

## Supplement A. Protocol

# **Crowdsourcing Versus Social Marketing Video Campaigns to Promote Condom Use: A Noninferiority Randomized Controlled Trial to Evaluate Promoting Condom Use Among MSM and Transgender Individuals in China**

## **Study Protocol**

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**Version 1.0**

### **1. STUDY TEAM**

*Partner Institutions:* 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

PIs: Joseph D. Tucker, Chongyi Wei

Survey development: Weiming Tang, Lai Sze Tso, Terrence Wong, Jessica Mao, Lulu Qin, Chuncheng Liu, Lisa Hightow-Weidman

Statisticians: Katie Mollan, Michael Hudgens, Chongyi Wei, Weiming Tang

Crowdsourcing Intervention Arm: Barry Bayus, Bin Yang, Shujie Huang, Lai Sze Tso, Rosanna Peeling

Social Marketing Intervention Arm: Chongyi Wei, Wei Ma, Meizhen Liao, Haochu Li, Dianmin Kang

Costing Analysis: Weiming Tang, Fern Terris-Prestholt, Peter Vickerman, Kate Mitchell

MSM recruitment: Terrence Wong, Baoli Ma, Hanhan

Oversight: Bin Yang, Shujie Huang, Chongyi Wei, Joseph Tucker

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## **2. SUMMARY**

Crowdsourcing may be a powerful tool to spur the development of innovative videos to promote condom use among key populations such as men who have sex with men (MSM) and transgender individuals (TG). The purpose of this randomized controlled trial is to compare the effect of a crowdsourced video and a social marketing video on condom use among Chinese MSM and TG who report condomless anal/vaginal sex during the past three months. The crowdsourced video was developed using an open contest, formal transparent judging, and several prizes. The hypothesis is that a crowdsourced video will not be inferior (within a margin

of 10%) to a social marketing video in terms of reported condomless sex after three to four weeks (with an additional follow-up at three months) following the one-time video watching.

### **3. BACKGROUND**

Although male condoms have long been recognized as an effective method for reducing the risk of HIV and other sexually transmitted diseases (STDs)<sup>1,2</sup>, men who have sex with men (MSM) practice inconsistent condom use in China.<sup>3-6</sup> The resulting high incidence of HIV and STDs among MSM suggests the need for novel health promotion campaigns. One systematic review<sup>7</sup> and one literature review among MSM<sup>8</sup> demonstrate that social marketing campaigns are effective in promoting condom use, but the persistence of these behavioral changes over time is unclear. Community engagement in these campaigns is also variable. We propose that crowdsourcing may substantially improve on existing methods for developing condom promotion campaigns. Crowdsourcing is the process of taking a task performed by an individual and outsourcing it to a large group in the form of a contest or open call, often enabled by the Internet.<sup>9</sup> Crowdsourcing has been used extensively in the private sector and championed by the Executive Office of the President of the United States as a cost-effective tool to generate creative, new ideas.<sup>10</sup> Similarly, crowdsourcing can be applied to enhance condom promotion and linkage programs by generating diverse ideas and increasing key population engagement.

A crowdsourced approach to promoting condom use substantially differs from social marketing approaches in three ways. First and foremost, crowdsourced campaigns are developed “bottom-up” based on crowd input while social marketing campaigns are “top-down” and often rely on public health expert opinions. Second, crowdsourced campaigns increase community

engagement from idea generation to implementation while social marketing approaches have limited community engagement. Third, crowdsourced campaigns have a high potential for innovation compared to social marketing approaches. Cognitive psychology and creativity research show how conventional approaches to the design and implementation of sexual health education programs may stifle creativity. This literature suggests that past experience is detrimental to future ideation efforts.<sup>11</sup> Experimental research demonstrates that cognitive fixation is a pervasive impediment to developing novel ideas.<sup>12-16</sup> People gravitate towards ideas that bear structural and technical resemblance to prior examples,<sup>14,17</sup> resulting in less creative ideas. Our team has used crowdsourcing to develop an effective HIV testing promotion video<sup>18</sup> and images promoting sexual health.<sup>19</sup>

#### **4. SPECIFIC 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 TG in China. This includes data at 3 weeks post-video and data from 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 among MSM and TG individuals in China.**

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

## **5. STUDY DESIGN**

*Formative work:* Two trained study team members will conduct interviews with MSM and stakeholders in order to inform development of the online survey. We will interview key informants specifically about conducting an Internet survey among MSM in China. We will partner with the community-based organization responsible for the largest MSM web portal in China ([www.danlan.com](http://www.danlan.com)). This MSM web platforms provide a structured mechanism for social networking, meeting friends, exchanging news and information, and banner advertising (Appendix 1). We will pilot the survey online with approximately 100 volunteer MSM. The purpose of the pilot study will be to gauge post-intervention condom usage rates and to estimate the necessary sample size for the non-inferiority study. We will also conduct semi-structured interviews to solicit feedback on 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<sup>20</sup> will be used to ensure completeness.

*Study Design:* This study will be a pragmatic, non-inferiority, randomized controlled trial comparing two groups – men who watch a crowdsourced video and men who watch a social marketing video.

*Main and Secondary Outcomes:* The main outcome of this study will be any condomless anal or vaginal sex with any sex partner at three weeks and three months following the video.

Individuals who do not reply to the three week message will receive a second message at four weeks. Secondary outcomes include cost, self-efficacy, and other behavioral variables (Appendix 2).

*Eligibility and Recruitment:* Participants will be recruited through a banner link on a popular MSM web portal home page and an announcement sent to registered users by email and other social media platforms. Interested participants who click on the link will then be directed to the survey with a description of its contents and an online informed consent form. The survey is voluntary and to be eligible, participants must state that they were born biologically male or are transgender, 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 provide their cell mobile number. Individuals identified by their cell phone number who enter the study twice and watch different videos will be excluded. No names or addresses will be collected from participants. All individuals who enroll in the study and reply to the text message will receive a 100 RMB (8.50 USD) pre-paid cell phone card for their time at the first FU and a 50 RMB pre-paid card for the second FU.

*Measures:* Survey items on socio-demographics and sexual behaviors will be collected using standardized survey instruments immediately before video watching, three weeks after video watching, and three months after video watching. Socio-demographic characteristics include participants' age, highest level of education completed, annual income, marital status, sexual orientation, and sexual orientation disclosure. Behavioral 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 specified in Appendix 2.

*Statistical Analysis:* The primary outcome will be condomless vaginal or anal sex (with any sex partner) among MSM and transgender individuals following the assigned video intervention. Participants will be asked about using condoms all the time or not using condoms all the time since watching the video (individuals who have not had sex in the interval will be classified as no condomless sex). Condomless vaginal or anal sex includes condomless sex of any frequency (e.g., always condomless sex, occasional condomless sex, etc.). We will examine 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 estimated, 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 bound is below 0%, then the crowdsourced intervention will be declared superior to social marketing.

Our secondary outcomes are condom use self-efficacy, cost, and related behavioral outcomes.

The objective of the cost analysis will be to estimate the total and incremental unit cost in using

video interventions to promote condom use. In this step, we will further collect cost related data from all the organizations involved in making condom use promotion videos. Detailed information that we will collect from these organizations is listed in Appendix 2. One of our secondary analyses will focus on those individuals who reported sex following the video intervention (excluding those who did not have sex in the interval between the video and the survey).

*Missing Data Plan:* Missing data in the primary outcome that accounts for <11% of participants will not be imputed and the complete-case approach will be used. However, in cases where missing data for the primary outcome is 11 to <20% of the total outcome, a sensitivity analysis using multiple imputation based on the PROC MI procedure in SAS (Cary, NC) will be used. If missing data accounts for  $\geq 20\%$  of participants then we will use multiple imputation in the primary analysis.

*Effect modification analyses:* Effect modification analyses will be undertaken based on prior exposure to condom promotion video watching to assess whether this exposure differs between the baseline groups. A linear probability model will be used to evaluate effect modification by testing for an interaction between intervention and prior video watching (e.g.,

$$Prob(Condomless\ Sex = 1|Arm, AgeGrp) = \alpha + \beta_1 Arm + \beta_2 AgeGrp + \beta_3 Arm * AgeGrp).$$

This model can be fit with the GENMOD procedure in SAS using the binomial distribution and identity link. If this model does not converge, then log-binomial regression will be used to estimate relative risks.



*Secondary analysis:* We will examine the subset of individuals who reported sex during the follow-up period (3 weeks and 3 months respectively) and use causal inference methods to account for post-randomization selection bias. We will compare the proportion of individuals who have any sex between the two arms to determine if the intervention results in less frequent sex.

*Sample size calculation:* To calculate sample size we assumed an equal probability of reported condomless sex in the crowdsourced video intervention and social marketing intervention arms. We calculated the sample size for this binary outcome non-inferiority trial using the formula below with a one-sided significance level ( $\alpha$ ) of 2.5% and power ( $1-\beta$ ) of 90%.<sup>21</sup> Assuming a 50% probability of condomless sex in each arm, a non-inferiority limit of 10%, and loss to follow-up of 10%, a total sample size of 1170 individuals is required (585 in each arm). The sample size calculation was made 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 probability of reported condomless sex in the social marketing intervention and crowdsourced video (experimental) intervention groups, respectively,  $d$  is the non-inferiority limit, and  $f(\alpha, \beta) = [\Phi^{-1}(\alpha) + \Phi^{-1}(\beta)]^2$ , where  $\Phi^{-1}$  represents the cumulative distribution function of the standard normal distribution.

#### **Sample size calculations for 90% power and a one-sided 0.025 significance level**

Probability of primary outcome in	Probability of primary outcome in	Non-inferiority limit	Probability of loss to follow-up $\epsilon$	N evaluable per	Total sample size for
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<b>control group<sup>*</sup></b>	<b>experimental group<sup>*</sup></b>			<b>arm</b>	<b>RCT</b>
0.50	0.50	0.1	0.1	526	1170
0.45	0.45	0.1	0.1	521	1158
0.40	0.40	0.1	0.1	505	1122
0.35	0.35	0.1	0.1	479	1064
0.30	0.30	0.1	0.1	442	982

Note: <sup>\*</sup>Based on the pilot study, 9/25 (95% confidence interval: 18% to 57%) had condomless sex at least once in the three week period immediately following the video intervention.

<sup>£</sup> According to one similar RCT we conducted at 2014, the lost to follow up rate was about 10%; adjustment for loss: required evaluable N per arm/(1-loss to follow up).

*Ethical review:* IRB approval will be obtained from the following institutional ethical review boards prior to study enrollment – Guangdong Provincial Center for Skin Diseases and STI Control, University of North Carolina at Chapel Hill, and University of California San Francisco.

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

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## Appendix 1. Overview of MSM web platforms and screen shots.

We will partner with the largest CBO, Danlan. This CBO provides sexual health services such as HIV and syphilis rapid testing and counseling, as well as linkage to care (accompaniment to clinical services for infected individuals). To engage MSM in health-seeking behaviors, the CBO also maintains a web platform where MSM can participate in sexual health forums, find out about LGBT-related events, and catch up on news stories concerning LGBT communities. These web platforms also serve as portals to other websites of interest to MSM, such as social networking sites WeiBo and BF99, movie databases, and gay mobile app sites like Blued and Jack'd.



**Figure 1. Screenshots of the MSM web portal in Beijing, Danlan Gongyi.**

**Appendix 2. Secondary outcomes measured as part of this RCT.**

<b>Secondary Outcome</b>	<b>Definition</b>
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective video interventions (development, start-up, implementation, condom use, intervention – see Table 1 below for details) per individual who reported no sex or sex with a condom during the follow-up period.
<i>Female condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with a woman divided by the total number of men who viewed the video in that arm.
<i>Male condomless sex</i>	Frequency of men, defined as number of men who reported condomless anal sex with a man divided by the total number of men who viewed the video in that arm
<i>Post-video condomless sex</i>	Frequency of men, defined as number of men who reported condomless vaginal or anal sex with any partner immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>Frequency of sex acts</i>	Frequency of men, defined as the number of men who had decreased total number of sex acts in the three weeks following the intervention compared to the three weeks immediately preceding the intervention in that arm
<i>Condom use social norms</i>	Frequency of men, defined as number of men who report higher levels of social norms when comparing their pre-intervention and post-intervention condom use norms*
<i>Condom self-efficacy</i>	Frequency of men, defined as number of men who had an increase in self-efficacy when comparing their pre-intervention and post-intervention self-efficacy**
<i>Condom negotiation</i>	Frequency of men, defined as the number of men who attempted to convince an unwilling partner to use a condom immediately following the video intervention divided by the total number of men who viewed the video in that arm
<i>HIV testing</i>	Frequency of men, defined as the number of men who reported being tested for HIV during the interval between watching the video and following up compared to the number of men who followed up
<i>STI testing</i>	Frequency of men, defined as the number of men who reported being tested for STIs (excluding HIV) during the interval between watching the video and following up compared to the number of men who followed up

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

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

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

<b>Phase</b>	<b>Financial costs</b>	<b>Economic costs</b>
<b>Contest development</b>	<i>Inputs to be captured, can all directly be found in the project financial accounts, main challenge is to allocate across components and to allocate SESH overhead costs</i>	<i>Extra inputs not already captured by financial costs</i>
<b>Video contest (including production)</b>	Money paid for planning and implementation	<p>For social marketing arm:</p> <ul style="list-style-type: none"> <li>• Personnel of CBOs/CDC(director of movie, actors, film editors)</li> <li>• Rental of professional video equipment (if applicable)</li> <li>• Building cost (office renting) for CBOs/CDC*</li> <li>• Equipment and software cost (if applicable) *</li> </ul> <p>For crowdsourced arm:</p> <ul style="list-style-type: none"> <li>• Personnel of SESH (although all volunteer)</li> <li>• Judging opportunity cost (volunteer)</li> <li>• Steering Committee planning meeting (three one-hour meetings)</li> <li>• Building cost (office renting)*</li> <li>• In-person promotion costs</li> </ul>

<b>Survey start up</b>	Money paid to launch the survey (start-up);	<ul style="list-style-type: none"> <li>• SESH personnel costs, to design and maintain the program</li> <li>• Equipment cost of SESH (computer and other items)*</li> <li>• Software (Proof Pilot, Qualtrics)*</li> </ul>
<b>Survey implementation and intervention</b>	Money paid to the participants (implementation); Money paid for the software used for follow up (implementation);	<ul style="list-style-type: none"> <li>• SESH personnel costs</li> </ul>
<b>Testing</b>		<ul style="list-style-type: none"> <li>• Cost for condoms (from CDC)</li> </ul>

\*The cost will be annualized and we will calculate a proportion of the cost to account for them 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 annualization of costs), while the implementation phase has a life only as long as the survey is running.