

**Crowdsourcing to Promote HIV Testing: A Pragmatic Stepped Wedge Randomized
Controlled Trial to Evaluate Promoting HIV Testing in China**

Study Protocol

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1 List of Abbreviations

CBO	Community-based organization
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
GD	Guangdong Province
GEE	Generalized estimating equations
GLMM	Generalized linear mixed models
HIVST	HIV self-testing
MSM	Men who have sex with men
RCT	Randomized controlled trial
SD	Shandong Province
SESH	Social Entrepreneurship for Sexual Health Group
SMS	Short Message Service text message

2 Summary

Crowdsourcing may be a useful tool for spurring innovation in HIV test promotion campaigns. Crowdsourcing is the process of shifting a task from an individual to a group, often in the form of an open contest. The purpose of this stepped wedge randomized controlled trial is to evaluate the effectiveness of a crowdsourced intervention on promoting HIV testing among Chinese MSM. The crowdsourced intervention will include an open contest, judging to determine finalists and prizes, a designathon, and contest-based MSM engagement. The hypothesis is that a crowdsourced intervention will be superior to conventional HIV test uptake campaigns in eliciting HIV test uptake.

3 Introduction

3.1 Background

Key population HIV testing, especially among young key populations, is urgently needed.¹ However, many young key populations are not well reached by conventional HIV testing campaigns. Operational research has demonstrated that many HIV testing campaigns do not reach them.² This is the case in China where approximately 40% of men who have sex with men (MSM) have never received HIV testing.³ Low levels of MSM community engagement,

hesitancy to access facility-based services, and low trust in facility-based services all constrain MSM HIV testing programs in China.⁴

Preliminary data from our team suggests that crowdsourcing may be a useful tool to overcome these challenges and increase HIV test uptake among MSM.⁵ An online RCT found that 37% of MSM without any HIV test experience who viewed a crowdsourced video subsequently reported receiving first-time HIV testing within one month.⁶ Qualitative data from our research group has shown that crowdsourcing contests empower individuals and result in a range of community engagement.⁷

3.2 *Specific Aims and Hypotheses*

Specific Aim 1: To compare HIV test uptake associated with a crowdsourced intervention to that associated with conventional HIV test uptake campaigns.

Hypothesis 1: A crowdsourced intervention is superior in eliciting HIV test uptake compared to conventional HIV test uptake campaigns.

Specific Aim 2: To compare secondary outcomes (including incremental cost, condom use, HIV testing social norms, syphilis testing, etc.) of a crowdsourced intervention to those of conventional HIV test uptake campaigns.

Hypothesis 2: A crowdsourced intervention is superior in promoting a range of healthy behaviors and HIV testing social norms.

4 Trial Design

4.1 *Type of Trial*

This study will use an adaptation of the stepped wedge randomized controlled trial (RCT) design (Figure 1). In the stepped wedge RCT, study sites are randomized to begin the intervention at different times so that by the end of the study period all sites have initiated the intervention. A total of eight major metropolitan cities - four from Guangzhou Province (Guangzhou, Jiangmen, Zhuhai, Shenzhen) and four from Shandong Province (Yantai, Jinan, Qingdao, Jining) - will implement the crowdsourced intervention. These cities were chosen based on the following criteria: 1) previous CDC MSM sentinel surveillance site; 2) capacity

for campaign implementation; 3) capacity for intervention implementation at community level. Four cities (Guangzhou, Shenzhen in Guangdong Province, Qingdao, and Jinan in Shandong Province) will implement more intensive in-person events to promote engagement during the intervention development phase. Intervention development and implementation are described in detail in later sections.

4.2 Rationale for Trial Design

A number of factors influenced our decision to adopt a pragmatic stepped wedge RCT design. Unlike a tightly controlled explanatory trial, a pragmatic trial evaluates an intervention in a real life context. We aim to understand whether crowdsourced interventions work in the range of local settings. A pragmatic design allows us to examine this intervention in eight different cities. In addition, two previous studies demonstrate that crowdsourcing can enhance HIV interventions among MSM.^{6,8} Given that we will recruit MSM with a known high risk of acquiring HIV infection, withholding our intervention to a subgroup of participants would be difficult. A stepped wedge RCT design addresses this ethical concern by ensuring all participants receive the intervention.

4.3 Randomization and Stratification

The eight cities will be randomized to initiate intervention in groups of two at three-month intervals (Figure 1). The order of intervention implementation at four cities within each province (Guangdong and Shandong Provinces) will be randomized using SAS software. One city in Guangdong Province and one city in Shandong Province will then begin intervention simultaneously, i.e. city-level randomization will be stratified by province. While waiting to initiate the intervention, cities will continue conventional campaigns that are part of the routine activities of local CDC and CBOs.

Figure 1. Stepped-wedge study design

Phase Months	Prep.			Intervention												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CDC surveillance survey																
Develop intervention and recruit online cohort in 8 cities																
Guangzhou (GD)				*			*			*			*			*
Yantai (SD)				*			*			*			*			*
Jiangmen (GD)				*			*			*			*			*
Jinan (SD)				*			*			*			*			*
Zhuhai (GD)				*			*			*			*			*
Qingdao (SD)				*			*			*			*			*
Shenzhen (GD)				*			*			*			*			*
Jining (SD)				*			*			*			*			*

*represents online survey at baseline and every 3 months thereafter. Gray shading represents roll-out of the intervention. 8 city clusters; 5 time periods; randomization stratified by 2 provinces (Guangdong, Shandong)

5 Trial Population and Measures

5.1 Eligibility

Eligibility criteria will include: currently living and planning to live in the eight cities for the next 12 months; not living with HIV; no HIV test in the past three months; born biologically male and identify as either male or transgender; had oral or anal sex with men at least once during their lifetime; 16 years and older; willing to provide cell phone number (for follow up and incentive delivery purposes); completed the informed consent document. MSM who meet all other eligibility criteria but received testing in the past three months or living with HIV will be invited to complete a single survey, but not followed over time in the cohort.

5.2 Recruitment

5.2.1 Online Recruitment

We will build our questionnaire on Sojump Survey Software (Sojump, Shanghai, China). Men will enter the study through website and social media banner/word advertisements, yet only those who lived in the 8 study cities could launch the questionnaire with the survey platform's IP address restriction function. China's largest gay app, BlueD, will be used to target recruitment within the eight cities. Eligible men will be invited to join the online cohort. No names or addresses will be collected from participants. In addition to the direct recruitment through websites and social media advertisements, participating individuals will be invited to refer up to three friends from their social networks, and 10 RMB will be given to them as incentive for each eligible participants they successfully invited. All individuals who enroll in the study will receive a 50 RMB (8.50 USD) pre-paid cell phone card for the first follow up and 50 RMB for each subsequent follow up. Those who complete all surveys will be given an opportunity to win an iPad mini. Surveys will be given at baseline and every three months thereafter (Figure 1).

5.2.2 CDC Data Collection

MSM surveillance sites in each of the eight cities will have additional questions added about viewing SESH images, social media engagement with SESH, contributing to SESH contests,

exposure to other ongoing campaigns, HIV/syphilis testing, HIV/syphilis test results. All men who enter surveillance sites in these cities will also be invited to take part in the online cohort. Following informed consent, cell phone numbers will be used to link CDC and online survey data sets.

5.3 Measures

Information on socio-demographics, sexual behaviors, and psychosocial conditions will be collected using standardized online survey tools. Socio-demographic characteristics include participants' age, highest level of education completed, annual income, marital status, sexual orientation, and sexual orientation disclosure. Behavioral and psychosocial variables include self-reported HIV testing, syphilis testing, HIV self-testing, HIV test-associated stigma, frequency of sex, condom use (condomless sex, sex always with condom, and no sex), HIV testing social norms, HIV testing self-efficacy, community engagement, campaign engagement, MSM empowerment.

6 Intervention

6.1 Intervention Development

The intervention will be developed from a nationwide crowdsourcing contest and a designathon (Figure 2). The crowdsourcing contest will generate intervention materials that will later be packaged via the designathon into core elements of an HIV testing campaign. This ensures crowd wisdom is utilized through the entire intervention, from idea generation to campaign implementation.

6.1.1 Crowdsourcing contest

The first part of the crowdsourcing contest will be an open call for concepts (< 500 characters) or images (photographs, posters, drawings, etc.) promoting HIV testing among young men in China. This open call will be announced on social media platforms nationwide. Social media promotion will include QQ, Weibo, WeChat announcements and short videos explaining the contest from SESH and our community partners in each city (CBOs and student groups interested in HIV testing). Social media will also serve as a channel for announcing prizes, deadlines, and other relevant information. Four cities (Guangzhou, Shenzhen in Guangdong Province, Qingdao, and Jinan in Shandong Province) will

implement in-person events in addition to social media promotion. In-person events will include community-based introductions, interactive feedback sessions, and community-driven events (decided by community partners). Multiple incentives, including chances to win an iPad Mini, cash, post cards, etc., will be included to encourage contest participation.

Crowdsourced entries will be evaluated by a crowd panel and an expert panel. The crowd panel consists of MSM from each of the eight cities while the expert panel consists of professionals from CDC, CBOs, and universities in the eight cities. These local panels increase the likelihood that local preferences would be incorporated, which may facilitate later implementation. The quality of crowdsourced ideas will be judged based on four established dimensions: novelty, relevance, feasibility, and elaboration. Judges will consider the four dimensions and score an entry on a 10-point scale. Given that a large number of judges evaluating a relatively small number of entries have been shown to be internally consistent and externally valid, each judge in our contest will evaluate no more than 20 entries. Based on the number of entries, we will ensure enough judges are recruited so that each entry has at least three independent ratings. Following these judging criteria, all entries will first be screened to check for relevance to our contest and plagiarism. Next, 40 concepts and/or images will be identified by the crowd panel and expert panel. Scores from the expert panel will be used to announce contest winners. All 40 concepts and/or images will be recognized as finalist entries and be presented as materials for the designathon. The crowdsourcing contest and judging are planned to span a three-month period.

6.1.2 Designathon

The designathon will use finalist concepts and/or images to develop core elements of an HIV testing campaign. A designathon is similar to a hackathon,^{9,10} but focused instead on designing a campaign. Teams are formed with an emphasis on multi-sectoral partnership. Each team consists of one CDC worker and one MSM CBO leader from each of the eight cities as well as three participants selected from a nationwide application. A group of mentors from communication, design, social work, and public health background will also be available for consultation to all teams. Teams will have 72 hours to brainstorm and generate a written intervention plan that incorporates concepts and images from the crowdsourcing contest. A group of judges will evaluate team entries and select design elements to be included in a final, HIV test promotion campaign. Winners will be recognized with awards.

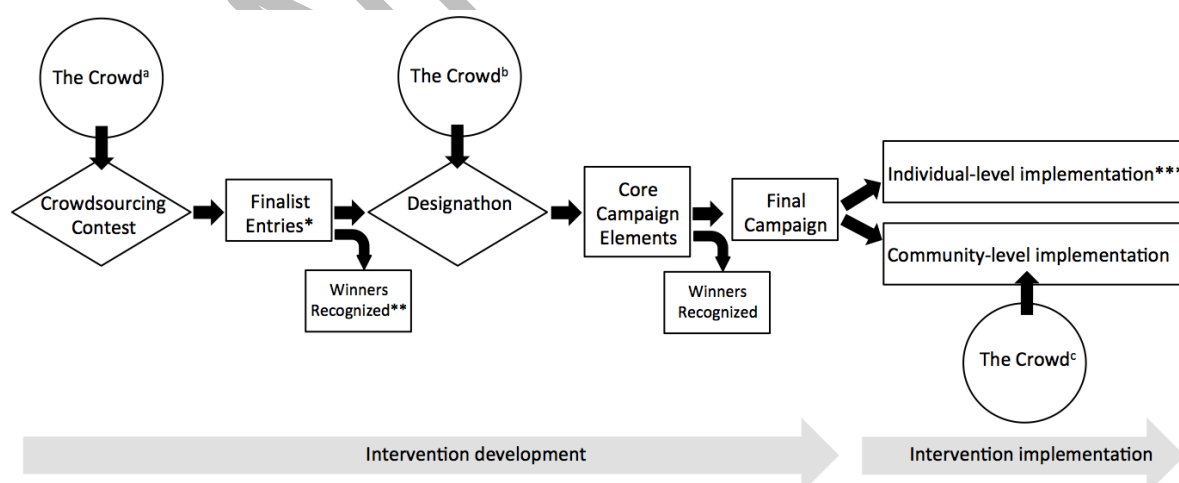
The final campaign will be implemented at both the individual and community levels using social media, in-person events, and other crowdsourced ideas for implementation. After the RCT is complete, we will launch an image bank that allows free access to images/taglines/concepts developed as part of the contest.

6.2 Intervention Implementation

Phased implementation will be carried out in the eight cities following the stepped wedge RCT design (Figure 1). Implementation in each city will be locally adapted based on crowd feedback from the contest and the designathon. The intervention will be implemented at the individual level (via WeChat messages and SMS) and at the community level (via community partners including CDC, CBOs, and social media influencers) (Figure 2).

For individual-level implementation, the campaign content (images and/or concepts) will first be shown to the online cohort at the end of the baseline survey, and then repeated once every two weeks for the next three months. Half of the online cohort will receive the campaign content via WeChat message while the other half will receive the campaign content via SMS text message. For community-level implementation, community partners in each city will facilitate the campaign using crowdsourced implementation ideas generated from the designathon.

Figure 2. Schematic diagram of intervention development and implementation.



*Finalist entries will be selected after an initial screening followed by crowd panel and expert panel judging (Detailed under “Crowdsourcing contest”).

**Crowdsourcing contest winners will be selected based on expert panel scores.

***Individual-level implementation will be divided based on delivery method into two groups: intervention via WeChat message vs. intervention via SMS text message.

a: Crowd involvement in crowdsourcing contest consists of a nationwide, open call for submission of concepts and/or images related to promoting HIV testing among untested individuals.

- b: Crowd involvement in designathon consists of multi-sectoral team members working with guidance from professionals to design an intervention plan.
- c: Crowd involvement in community-level implementation entails participation in contests and campaign events held by local CDC and CBOs.

HIV self-testing intervention

SESH implementation team will send out cohort participants an invitation of receiving free HIV testing kit through a confidential message on social media. Our research team had friended the participants on social media (WeChat) which allows private interaction with them. Individuals who would like to receive this test kit will be directed to an online form that allows them to provide an alias (not their real name), an address, and their cell phone number. These three identifiers will be stored separately in Guangzhou in a locked cabinet. Our research assistant will identify the cohort participants by checking whether the mobile phone number is registered in our baseline survey. Men who provide their address will have a test kit mailed to them. The HIV self-testing package will be sent to participants. The HIV self-test kit is organized in partnership with Guangzhou Tongzhi (GZTZ), a local CBO. The test kits will be offered by SESH. The cover of the mail box will be labeled as “gift”. The mail boxes will be delivered by a courier service. Individuals will be able to implement and interpret the test wherever they want, but will be encouraged to send a photograph of the test result back to our research team through WeChat, which is convenient with a smartphone and has no cost. Individuals who have questions can also contact the study research office in Guangzhou over phone or through social media. Individuals who have a positive test will be able to contact the study research office for information about linkage to care and counseling.

7 Statistical Considerations

7.1 Primary Outcomes

The primary outcome of this study will be HIV test uptake over the previous three months. This will be assessed by self-report during follow up survey and triangulated with HIV

testing surveillance data from the CDC. A difference of 10% in testing rate (assuming a proportion of HIV testing of 35% during the crowdsourced intervention period and 25% during the conventional intervention period) was chosen based on existing levels of HIV testing and what would be feasible and have public health importance in the Chinese context. The CDC measurement of the primary outcome will be the difference between HIV testing comparing the three months immediately prior to the intervention and the three months of the intervention.

7.2 Secondary Outcomes

A number of secondary outcomes will also be measured. These include syphilis testing, condomless sex, community engagement, testing stigma, and others (Appendix 1). Outcomes will also be stratified based on the level of engagement in developing the intervention, and based on the personal level of engagement during the stage of intervention implementation.

7.3 Sample Size Calculation

We used a binary outcome stepped-wedge randomized controlled trial design for sample size calculation. The required sample size is calculated for the primary outcome. To calculate sample size, we assumed that a crowdsourced intervention will be superior to a conventional method in promoting HIV testing among MSM who never tested for HIV. Assuming a proportion of HIV testing of 35% during the crowdsourced period and 25% during the conventional period, total number of clusters of eight, total number of time period for intervention of four, coefficient of variation of 0.4 (usually between 0.15 and 0.4), 2-sided $\alpha=0.05$, 90% power, and 30% loss to follow up, then the total sample size will be 1040 men (130 for each city). To further improve the power for sub-analysis and secondary outcomes, we will increase the sample size to 1280 men (160 for each city). The calculation was made using the formulas developed by Michael A. Hussey et al.¹¹ (<http://faculty.washington.edu/jphughes/pubs.html>).

Table 2: sample size calculation

P_i^*	P_c^s	Number of clusters	Number of time periods	Coefficient of variation [@]	Alpha	Power	Sample size/no LTFU	Loss to follow up	Sample size for each cluster	Total sample size (8 clusters)
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30	20	8	5	0.4	0.05	0.9	80	30%	114	912
30	20	8	5	0.15	0.05	0.9	71	30%	101	808
30	15	8	5	0.4	0.05	0.9	31	30%	44	352
30	15	8	5	0.15	0.05	0.9	26	30%	37	296
35	25	8	5	0.4	0.05	0.9	91	30%	130	1040
35	25	8	5	0.15	0.05	0.9	83	30%	119	952
35	20	8	5	0.4	0.05	0.9	37	30%	53	424
35	20	8	5	0.15	0.05	0.9	31	30%	44	352
40	30	8	5	0.4	0.05	0.9	99	30%	141	1128
40	30	8	5	0.15	0.05	0.9	93	30%	133	1064
40	25	8	5	0.4	0.05	0.9	42	30%	60	480
40	25	8	5	0.15	0.05	0.9	36	30%	51	408
45	35	8	5	0.4	0.05	0.9	104	30%	149	1192
45	35	8	5	0.15	0.05	0.9	99	30%	141	1128
45	30	8	5	0.4	0.05	0.9	45	30%	64	512
45	30	8	5	0.15	0.05	0.9	40	30%	57	456

Note: *Pi: probability of HIV testing during intervention period; ^sPc: probability of HIV testing during control period; @ usually between 0.15-0.4.

7.4 Analysis Plan

7.4.1 Primary Outcome Analyses

The primary outcome will be self-reported HIV testing uptake in the past three months. We will examine the hypothesis comparing the superiority of the crowdsourced intervention compared to conventional HIV test uptake campaigns. In our study, since the outcome is binary, generalized linear mixed models (GLMM) and generalized estimating equations (GEE) can be used in our study for the primary outcome analysis. However, since we only have eight clusters, GLMM will be used for primary data analysis in our study; GLMM is preferred in studies with a small number of clusters¹². The model will include intervention status and time as fixed effects and site and individuals as random effects. The estimated intervention effects will be reported with 95% CIs and p values. Descriptive analysis will be

used to summarize the characteristics and behaviours of the participants at baseline and follow-up surveys.

7.4.2 Secondary Outcome Analyses

Similar analyses will be conducted for binary secondary outcomes (continuous variables will be categorized into binary variable), including frequency of syphilis testing, frequency of HIV testing (among those with previous HIV testing), condomless sex, community engagement, awareness of HIV status, empowerment and others. In addition, since four cities will implement more intensive in-person events to promote engagement (Guangzhou, Shenzhen, Qingdao, and Jinan) during intervention development, sub-analysis will be conducted to evaluate the potential effect of in-person events to promote HIV testing and other secondary outcomes among Chinese MSM. In addition, secondary analysis will investigate an interaction effect between intervention and community engagement (both for engagement during the intervention development stage and engagement during the intervention implementation stage, at personal level).

7.4.3 Sub-Analyses

Sub-analysis will also be conducted to compare the effect of the intervention in participants with different age (less than 30 versus 30 or older), and to compare two delivery methods for individual-level intervention: WeChat message vs. SMS text message.

8 Ethical approval

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

9 Trial status

At the time of this draft, intervention development and participant recruitment have initiated. Study outcomes, data cleaning, and analysis are pending. The study is registered in the Clinical Trials.gov database (NCT02796963).

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

Secondary Outcome	Definition
<i>Incremental cost</i>	Incremental cost, defined as the cost associated with respective interventions (development, start-up, implementation, condom use, intervention per individual who reported no sex or sex with a condom during the follow-up period.)
<i>Condom use</i>	Frequency of men, defined as the number of men who reported increased condom use (in anal, vaginal, and/or oral sex with either male and female sex partners) comparing pre-intervention and post-intervention values
<i>HIV testing social norms¹</i>	Frequency of men, defined as number of men who report higher levels of social norms when comparing their pre-intervention and post-intervention HIV testing norms
<i>HIV testing self-efficacy²</i>	Frequency of men, defined as number of men who had an increase in HIV testing self-efficacy when comparing their pre-intervention and post-intervention self-efficacy
<i>Community engagement/ MSM community affiliation</i>	Frequency of men, defined as an increase in closer affiliation with the MSM community (i.e., tongzhi circle, gay online networks or groups) when comparing their pre-intervention and post-intervention engagement
<i>Campaign engagement</i>	Frequency of men, defined as number of men who had an increase in taking part in the HIV testing campaign when comparing their pre-intervention and post-intervention engagement
<i>HIV self-testing</i>	Frequency of men, defined as the number of men who reported being self-tested for HIV during the previous three months
<i>Anticipated HIV stigma³</i>	Frequency of men, defined as number of men who report anticipated HIV stigma when comparing their pre-intervention and post-intervention
<i>Syphilis testing</i>	Frequency of men, defined as the number of men who reported being tested for syphilis (excluding HIV) during the previous three months
<i>Weibo engagement</i>	Frequency of men, defined as the number of men who reported using Weibo in the past three months to give or receive information about HIV testing comparing their pre-intervention and post-intervention engagement (Except the intervention delivered by SESH)
<i>Wechat engagement</i>	Frequency of men, defined as the number of men who reported using Wechat in the past three months to give or receive information about HIV testing comparing their pre-intervention and post-intervention engagement (Except the intervention delivered by SESH)
<i>QQ engagement</i>	Frequency of men, defined as the number of men who reported using QQ in the past three months to give or receive information about HIV testing comparing their

	pre-intervention and post-intervention engagement (Except the intervention delivered by SESH)
<i>Mobile app engagement</i>	Frequency of men, defined as the number of men who reported using mobile apps in the past three months to give or receive information about HIV testing comparing their pre-intervention and post-intervention engagement

¹ HIV testing social norms will be measured using six survey items that are each on a five point Likert scale. Increased HIV testing social norms will be defined as having an increase from baseline in any two of these six survey items and dichotomized accordingly (social norm change will be categorized into three groups: increased, stable and decreased social norm). The HIV testing social norm outcome will be assessed in the entire group as well as the subgroup of men who were referred by their friends. This is adapted from Pettifor, A., MacPhail, C., Suchindran, S., & Delany-Moretlwe, S. (2015). Factors associated with HIV testing among public sector clinic attendees in Johannesburg, South Africa. *AIDS and Behavior*, 14, 913-921.

² Self-efficacy will be measured using six 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 (self-efficacy change will be categorized into three groups: increased, stable and decreased self-efficacy). This is adapted from Gu, J., Lau, J. T. F., & Tsui, H. (2011). Psychological factors in association with uptake of voluntary counselling and testing for HIV among men who have sex with men in Hong Kong. *Public Health*, 125, 275-282.

³ The Anticipated HIV Stigma will be assessed using 7 survey items that are each on a four point Likert scale. Reduced anticipated HIV stigma will be defined as having a decrease from baseline in the mean score (Continuous variable). This is adapted from Golub, S. A. & Gamarel, K. E. (2013). The impact of anticipated HIV stigma on delays in HIV testing behaviors: Findings from a community-based sample of men who have sex with men and transgender women in New York City. *AIDS Patient Care and STDs*, 27(11), 621-627.

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