N/A</td>
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</table>

**Appendices**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
<td>25</td>
</tr>
<tr>
<td>33</td>
<td>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</td>
<td>23</td>
</tr>
</tbody>
</table>

*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 license.*