

Reimagining Health Communication: A Non-Inferiority Randomized Controlled Trial of Crowdsourced intervention in China

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Short Summary: The Crowdsourced intervention was non-inferior to social marketing intervention in promoting condom use with low cost. The two arms also had similar HIV testing rates and other condom-related secondary outcomes

Contributors: JT and CW (Chongyi Wei) conceived the study. JT, CW (Chongyi Wei), WT, JM, CL, and TW designed the methods. WT did the analyses with the input from KM (Katie Mollan), MH and LH. WT drafted the manuscript with inputs from JM, CL, HL, YZ, MH, KM (Katie Mollan), CW (Chongyi Wei) and JT. TW, ST, YQ, BM, ML, BY, WM, DK, LH, BB, FT, LY, RP, KF, SH, CW (Cheng Wang), HZ, PV, KM (Kate M Mitchell), ZC, TT, JB, and NW, WZ and LT also contributed to study design and implementation. All authors critically revised the manuscript.

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Abstract

Background: Crowdsourcing, the process of shifting individual tasks to a large group, may be useful for health communication, making it more people-centered. We aimed to evaluate whether a crowdsourced video is non-inferior to a social marketing video in promoting condom use.

Methods: Men who have sex with men (MSM) (≥ 16 years old, had condomless sex within three months) were recruited and randomly assigned to watch one of the two videos in 2015. The crowdsourced video was developed through an open contest and the social marketing video was designed by using social marketing principles. Participants completed a baseline survey and follow-up surveys at three weeks and three months post-intervention. The outcome was compared with a non-inferiority margin of +10%.

Results: Among the 1173 participants, 907 (77%) and 791 (67%) completed the three-week and three-month follow-ups. At three weeks, condomless sex was reported by 146/434 (33.6%) and 153/473 (32.3%) participants in the crowdsourced and social marketing arms, respectively. The crowdsourced intervention achieved non-inferiority (estimated difference: +1.3%, 95% CI: -4.8 to 7.4%). At three months, 196/376 (52.1%) and 206/415 (49.6%) individuals reported condomless sex in the crowdsourced and social-marketing arms (estimated difference: +2.5%, 95% CI: -4.5 to 9.5%). The two arms also had similar HIV testing rates and other condom-related secondary outcomes.

Conclusions: Our study demonstrates that crowdsourced message is non-inferior to a social marketing intervention in promoting condom use among Chinese MSM. Crowdsourcing contests could have a wider reach than other approaches and create more people-centered intervention tools for HIV control.

Keywords: Condomless sex; Crowdsourcing; Health communication; Men who have sex with men; Randomized Controlled Trial

Introduction

Health communication is the practice of using social media to promote healthy behaviors¹. The explosion of new communication technologies has created new opportunities for promoting health². This explosion is reflected in major public health initiatives focused on enhancing health communication in the United States³ and China⁴. Health communication interventions are especially helpful in improving health knowledge, supporting health services, and spurring behavior change. Health communication has been shown to increase demand for health services, reduce risk behaviors, and improve health service delivery^{5 6}.

Many health communication interventions draw on the concept of social marketing, which is the systematic application of commercial marketing concepts and techniques to the planning, execution, analysis, and evaluation of programs^{7 8}. Companies often use evidence-based social marketing principles to develop health communication intervention tools for health improvement^{7 8}. Social marketing has emerged as a standard method for developing and implementing health communication interventions⁹. However, the social marketing approach has generally been a “top-down” approach, relying mostly on experts¹⁰. This approach may neglect the knowledge, creativity, and power of non-experts. Insufficient community engagement during the development of social marketing campaigns may result in ultimately less appealing and less effective campaigns.

Crowdsourcing, the process of shifting individual tasks to a group, has the potential to overturn the top-down paradigm of corporate health communication projects. Crowdsourcing differs from conventional health communication methods in two ways¹⁰. First, rather than using experts for idea generation, crowdsourcing methods assign idea-generating tasks to the community,

promoting direct community engagement. Second, a crowdsourcing approach can be used to design more effective images, policy, and videos^{10 11}. By using some principles of community-based participatory research (involving members of a study population as active and equal participants in the phases of intervention development), crowdsourcing can tap community wisdom to generate new messages to promote condom use among populations that have been challenging to reach through conventional health communication methods. China provides a favorable setting for evaluating crowdsourcing because of two trends. First, government policies encourage innovation, and specifically crowdsourcing, to improve health¹². Second, China has large populations among second and third-tier cities, providing a range of in-person and online crowds. In addition, most of the current condom promotion strategies in China were only limited to community-based intervention (i.e. distribute condoms in venues)¹³, and promote condom use through social media would be essential.

The purpose of this study was to compare the effectiveness of a crowdsourced video to a social marketing video in promoting condom use among high-risk MSM in China. And a non-inferiority randomized controlled trial was chosen for the following reasons: First, there is a well-established literature on social marketing approaches, and social marketing approach has emerged as a standard method for developing interventions⁹. Second, a previous study proved that crowdsourced video was non-inferior to social marketing intervention in promoting HIV testing among MSM¹⁴, but whether it is also non-inferior to social marketing intervention in promoting condom use is still unclear. Third, the rate of condomless sex is high among MSM in China¹⁵. Specifically, given crowdsourcing is a bottom-up approach¹⁰, it can substantially increase community engagement and reduce stigma^{16 17}. We anticipated that a crowdsourced

intervention has a high likelihood of motivating behavior change among MSM, including condom use.

Materials and Methods

Design

This non-inferiority randomized controlled trial (RCT) evaluated whether a crowdsourced video is non-inferior to a social marketing video in promoting condom use among MSM in China. A control group without a video intervention was not included. The study was conducted between November of 2015 to February of 2016. Prior to participant recruitment, a pilot study with 150 MSM was conducted to evaluate the survey instrument and inform sample size calculation.

The study protocol was approved by Chinese (Guangdong Provincial Centre for Skin Diseases and STI Control) and American (University of North Carolina at Chapel Hill and University of California, San Francisco, No. 15-1522) institutional review boards (Supplement A, Protocol), and has been published¹⁸.

Intervention development

This study used a one-minute crowdsourced video intervention and a social marketing video intervention. The crowdsourced video was developed through a crowdsourcing contest in 2015. The reasons for using crowdsourcing contest include: 1) crowdsourcing method is a bottom-up approach, and it uses some principles of community-based participatory research (CBPR), and it has strong potential to engage the people to participate in; 2) crowdsourcing approach was considered to a time-saving, cost-efficient, and useful approach for getting a variety of potentially compelling and effective health communication messages.¹⁹⁻²¹ We followed the

following steps to develop the crowdsourced intervention. First, the eligibility of the crowdsourced video (one-minute short video, relevant, and has the potential to promote condom use among Chinese MSM) was determined by the organizers, and a call for entry was drafted and discussed. Second, the call for entries was publicized on the group websites (gay websites), and through lectures and interactive feedback sessions at college campuses (introduced the crowdsourcing contest through lectures and answered relevant questions to audiences after the lectures). The call for entries was also shared publicly on WeChat (an instant messaging system similar to Facebook and Twitter, with about 1 billion users). Anyone was eligible (not restricted to MSM) to submit a video, while a prize was only provided to the finalist video. After entries had been collected, a group of expert panel was recruited from public health, business, and research sectors selected the finalist video from all entries, by providing each of the video entries with a score of 1 to 10 (1 = worst, 10 = best). The judges identified the contest winner based on the capacity to reach untested individuals, generate excitement, and community responsiveness. Overall, 11 eligible videos were received and scored. The finalist video emphasized the protective function of condoms by showing a wall protecting against cartoon virus (<http://v.qq.com/x/page/j0171qo8h75.html>). The one-minute social marketing video was shot by a marketing company in Jinan (Shandong, China) following a script was written by social marketing experts in San Francisco (California, USA) and approved by young MSM in the gay community (<http://v.qq.com/x/page/c016616uiyl.html>). This social-marketing video was specifically designed for this study. It emphasized sexual health as love, with two men negotiating on condom use before having sex ¹⁸.

Setting and participants

This is an online RCT, and participants were recruited across China. We partnered with Danlan (Beijing, China), an organization that runs Blued (a gay partner-seeking mobile app with over 27 million users) to recruit the participants online. Banner advertisements were placed on the mobile

app, inviting participants to join the survey. This organization also sent announcements through its social media platforms, WeChat and Weibo. All participants who clicked the link for the survey were screened for eligibility. Inclusion criteria included: born biologically as a male, anal sex with a man at least once during their lifetime, condomless anal or vaginal sex in the last three months, and at least 16 years of age. After meeting the screening criteria, participants were asked to sign the informed consent form electronically and to provide a mobile telephone number (only for follow up purpose) and finish an online baseline survey.

After the baseline survey, eligible participants were randomized in a 1:1 ratio using computer-based randomization in Qualtrics (Provo, Utah, USA). This is a blind study, participant recruitment, randomization, and intervention delivery were all computer-based, and the participants did not know whether the video they watched is a crowdsourced video. After finishing the baseline survey, all eligible participants viewed either the crowdsourced video or the social marketing video (without noticing which video they watched). The videos were embedded in the baseline survey, they have to watch the video before they can submit the survey. They completed three-week and three-month follow-up surveys after video watching to assess their condom use after the intervention.

At three weeks and three months post-intervention, the research group sent each participant a text message with a survey link. The surveys included 30 questions about the primary outcome (condom use) and secondary outcomes. Upon completion of the three-week and three-month post-intervention surveys, participants received a mobile credit valued at \$16 USD (including \$8 USD for the baseline survey) and \$8 USD, respectively.

Outcomes

The primary outcome of this study was self-reported condomless sex with a man or woman in the three weeks and three months after intervention. Secondary outcomes for both three weeks and three months post-intervention included condomless sex with a man, condomless sex with a woman, improvement in condom use social norms, improvement in condom self-efficacy, condom negotiation, HIV testing, and syphilis testing.

The baseline survey collected data on socio-demographic characteristics including age, education, annual income, student status, marital status, self-identified sexual orientation, and disclosure of sexual orientation to healthcare provider(s).

Questions on condom use social norms investigated a participant's perception of their friends' attitudes towards condom use and safe sex. Each participant was asked to answer six survey items (five-point Likert scale: 1=strongly disagree, 5=strongly agree)²². Mean social norm scores were compared to evaluate whether participants experienced a change in social norms after viewing the intervention. Questions on condom use self-efficacy investigated a participant's intent to use condoms, also measured at both baseline and at the three weeks and three months follow-up, using seven survey items each graded on a five-point Likert scale (graded as above)²³. Condom negotiation was defined as an attempt to convince an unwilling partner to use a condom.

Statistical analysis

The sample size for this non-inferiority RCT was determined to assume 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 α of 2.5%, a non-inferiority limit

of 10%, and loss to follow-up of 10%, a total of 1170 individuals was required (585 in each arm) to have 90% power ($1-\beta$).

Participant demographic characteristics and sexual risk behaviors were described in each of the intervention arms. The primary endpoint was evaluated using the difference in proportions between the two arms of participants still engaging in condomless sex within three weeks and three months after either intervention (crowdsourced minus social marketing), with a non-inferiority margin of +10%. The upper limit of a Wald 2-sided 95% confidence interval (CI) was used to evaluate non-inferiority.

For the primary outcome, a complete-case analysis was conducted only for participants who completed the three-week and three-month follow-up surveys. A multiple imputation method was conducted as a sensitivity analysis. Covariates in the imputation model were intervention arm, age group, education, home province, sexual orientation, the number of partners in the last three months (prior to baseline) and condom use during a first sexual encounter with another man. Statistical analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC, USA). Effect modification was assessed using a linear probability model that included an interaction term between intervention arm and the specified covariate. The purpose of the effect modification is to analyze whether the intervention would have a different effect in different subgroups of MSM. The four pre-specified covariates (whether watched a condom promotion video in the last three weeks prior to intervention, whether watched a testing promotion video in the last three weeks prior to intervention, number of male partners in the last three months prior to intervention, and whether were students) were evaluated.

Results were reported following standardized guidelines (Supplement B, CONSORT Checklists). The study was registered with ClinicalTrials.gov (NCT02516930).

Results

Study participants

Overall, the study link was clicked 7892 times. Of these, 341 withdrew from the survey prior to eligibility screening, 5747 did not meet the inclusion criteria, and 194 withdrew before reaching the informed consent, and 413 people did not complete the baseline survey. From the 1197 people who finished our online survey, 24 people were further excluded (5 duplicates, and 19 invalids). Of the remaining 1173 individuals, 578 and 595 were randomly assigned to either the crowdsourced or the social marketing intervention group (Figure 1). Of the 1173 participants, 907 (77%) completed our three-week follow-up online survey, and 791 (67%) completed our three-month follow-up online survey. The response rate was comparable in both arms. The participants who responded to follow-up were similar to those who did not at three weeks, except marital status and sexual orientation (Supplement C).

Overall, participants were recruited from 269 cities in 32 provinces of China. Of the 1173 participants, the majority were over 20 years old (71%), never married (83%), and had an annual income less than \$15000 United States dollars (USD) (94%). Most of the participants self-identified as homosexual (70%) and over a third were students (36%). All participants identified as men and no participant identified as transgender. Demographics and behaviors were similar between the two intervention arms (Table 1).

Primary condom use outcome

Of the 907 respondents at three weeks, 299 (33%) reported engaging in condomless sex in the three weeks after watching their assigned condom promotion video. In the crowdsourced video arm, 146 of 434 (33.6%) reported condomless sex compared to 153 of 473 (32.3%) in the social marketing video arm. For the complete-case analysis (907 respondents), the estimated difference in proportions between arms was +1.3% (CI: -4.8%, 7.4%). The estimated difference in imputation analysis was +1.3% (95% CI: -4.1%, 6.6%) (Figure 2).

Of the 791 respondents at three months, 537 (68.0%) reported engaging in sex with male only, 28 (3.5%) reported engaged in sex with female only, and 65 (8.2%) reported engaging in sex with both male and female. 402 (50.8%) reported engaging in condomless sex after watching their assigned condom use promotion video. Among the 365 people who reported engaged in condomless sex with male partner in the past three months, 245 (67.1%) engaged in condomless sex with regular partner only, 83 (22.7%) engaged in condomless sex with casual partner only, and 37 (10.1%) engaged in condomless sex with both regular and casual partners. In addition, 58 men engaged in condomless sex with female partners in the last three months. In the crowdsourced video arm, 196 of 376 (52.1%) reported condomless sex compared to 206 of 415 (49.6%) in the social marketing video arm. For the complete-case analysis, the estimated difference in proportions between arms was +2.5% (95% CI: -4.5%, 9.5%, the non-inferiority criteria were met. No significant modification of the intervention effect was observed (Supplement D).

Secondary outcomes at three weeks

For the complete-case analysis, the estimated differences in proportion of condomless sex with a male or female partner between arms were +0.7% (95% CI: -5.2%, 6.6%) and +2.3% (95% CI: -0.8%, 5.3%) for the crowdsourced arm and social marketing arms, respectively (Figure 3).

The complete-case analysis showed that the estimated differences between the two intervention arms for condom social norms and condom use self-efficacy, respectively, were +1.0% (95% CI: -5.6%, 7.5%) and +5.6% (95% CI: -1.1%, 12.0%). The post-intervention condom negotiation rates were also similar between the two intervention arms, with a difference of -3.3% (95% CI: -9.8%, 3.2%). The estimated differences in proportions for HIV and syphilis testing between arms from the complete-case analysis were -0.7% (95% CI: -5.6%, 4.3%) and +2.4% (95% CI: -1.9%, 6.6%), respectively.

The secondary outcomes investigated at three months post-intervention are listed in Supplement E. They were similar to those at three weeks post-intervention. At three weeks and three months post-intervention, consistent increased mean total scores for condom use social norm and condom use self-efficacy were observed (Supplement F). Supplement F also indicated that there was no interaction between the other videos watching and the intervention on promoting condom use.

Discussion

This RCT demonstrated that a crowdsourced video was not inferior to a social marketing video in promoting condom use among high-risk MSM in China. Promoting condom use among MSM is challenging²⁴. However, by engaging the community in developing novel and creative solutions,²⁵ crowdsourcing has the potential to create effective interventions that are more

acceptable to the community²⁶. Our study extends previous research in condom use promotion among MSM by using crowdsourcing, recruiting only high-risk MSM at greatest risk for HIV, and evaluating both short- and medium-term effects of the intervention.

Our results showed that the video developed through crowdsourcing contest was not inferior to the social marketing video in promoting condom use. This finding is consistent with the sparse literature on using crowdsourcing as a health communications tool for intervention development²⁵. However, the previous study indicated that health communication tools such as video interventions usually have short-term effects, observable immediately after viewing²⁷. One potential method to increase the effect duration is to deliver the intervention through social media platforms more frequently. In addition, since all participants engaged in condomless sex within three months prior to the intervention, and about half of them consistently used condom within three months after the intervention, indicated that both interventions successfully increased condom use among Chinese MSM.

At three months post-intervention, we also found evidence of persistent effects from the crowdsourced intervention, both in the primary outcome (with roughly half of the participants engaging in condomless sex in the three-month post-intervention) and some secondary outcomes, including condom use self-efficacy and social norms total scores. This was especially important, considering the inclusion criteria for our study required participants to have had condomless sex in the three months prior to the study. Our results were promising in terms of the long-term effectiveness of a crowdsourced intervention. However, further research would be useful to determine the optimal frequency of campaigns.

This study has several policy and implementation implications. First, crowdsourcing contests are adaptable to many settings to develop local health campaigns. The multi-sectoral networks and infrastructure necessary for the implementation of such contests are commonly found in a wide range of low- and middle-income countries. By using such networks, crowdsourcing can be used to collect wisdom from large numbers of people to develop health communication tools that are responsive to local challenges. Furthermore, the crowdsourcing contest model used in this study and models using networks could be useful in settings where civil society organizations are constrained or less able to inform public health programs directly⁷.

Three potential limitations of our study merit discussion. First, the self-selection processes for trial participation itself is an intervention. Especially, the recruited participants were primarily MSM who were young and well educated²⁸, cannot represent all MSM in China, and even cannot represent the registered gay dating app users. However, we anticipated that the bias of the self-selection process would be balanced between the two intervention groups. Second, one-third of participants were lost to follow-up at three months, which could have introduced a selection bias. However, both those who did and did not respond to the follow-up survey were similar in socio-demographic and sexual risk behaviors, and the imputation results accounting for non-response closely matched the complete case data. Third, all the behaviors measured in our study were self-reported, and social desirability bias may be a concern. However, since all of the surveys conducted in our study were computer based²⁹, we anticipated that the strength of this bias was minimal. Fourth, some of our assumptions for sample size calculation (10% loss to follow-up) was not met, as around one-third of the participants lost to follow up in three months. This may reduce the power of the currently reported study. However, based on the remaining samples, our

study did achieve a non-inferiority. Fifth, the sample size calculation was based on the primary outcome and may do not have enough power to detect the effect of modification.

Conclusions

While our study demonstrates that a crowdsourced video is non-inferior to social marketing tool in promoting condom use among Chinese MSM, research on crowdsourcing is still very limited. Future studies on crowdsourcing implementation should aim to refine crowdsourcing methods, employ versatile strategies to promote crowdsourcing contests, and induce and sustain community engagement during the entire crowdsourcing process. In addition, studies to evaluate the long-term effects of multiple crowdsourcing communication tools will be critical, as the effect of a single message intervention is very likely to fade over time.³⁰

Abbreviations

CI: confidence interval

MSM: Men who have sex with men

RCT: randomized controlled trial

STI: Sexually transmitted infection

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Licence statement: The original dataset of this study is free to share with anyone, and we have included a de-identified dataset for all the readers (Supplement G).

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Figure Legend

Figure 1. Study cohort (n=1173).

Figure 2 Non-inferiority analysis of the RCT in China, 2015 (n = 1173)

Figure 3. Non-inferiority analysis of secondary outcome at three weeks post-intervention of RCT in China, 2015 (n = 907).

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Supplement legend

Supplement A. Protocol

Supplement B. CONSORT Checklist

Supplement C. Comparison of Socio-demographic and Sexual Risk Behaviours between Participants Who Did and Did Not Respond to Three Weeks Follow-up Survey in China, 2015 (n=1173)

Supplement D. Effect Modification Analysis of Crowdsourced and Social Marketing Interventions in RCT in China at Three Weeks Post-intervention, 2015 (n=907)

Supplement E. Secondary Outcomes of RCT at Three Months in China, 2015 (n =791)

Supplement F. Total Scales for Social Norm* and Self-efficacy[#] at Baseline, Three weeks and Three months among Chinese MSM, 2015

Note: *A total score for social norms was calculated at baseline and for both follow-up surveys at three-week and three-month post-intervention for all the six survey items (five-point Likert scale: 1=strongly disagree, 5=strongly agree); [#] A total score for self-efficacy was calculated to reflect the condom use self-efficacy of the participants at baseline and for both follow-up surveys for all the seven survey items (five-point Likert scale: 1=strongly disagree, 5=strongly

Figure 1

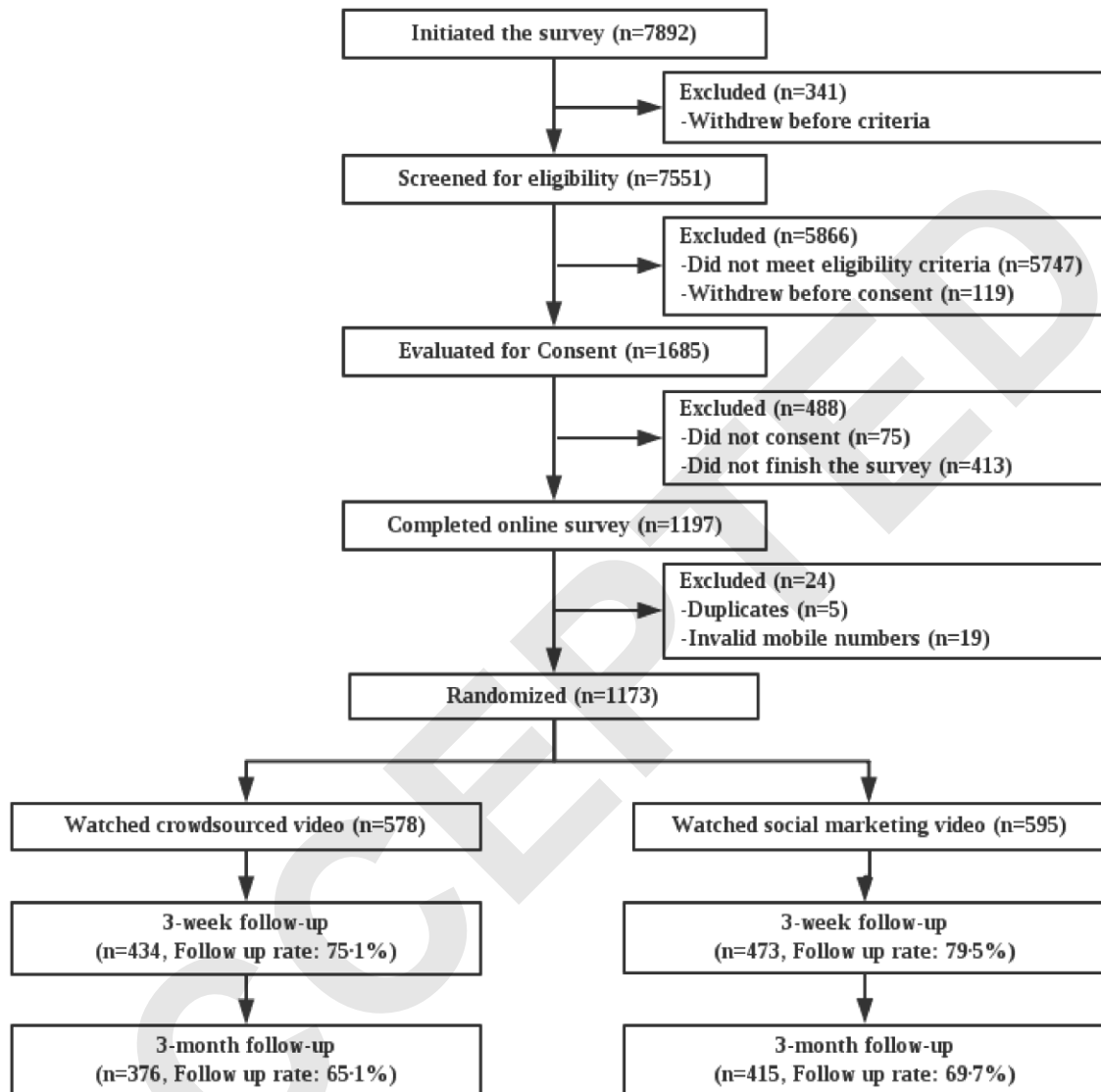
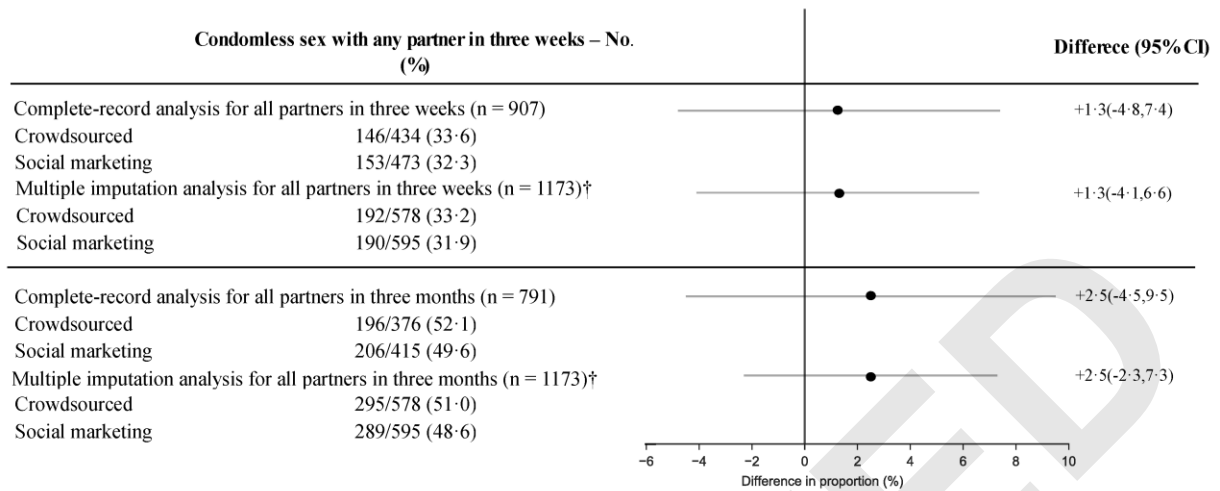


Figure 2



ACCEPTED

Figure 3

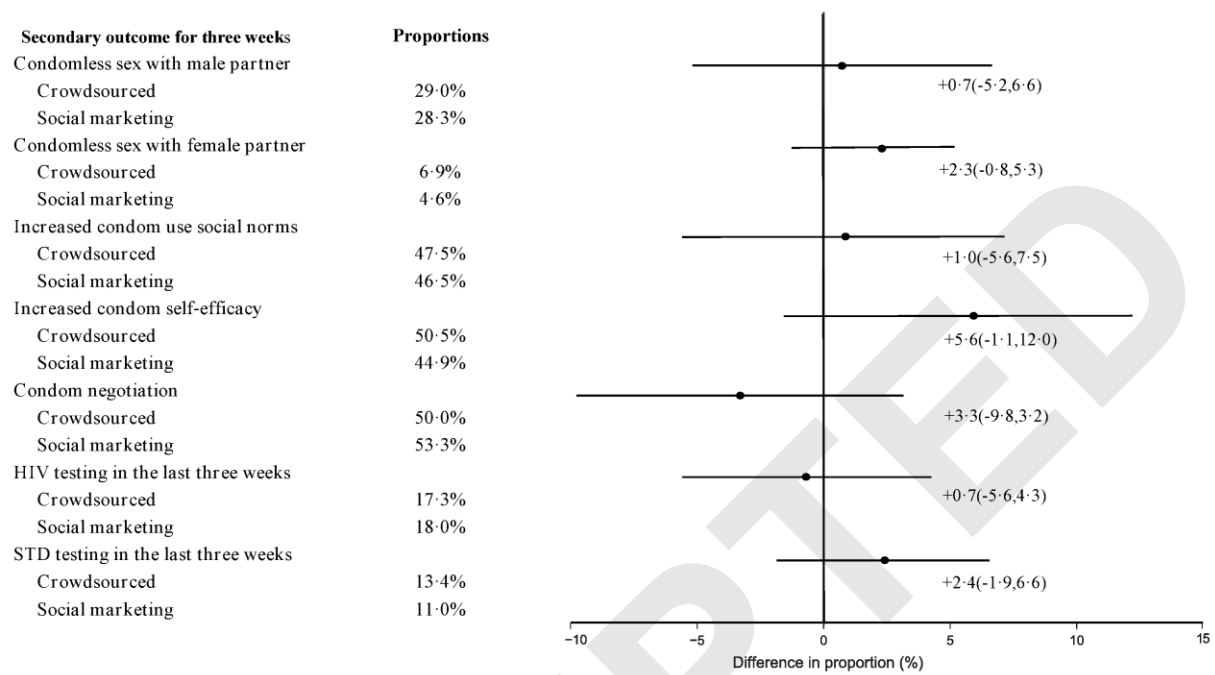


Table 1. Baseline characteristics of study participants recruited into the RCT in China, 2015 (n=1173) *.

		Crowdsourcing (n=578)	Social Marketing (n=595)
Age (years)	16-20	170(29%)	168(28%)
	21-25	200(35%)	221(37%)
	Over 25	208(36%)	206(35%)
Marital status	Never married	473(82%)	504(85%)
	Ever married	105(18%)	91(15%)
Education	High school or below	174(30%)	214(36%)
	College	164(28%)	140(24%)
	Graduate education	240(42%)	241(41%)
Annual income (USD)	5,000 or less	314(54%)	322(54%)
	5001-15000	228(39%)	237(40%)
	>15000	36(6%)	36(6%)
Sexual orientation	Homosexual	412(71%)	414(70%)
	Bisexual	166(29%)	181(30%)
Student	Yes	217(38%)	209(35%)
	No	361(62%)	386(65%)
Disclosure of sexual orientation to health providers	Yes	180(31%)	188(32%)
	No	398(69%)	407(68%)
Gender of first sexual partner	Male	497(86%)	517(87%)
	Female	81(14%)	78(13%)
Used condom during first sexual encounter with another man	Yes	274(47%)	294(49%)
	No	304(53%)	301(51%)
Number of male partners in the last three months	0 partners	21(4%)	29(5%)
	1 partner	266(46%)	277(46%)
	2 or more	291(50%)	289(49%)
Have primary male partner in the last three months§	Yes	410(73%)	419(73%)
	No	151(27%)	153(27%)
Have casual male partner in the last three months§	Yes	293(50%)	309(54%)
	No	268(48%)	263(46%)

*Baseline characteristics are shown for individuals who had cond

omless sex in the last three months and were thus eligible for the randomized video intervention.

§40 participants had no male partners in the last three months at baseline

Supplements

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ACCEPTED

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

12 September 2015

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

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Funding support: National Institutes of Health (NIAID 1R01AI114310-01), UNC-South China STD Research Training Center (FIC 1D43TW009532-01), UNC Center for AIDS Research (NIAID 5P30AI050410-13), UCSF Center for AIDS Research (NIAID P30 AI027763), NIMH (R00MH093201), UJMT Fogarty Fellowship (FIC R25TW0093), and SESH Global (www.seshglobal.org). Administrative assistance from the Guangdong Provincial Center for Skin Diseases and STI Control. UNC Chapel Hill, ProofPilot, and UNC Project-China in Guangzhou, China.

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)^{1,2}, men who have sex with men (MSM) practice inconsistent condom use in China.³⁻⁶ The resulting high incidence of HIV and STDs among MSM suggests the need for novel health promotion campaigns. One systematic review⁷ and one literature review among MSM⁸ 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.⁹ 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.¹⁰ 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.¹¹ Experimental research demonstrates that cognitive fixation is a pervasive impediment to developing novel ideas.¹²⁻¹⁶ People gravitate towards ideas that bear structural and technical resemblance to prior examples,^{14,17} resulting in less creative ideas. Our team has used crowdsourcing to develop an effective HIV testing promotion video¹⁸ and images promoting sexual health.¹⁹

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). 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 surveys²⁰ 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.,

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

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 (α) of 2.5% and power ($1-\beta$) of 90%.²¹ 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 π_s and π_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 Φ^{-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 control group*	Probability of primary outcome in experimental group*	Non-inferiority limit	Probability of loss to follow-up £	N evaluable per arm	Total sample size for RCT
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: *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.

£ 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.

ACCEPTED



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

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

Secondary Outcome	Definition
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective video interventions (development, start-up, implementation, condom use, intervention – see Table 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.

ACCEPTED

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

Phase	Financial costs	Economic costs
Contest development	<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>
Video contest (including production)	Money paid for planning and implementation	<p>For social marketing arm:</p> <ul style="list-style-type: none"> • Personnel of CBOs/CDC(director of movie, actors, film editors) • Rental of professional video equipment (if applicable) • Building cost (office renting) for CBOs/CDC* • Equipment and software cost (if applicable) * <p>For crowdsourced arm:</p> <ul style="list-style-type: none"> • Personnel of SESH (although all volunteer) • Judging opportunity cost (volunteer) • Steering Committee planning meeting (three one-hour meetings) • Building cost (office renting)* • In-person promotion costs
Survey start up	Money paid to launch the survey (start-up);	<ul style="list-style-type: none"> • SESH personnel costs, to design and maintain the program • Equipment cost of SESH (computer and other items)* • Software (Proof Pilot, Qualtrics)*
Survey implementation and intervention	<p>Money paid to the participants (implementation);</p> <p>Money paid for the software used for follow up (implementation);</p>	<ul style="list-style-type: none"> • SESH personnel costs

Testing		<ul style="list-style-type: none">• Cost for condoms (from CDC)
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*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.

ACCEPTED

Supplement B, CONSORT Checklist

CONSORT Statement 2006 - Checklist for Non-inferiority and Equivalence Trials



Items to include when reporting a non-inferiority or equivalence randomized trial

<i>PAPER SECTION</i> And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned"), <i>specifying that the trial is a non-inferiority or equivalence trial.</i>	1,3
<i>INTRODUCTION</i> Background	2	Scientific background and explanation of rationale, <i>including the rationale for using a non-inferiority or equivalence design.</i>	4
<i>METHODS</i> Participants	3	Eligibility criteria for participants (<i>detailing whether participants in the non-inferiority or equivalence trial are similar to those in any trial(s) that established efficacy of the reference treatment</i>) and the settings and locations where the data were collected.	6
Interventions	4	Precise details of the interventions intended for each group <i>detailing whether the reference treatment in the non-inferiority or equivalence trial is identical (or very similar) to that in any trial(s) that established efficacy</i> , and how and when they were actually administered.	6
Objectives	5	Specific objectives and hypotheses, <i>including the hypothesis concerning non-inferiority or equivalence.</i>	5
Outcomes	6	Clearly defined primary and secondary outcome measures <i>detailing whether the outcomes in the non-inferiority or equivalence trial are identical (or very similar) to those in any trial(s) that established efficacy of the reference treatment</i> and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	7

Sample size	7	How sample size was determined <i>detailing whether it was calculated using a non-inferiority or equivalence criterion and specifying the margin of equivalence with the rationale for its choice</i> . When applicable, explanation of any interim analyses and stopping rules (<i>and whether related to a non-inferiority or equivalence hypothesis</i>).	8
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)	6
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	6
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	6
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s), <i>specifying whether a one or two-sided confidence interval approach was used</i> . Methods for additional analyses, such as subgroup analyses and adjusted analyses.	8,9
RESULT S Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	9
Recruitment	14	Dates defining the periods of recruitment and follow-up.	9
Baseline data	15	Baseline demographic and clinical characteristics of each group.	10
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was <i>"intention-to-treat" and/or alternative analyses were conducted</i> . State the results in absolute numbers when	9

		feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval). <i>For the outcome(s) for which non-inferiority or equivalence is hypothesized, a figure showing confidence intervals and margins of equivalence may be useful.</i>	9,10
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	9,10
Adverse events	19	All important adverse events or side effects in each intervention group.	
<i>DISCUSSION</i> Interpretation	20	Interpretation of the results, taking into account the <i>non-inferiority or equivalence hypothesis and any other study hypotheses</i> , sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	11-13
Generalizability	21	Generalizability (external validity) of the trial findings.	13
Overall evidence	22	General interpretation of the results in the context of current evidence.	13

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Supplement C. Comparison of socio-demographic and sexual risk behaviours between participants who did and did not respond to 3-week follow-up survey (n=1173)

Characteristics		Responded to follow-up (n=907)		Did not respond to follow-up (n=266)		X ² Test (p-value)
		Frequency	Percent	Frequency	Percent	
Age (years)	16-20	266	29	67	25	6.01 (0.05)
	21-25	333	37	88	33	
	Over 25	303	34	111	42	
Marital status	Never married	770	85	207	78	7.40 (0.01)
	Ever married	137	15	59	22	
Education	High school or below	293	32	95	36	2.89 (0.24)
	College	573	63	160	60	
	Graduate education	41	5	11	4	
Annual income (USD)	5,000 or less	496	55	140	53	0.89 (0.64)
	5001-15,000	359	40	106	40	
	>15,000	52	6	20	8	
Sexual orientation	Homosexual	657	72	169	64	7.83 (0.01)
	Bisexual	250	28	97	36	
Student	Yes	339	37	87	33	1.94 (0.16)
	No	568	63	179	67	
Disclosure of sexual orientation to health providers	Yes	292	32	76	29	1.25 (0.26)
	No	615	68	190	71	
Condomless sex in the last month	Yes, anal	210	23	59	22	1.05 (0.59)
	Yes, vaginal	18	2	8	3	
	No	685	76	203	76	
Number of male partners in the last three months	0 partners	39	4	6	2	3.02 (0.22)
	1 partner	412	45	131	49	
	2 or more	456	50	129	49	
Sex while drunk	Yes	122	13	40	15	0.44 (0.501)
	No	785	87	226	85	
Group Sex	Yes	87	10	26	10	0.01 (0.93)
	No	820	90	240	90	

Supplementary D. Effect modification analysis of crowdsourced and social marketing interventions in RCT in China in three-week post-intervention, 2015 (n=907). *

Subgroup	Crowdsourced condomless sex/Total (%)	Social Marketing condomless sex /Total (%)	Difference in proportions (95% CI)	P value for interaction †
Condom Promotion Video Watching in the last three weeks prior to intervention				
Yes	39/131 (29.8)	28/106 (26.4)	3.4 (-8.1, 14.8)	0.76
No	107/303 (35.3)	125/367 (34.1)	1.3 (-6.0, 8.5)	--
HIV Testing Promotion Video Watching in the last three weeks prior to intervention				
Yes	49/150 (32.7)	43/137 (31.4)	1.3 (-9.5, 12.1)	0.98
No	97/284 (34.2)	110/336 (32.7)	1.4 (-6.0, 8.9)	--
Number of male partners in the last three months prior to intervention				
One or none	76/211 (36.0)	77/245 (31.4)	4.6 (-4.1, 13.3)	0.30
Two or more	70/223 (31.4)	76/228 (33.3)	-1.9 (-10.6, 6.7)	--
Student				
Yes	47/167 (28.1)	48/172 (27.9)	0.2 (-9.3, 9.8)	0.76
No	99/267 (37.1)	105/301 (34.9)	2.2 (-5.7, 10.1)	--

* Linear probability model fit using maximum likelihood estimation was used to assess the effect of video intervention upon the proportion having condomless sex by pre-specified subgroups † Wald test

Supplementary E. Secondary outcome of RCT in three-month in China, 2015 (n =791).*

Video	Yes– No. (%)	Difference in proportions (%)	95% CI (%)
Condomless sex with male partner			
Crowdsourced	175/376 (46.5)	+0.7	(-6.2, 7.7)
Social marketing	190/415 (45.8)		
Condomless sex with female partner			
Crowdsourced	32/376 (8.5)	+2.2	(-1.4, 5.9)
Social marketing	26/415 (6.3)		
Increased condom uses social norms			
Crowdsourced	204/376 (54.3)	+3.6	(-2.1, 11.8)
Social marketing	205/415 (49.4)		
Increased condom self-efficacy			
Crowdsourced	193/376 (51.3)	+3.6	(-5.8, 8.2)
Social marketing	208/415 (50.1)		
Condom negotiation			
Crowdsourced	248/376 (66.0)	+3.8	(-2.9, 10.5)
Social marketing	258/415 (62.2)		
HIV testing in the last three months			
Crowdsourced	143/376 (38.0)	+3.5	(-3.1, 10.3)
Social marketing	143/415 (34.5)		
STD testing in the last three months			
Crowdsourced	85/376 (22.6)	+0.4	(-5.4, 6.3)
Social marketing	92/415 (22.2)		

* Non-inferiority analysis assessed the difference in proportions between crowdsourced and social marketing interventions.

Supplement F, Total scales for social norm and self-efficacy at baseline, three-weeks and three months among Chinese MSM, 2015

