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ORIGINAL PAPER

# A Randomized Controlled Trial Evaluating Efficacy of a Brief Setting-Based and Theory-Based Intervention Promoting Voluntary Medical Male Circumcision Among Heterosexual Male Sexually Transmitted Disease Patients in China

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**Abstract**
Voluntary medical male circumcision (VMMC) is an evidence-based biomedical HIV prevention but under-utilized by male sexually transmitted diseases patients (MSTDP) in China. A parallel-group, non-blinded randomized controlled trial was conducted. Participants were uncircumcised heterosexual MSTDP attending four sexually transmitted diseases (STD) clinics in three Chinese cities. A total of 244 MSTDP were randomized 1:1 into the intervention group (n = 108) and the control group (n = 136). In addition to the education booklet received by the control group, the intervention group watched a 10-min video clip and received a brief counseling delivered by clinicians in the STD clinics. The interventions were developed based on the Health Belief Model and the Theory of Planned Behavior. At Month 6, participants in the intervention group reported significantly higher uptake of VMMC (14.8% versus 2.9%; RR 5.03, 95% CI 1.73, 14.62, p = 0.001). The brief STD clinic-based intervention was effective in increasing VMMC uptake among MSTDP in China.
**Trial registry**: This study is registered at ClinicalTrials.gov, number NCT03414710. https://clinicaltrials.gov/ct2/show/NCT03414710.

**Keywords** Voluntary medical male circumcision · Promotion · Heterosexual male sexually transmitted disease patients · Randomized controlled trial · China

## Introduction

In China, the annual surveillance reports showed a rapid increase in the number of new sexually transmitted diseases (STD) cases, from 166 in 1981 to 553,233 in 2016 [1, 2], over half of these new cases were heterosexual men [3, 4]. Male sexually transmitted diseases patients (MSTDP) in China are at high risk of transmitting HIV and STD to others. The HIV prevalence was 0.46–0.8% in this group [5, 6], which was much higher than general population (0.09% in 2018) and was probably underestimated [7]. About half of the MSTDP were clients of female sex workers, and 42.9% of them reported inconsistent condom use with their wives

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and/or steady girlfriends, even with STD symptoms and/or after knowing about the diagnosis [8].

Voluntary medical male circumcision (VMMC) is an evidence-based biomedical HIV intervention for prevention of HIV-1 and other STD among heterosexual men [9–16]. VMMC is a potentially useful HIV/STD prevention strategy for heterosexual MSTDP. In China, previous studies showed that over half of the MSTDP were willing to take up VMMC at market price (700 RMB or about 108 USD) for HIV prevention, after received a simple briefing about its efficacies [17]. The relatively low prevalence of VMMC in this group (12%) suggested that there is much room for improvement [17].

To our knowledge, six randomized controlled trials (RCTs) evaluated efficacy of interventions promoting VMMC among heterosexual males [18–23]. These interventions included provision of monetary incentives (e.g., fixed compensation or lottery-based rewards) [19, 20], group education sessions [18, 21, 23], and integrating VMMC promotion with soccer games [22]. All these interventions targeted male general populations; only one of them was conducted outside Africa (male migrant workers in China) [23]. The promotion of VMMC among high-risk heterosexual males (e.g., MSTDP) may contribute to the control of the HIV/STD epidemic in China.

HIV interventions using setting approaches were effective [24]. Promotion of VMMC in STD clinics has the advantages as MSTDP are psychologically prepared to receive health communication related to HIV/STD prevention during their visits, including information about VMMC, and would thus feel less embarrassed or stigmatized. A meta-analysis showed that theory-based interventions were more effective than non-theory-based ones [25]. Based on a formative study [17], a brief setting-based and theory-based intervention promoting VMMC among MSTDP in China was developed and pilot tested by using pre-test post-test design [26]. The intervention was based on some constructs of the Health Belief Model (HBM) (perceived benefits, perceived barriers, perceived cue to action, and perceived self-efficacy related to VMMC) and the theory of planned behavior (TPB) (perceived support from significant others) [27, 28].

Globally, there were very few effective evidence-based interventions targeting high-risk heterosexual male population (e.g., MSTDP). Fewer had been implemented in China. To our knowledge, this was the first RCT evaluating a brief intervention promoting VMMC among heterosexual MSTDP. Since this intervention promoted VMMC at market rate and was built on the existing facilities of STD clinics, it can be easily integrated into existing services of these clinics if it is found to be effective. The primary objective of the present RCT was to evaluate the relative efficacy of a modified version of the brief setting-based and theory-based intervention versus an information-based control group (provision of a health promotion booklet) in increasing VMMC uptake among MSTDP in China over a 6-month follow-up period. The secondary objective was to evaluate the between-group differences in perceptions related to VMMC based on the HBM (perceived benefit, perceived barrier and perceived self-efficacy) and the TPB (perceived subjective norm) at Month 6. We further tested whether these theory-based constructs that were used to guide the design of the intervention would mediate any between-group differences in prevalence of VMMC uptake.

## Methods

### Study Design

A parallel-group and non-blinded RCT was conducted. Face-to-face interviews were conducted at the baseline in four collaborating STD clinics. A 5-min telephone survey was conducted 6 months afterwards by some blinded interviewers. Up to five calls were made at different timeslots during weekdays/weekends before considering a case as loss-to-follow up. This study was registered at ClinicalTrials.gov, number NCT03414710. The consort flow diagram was shown in Fig. 1.

### Participants

All participants were different from those in the pilot study. Participants were recruited from the four largest governmental STD clinics in the Guangdong Province, China during January to December 2017. These clinics were located in three cities (one in Guangzhou, two in Shenzhen and one in Jiangmen). Inclusion criteria were: (1) males who were ethnic Chinese aged ≥ 18 years, (2) no previous circumcision, (3) diagnosis of any one of the five types of STDs listed in the national surveillance system, and (4) willingness to leave contact information (mobile and/or electronic) and be followed up at Month 6. The listed diagnoses included: (1) primary, secondary or latent syphilis determined by Treponema-pallidum Particle Assay and Toluidine Red Unheated Serum Test, (2) genital warts diagnosed by the presence of clinical symptoms and supported by results of biopsy, (3) clinically diagnosed genital herpes supported by ELISA, and (4) gonorrhea or nongonococcal urethritis (NGU) diagnosed by using Polymerase Chain Reaction. Men who had ever had had oral or anal sex with men and those who were known to be HIV positive were excluded from the study.

### Recruitment Procedures

To reduce selection bias, the research team invited all MSTDP attending the four participating clinics during the recruitment period to join the study. A clinician confirmed

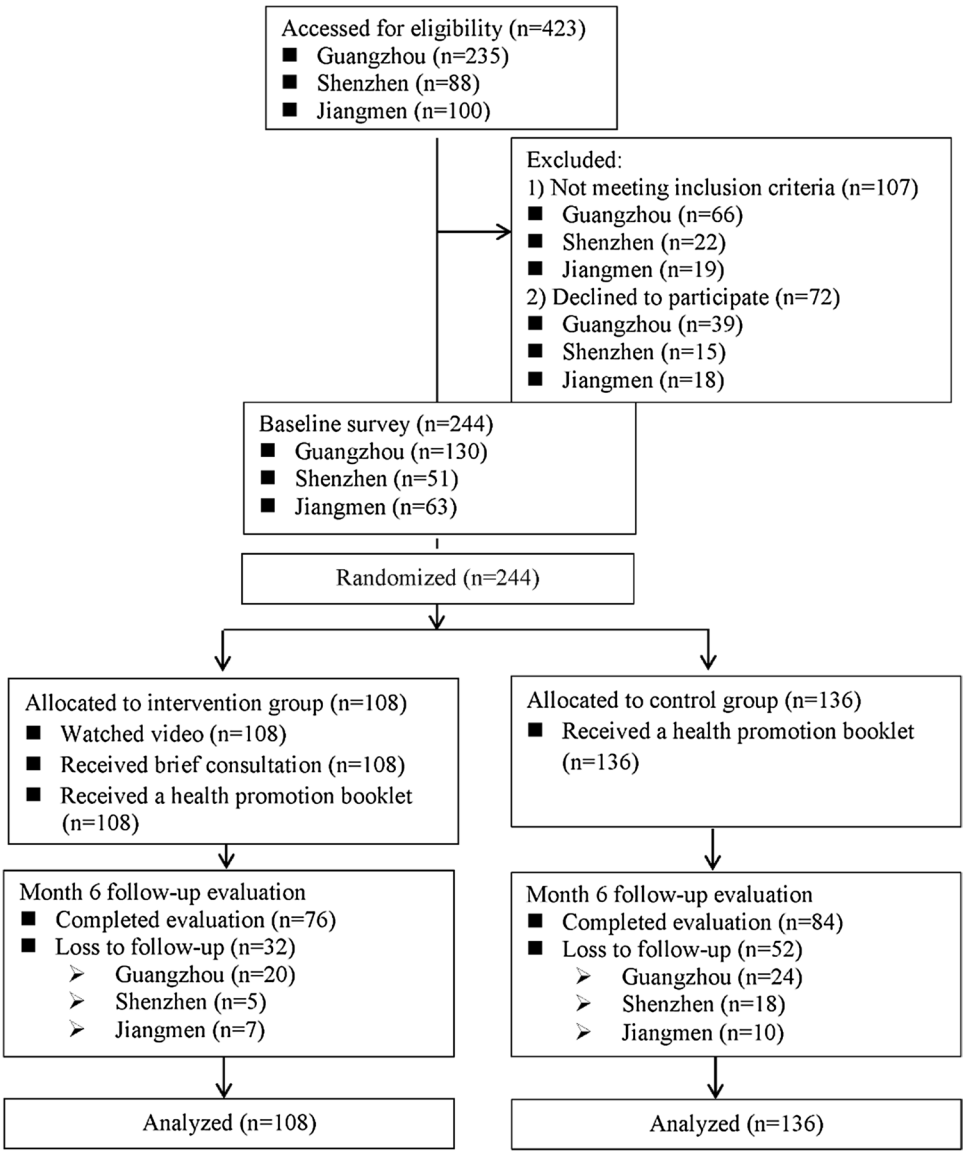


**Fig. 1** Consort flowchart of the study

their eligibility in a consultation room, and referred them to the trained interviewers who were also STD clinicians. The interviewers then briefed the participants about the study, assured them that refusals would not affect their right to use any services and that they could quit any time without being questioned. A monetary compensation (50 RMB or 8 USD) was given to participants upon completion of the baseline survey and the intervention. Written informed consent was sought. Ethics approval was obtained from the Ethics Committee of Guangdong Provincial Dermatology Hospital, Guangzhou, China.

## The Baseline Survey and Random Allocation Process

After completion of the baseline face-to-face interview, participants were randomized 1:1 to either the intervention group or the control group. Computer-generated random allocation codes were produced and sealed in opaque envelopes by a research staff with no involvement in recruitment or baseline survey. One envelope was drawn and opened in front of the participant by the interviewers. They then informed the participant which group he was assigned to. Block randomization with block size of eight was used.

## The Control Group

After randomization took place, the control group received an education booklet containing some factual information of VMMC. The contents included: (1) recommendation of VMMC made by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), (2) efficacy and surgical complications of VMMC, and (3) a list of public clinics/hospitals providing

VMMC in the city (location and phone numbers). If the participants were willing to take up VMMC, the interviewers would facilitate them to make an appointment for check-up and surgery in the same clinics at the market price if desired (700 RMB or 108 USD). No subsidization was provided to the participants. We did not limit participants' choice to take up VMMC in other hospitals/clinics.

## The Intervention Group

In addition to the educational booklet received by the control group, the intervention group was exposed to two other intervention components.

### Watching a Video Clip Promoting VMMC on a Tablet in the Waiting Room

The video clip developed by our team was modified for this study based on the results of the pilot study [26]. The modifications included: (1) contents related to severity of STD infection was removed as it did not predict VMMC uptake in the pilot study, (2) testimonial about pain, surgical complications and recovery time was added into the video as these were frequently asked by participants in the pilot study, (3) the video was modified to be suitable to play on a tablet, (4) the video was formatted in a way that participants cannot fast forward to ensure exposure, and (5) the length of the video was reduced from 10 to 8 min.

In the modified version of the video, a well-known clinician talked about benefits of VMMC in reducing risk of HIV/STD infection and protecting female sex partners to increase perceived benefit, and gave reminders about the importance of consistent condom use after VMMC to prevent potential risk compensation. He also strongly recommended MSTDP to take up VMMC as a cue to action. One MSTDP who had taken up VMMC then shared his positive experience related to VMMC, including mild pain, surgical complications and quick recovery from the surgery, improvement in sexual pleasure/sexual functioning after taking up VMMC, and support received from his female sex partners and peers. The testimonial aimed to reduce perceived barrier, increase perceived benefit and perceived subjective norm related to VMMC.

### Brief Counseling Promoting VMMC Provided by the Interviewers

The contents of the counseling were similar to those in the pilot study [26] and were tailored to participants' stage of change related to VMMC uptake according to the Transtheoretical Model [29]. For participants who planned to take up VMMC (preparation stage), interviewers facilitated them to make an appointment for check-up and surgery. For those who considered taking up VMMC but without specific plan to do so (contemplation stage), interviewers discussed with them about their concerns and barriers. For those without intention to take up VMMC (pre-contemplation stage), interviewers reminded them about their risk of HIV/STD infection and benefits of VMMC. The time duration of the brief counseling ranged from 7 to 16 min. The referrals for implementation of VMMC was the same as that of the control group. The entire intervention took about 20 min to complete.

## Measures

### Primary Outcome

The primary outcome was self-reported uptake of VMMC within the 6-month follow-up period. This outcome was validated by requesting participants to provide details about VMMC uptake (e.g., date, location, and cost). Those who failed to provide such details would not be counted.

### Secondary Outcomes

Four scales assessed cognitions at baseline and the follow-up. Three of them were based on the HBM. They were: (1) the 5-item perceived benefit scale; (2) the 5-item perceived barrier scale, and (3) the 4-item perceived self-efficacy scale. In addition, three items were used to measure perceived subjective norm of the TPB. Response categories of these scales were: 1 = strongly disagree to 5 = strongly agree. Cronbach's alphas of these four scales were acceptable (0.708–0.760). Single factors were identified for these four scales in explanatory factor analysis, explaining 59.1–84.9% of the total variances.

### Potential Confounders

Potential confounders were recorded in the baseline survey, including socio-demographics, utilization of HIV/STD prevention services, STD history, and condomless sex with regular female sex partners (RP: defined as their wives or stable girlfriends), female sex workers (FSW: defined as a female who exchanged sex for money) and non-regular female sex partners (NRP: defined as a female who was neither FSW nor RP) since having STD symptoms or receiving an STD diagnosis.

### Process Evaluation

Process evaluation of health promotion was also conducted at Month 6. Participants in both groups were asked: (1)

whether the content of the health promotion was clear, (2) whether the materials (video or booklet) was attractive to them, (3) whether the health promotion had increased their understanding about the benefit of VMMC and willingness to take up VMMC. Participants in the intervention group were asked an additional question about their satisfaction with the counseling session.

#### Post-surgical Experience

At Months 6, circumcised participants were asked whether they have any surgical complications, and whether they had sought medical consultation due to such complications. Sexually active circumcised participants were asked whether they had reduced condom use with RP, NRP or FSW, or increase the number of such female sex partners after taking up VMMC.

### Sample Size Planning

In the pilot study, 19.9% of MSTDP had taken up VMMC during the 4-month follow-up period [26]. In this study, we assumed that 20% of the participants in the intervention group would take up VMMC within the 6-month follow period. Since participants in the control group received minimal intervention (an educational booklet), we expected about 5% of them would take up VMMC within the follow-up period. A sample size of 71 per group would allow us to detect a between-group difference in the uptake of VMMC of 15% or above ($a = 0.05$, 2-sided test with statistical power of 0.8; PASS). Taking into account an expected drop-out rate of not higher than 40% at Month 6, a sample size of 119 per group was required. The total sample size would be 238.

### Statistical Analysis

Intention-to-treat (ITT) analysis was used for outcome analyses. Missing data was handled by the imputation strategy of last-observation-carried-forward, a standard method in ITT analysis [30]. The Chi square test was used to inspect between-group balances of potential confounders at baseline, and adjustments would be made if any potential confounders showed $p < 0.20$ in the comparisons. Relative risk (RR), absolute risk reduction (ARR), and number needed to treat (NNT) statistics were used to test between-group difference in primary outcome. Two-sample *t* test and paired *t* test were used to test the between-group and within-group differences in secondary outcomes, respectively.

To test the hypothesis whether change in the studied perceptions based on the HBM/TPB that were used to design intervention messages would mediate the between-group difference (intervention effect), the Baron and Kenny's method was used [31]. Variables were constructed to assess changes in the HBM/TPB-related perceptions (Month 6 minus baseline). The mediation hypothesis was tested by first inspecting the association between changes in HBM/TPB-related perceptions and randomization status. Logistic regression models were then fit using VMMC uptake as the dependent variable, and adjusted for potential confounders measured at baseline. Model 1 included randomization status (intervention versus control group) as the independent variable; Model 2 included the changes in HBM/TPB-related perceptions as the independent variables; Model 3 contains variables of both Model 1 and 2. If the association between the randomization status and VMMC uptake became statistically non-significant after adjusting for the changes in HBM/TPB-related perceptions, the changes in such perception were seen to fully mediate the association between randomization status and VMMC uptake. Partial mediation occurred when the strength of association between randomization status and VMMC uptake was reduced but remained statistically significant when changes in HBM/TPB-related perceptions were controlled. SPSS version 16.0 was used, and p values $< 0.05$ was considered as statistically significant.

## Results

### Descriptive Statistics

We approached 423 MSTDP and invited 316 eligible patients to join the study; 72 (22.8%) declined to participate; 244 (77.2%) completed the baseline survey and the intervention (Guangzhou: 130; Shenzhen: 51, and Jiangmen: 63). At Month 6, the researchers were not able to contact 32 participants in the intervention group and 52 participants in the control group; these participants were considered as loss-to-follow up. A total of 76 participants in the intervention group and 84 participants in the control group completed the telephone follow-up evaluation at Month 6.

The baseline characteristics of the participants are shown in Table 1. The between-group difference in these characteristics were statistically non-significant (p ranged from 0.266 to 0.980, see Table 1). Hence, no statistical adjustment was required for subsequent analyses of primary or secondary outcomes.

The loss-to-follow-up rate in the intervention group and the control group was 29.6% and 38.2%, respectively. No significant difference was found in the measured baseline characteristics between the drop-outs and non-drop-outs (Table 2).

**Table 1** Characteristics of participants at baseline

| | All N = 244 (%) | Intervention N = 108 (%) | Control N = 136 (%) | p value |
|---|---|---|---|---|
| Socio-demographic variables | | | | |
| Age group | | | | |
| 18–30 years | 31.1 | 30.6 | 31.6 | |
| 31–40 years | 35.2 | 36.1 | 34.6 | |
| 41–50 years | 25.8 | 25.0 | 26.5 | |
| > 50 years | 7.8 | 8.3 | 7.4 | 0.980 |
| Registered permanent residents | | | | |
| No | 63.5 | 66.7 | 61.0 | |
| Yes | 36.5 | 33.0 | 39.0 | 0.364 |
| Marital status | | | | |
| Single | 16.4 | 19.4 | 14.0 | |
| Married or cohabited with a woman | 75.0 | 73.1 | 76.5 | |
| Divorced, separated or widowed | 8.6 | 7.4 | 9.6 | 0.469 |
| Highest education level attained | | | | |
| Junior high or lower | 25.8 | 30.6 | 22.1 | |
| Senior high (or equivalent) | 28.7 | 25.0 | 31.6 | |
| College | 16.8 | 15.7 | 17.6 | |
| University and above | 28.7 | 28.7 | 28.7 | 0.435 |
| Monthly personal income (RMB) | | | | |
| < 3000 | 13.9 | 16.7 | 11.8 | |
| 3000–4999 | 22.1 | 21.3 | 22.8 | |
| 5000–9999 | 36.1 | 38.9 | 33.8 | |
| ≥ 10,000 | 27.9 | 23.6 | 31.6 | 0.380 |
| Study site | | | | |
| Guangzhou | 53.3 | 54.6 | 52.2 | |
| Shenzhen | 20.9 | 16.7 | 24.3 | |
| Jiangmen | 25.8 | 28.7 | 23.5 | 0.308 |
| HIV/STD-related service utilization in the last 6 months | | | | |
| HIV antibody testing | | | | |
| No | 69.3 | 65.7 | 72.1 | |
| Yes | 30.7 | 34.3 | 27.9 | 0.288 |
| Other HIV/STD-related prevention service[a] | | | | |
| No | 42.4 | 44.9 | 40.4 | |
| Yes | 57.6 | 55.1 | 59.6 | 0.489 |
| STD history of the participants | | | | |
| Type of current STD infection | | | | |
| Syphilis | 26.6 | 30.6 | 23.5 | |
| Genital warts | 46.3 | 48.1 | 44.9 | |
| Genital herpes | 13.1 | 11.1 | 14.7 | |
| Gonorrhea | 8.2 | 5.6 | 10.3 | |
| NGU | 5.7 | 4.6 | 6.6 | 0.418 |
| Time since STD diagnosis | | | | |
| < 1 month | 52.9 | 52.8 | 52.9 | |
| 1–3 months | 21.3 | 20.4 | 22.1 | |
| 4–6 months | 13.9 | 13.0 | 14.7 | |
| > 6 months | 11.9 | 13.9 | 10.3 | 0.833 |
| Presence of STD-related symptoms | | | | |
| No | 24.2 | 25.0 | 23.5 | |
| Yes | 75.8 | 75.0 | 76.5 | 0.790 |

**Table 1** (continued)

| | All N = 244 (%) | Intervention N = 108 (%) | Control N = 136 (%) | p value |
|---|---|---|---|---|
| On STD treatment | | | | |
| No | 20.1 | 17.6 | 22.1 | |
| Yes | 79.9 | 82.4 | 77.9 | 0.387 |
| Sexual behaviors since exhibiting STD symptoms or receiving an STD diagnosis | | | | |
| Condomless sexual intercourse with female regular sex partners (RP) | | | | |
| Had not had sex with RP since STD diagnosis | 41.0 | 40.7 | 41.2 | |
| No | 29.5 | 30.6 | 28.7 | |
| Yes | 29.5 | 28.7 | 30.1 | 0.943 |
| Condomless sexual intercourse with non-regular female sex partners (NRP) | | | | |
| Had not had sex with NRP since STD diagnosis | 73.4 | 75.0 | 72.1 | |
| No | 16.8 | 18.5 | 15.4 | |
| Yes | 9.8 | 6.5 | 12.5 | 0.269 |
| Condomless sexual intercourse with female sex workers (FSW) | | | | |
| Had not had sex with FSW since STD diagnosis | 80.7 | 78.7 | 82.4 | |
| No | 12.7 | 16.7 | 9.6 | |
| Yes | 6.6 | 4.6 | 8.1 | 0.266 |
| Perceptions related to voluntary medical male circumcision (VMMC) | | | | |
| Perceptions based on the Health Belief Model (HBM) | | | | |
| Perceived benefit of VMMC (% agree/strongly agree) | | | | |
| VMMC would reduce the risk of HIV infection | 30.7 | 27.8 | 33.1 | 0.372 |
| VMMC would reduce the risk of STD infection | 46.7 | 45.4 | 47.8 | 0.706 |
| VMMC would increase sexual pleasure | 40.2 | 37.0 | 42.6 | 0.375 |
| VMMC would reduce female sex partner's risk of STD infection | 52.5 | 51.9 | 52.9 | 0.866 |
| VMMC would increase female sex partner's sexual pleasure | 29.5 | 26.9 | 31.6 | 0.418 |
| Perceived benefit scale[b] (mean/SD) | 16.7 (2.9) | 16.7 (2.8) | 16.7 (2.9) | 0.989 |
| Perceived barrier of taking up VMMC (% agree/strongly agree) | | | | |
| VMMC is expensive for me | 13.5 | 13.9 | 13.2 | 0.882 |
| VMMC would cause pain on penis | 46.3 | 50.0 | 43.4 | 0.303 |
| VMMC would result in severe surgical complications (e.g., bleeding, edema or inflammation) | 39.3 | 43.5 | 36.0 | 0.234 |
| VMMC would result in erectile dysfunction | 14.3 | 13.9 | 14.7 | 0.856 |
| I am embarrassed to take up VMMC | 29.5 | 30.6 | 28.7 | 0.749 |
| Perceived barrier scale[c] (mean/SD) | 14.3 (2.7) | 14.5 (2.4) | 14.1 (2.4) | 0.278 |
| Perceived self-efficacy of taking up VMMC (% agree/strongly agree) | | | | |
| I am confident that I can take up VMMC if desired | 76.2 | 77.8 | 75.0 | 0.613 |
| Whether to take up VMMC or not is completely under my control | 83.6 | 81.5 | 85.3 | 0.424 |
| I am confident that I can take up VMMC in the next 6 months | 23.0 | 23.1 | 22.8 | 0.948 |
| I have sufficient resources enabling me to take up VMMC in the next 6 months | 27.9 | 28.7 | 27.2 | 0.795 |
| Perceived self-efficacy scale[d] (mean/SD) | 13.5 (2.2) | 13.7 (3.0) | 13.4 (2.9) | 0.280 |
| Perceptions based on the theory of planned behavior (TPB) | | | | |
| Perceived subjective norm related to VMMC uptake (% agree/strongly agree) | | | | |
| Some doctors would support you taking up VMMC | 55.7 | 57.4 | 54.4 | 0.640 |
| Your peers would support you taking up VMMC | 37.7 | 38.9 | 36.8 | 0.734 |
| Your female sex partners would support you taking up VMMC | 48.0 | 49.1 | 47.1 | 0.754 |
| Perceived subjective norm scale[e] (mean/SD) | 10.1 (2.5) | 10.1 (2.6) | 10.2 (2.5) | 0.948 |

**Table 1** (continued)

p values were obtained by using Chi square test (categorical variables) and two-sample *t* test (continuous variables)

Regular female sex partners (RP): defined as their wives/stable girlfriends

Female sex workers (FSW): defined as women who exchanged sex for money

Non-regular female sex partners (NRP): defined as women who were neither FSW nor RP

[a]Including receiving condoms, peer education, HIV/STD-related pamphlets and/or lectures

[b]Perceived Benefit Scale, 5 items, Cronbach's alpha = 0.760, 1 factor was identified by exploratory factor analysis, explaining for 75.9% of the total variance

[c]Perceived Barrier Scale, 5 items, Cronbach's alpha = 0.708, 1 factor was identified by exploratory factor analysis, explaining for 59.1% of the total variance

[d]Perceived Self-Efficacy Scale, 4 items, Cronbach's alpha = 0.719, 1 factor was identified by exploratory factor analysis, explaining for 84.9% of the total variance

[e]Subjective Norm Scale, 3 items, Cronbach's alpha = 0.725, 1 factor was identified by exploratory factor analysis, explaining for 66.1% of the total variance

## Between-Group Difference in Primary Outcome

A total of 20 participants self-reported having had taken up VMMC at Month 6, all of them were able to provide details to verify their VMMC uptake. Participants in the intervention group reported significantly higher prevalence of VMMC at Month 6 than the control group (14.8% vs. 2.9%; RR 5.03, 95% CI 1.73, 14.62; ARR 11.9, 95% CI 4.6, 19.2, NNT 8.4, 95% CI 5.2, 21.8, p = 0.001) (Table 3).

## Between-Group and Within-Group Differences in the Secondary Outcomes

At baseline, the between-group differences in perceptions related to VMMC based on the HBM/TPB were statistically non-significant (p = 0.278–0.989). As compared to the control group, participants in the intervention group reported higher perceived benefit, perceived self-efficacy and perceived subjective norm (p values: < 0.001–0.022), and lower perceived barriers (p = 0.026) at Month 6. When comparing Month 6 versus baseline data, statistically significant increases in perceived benefit, perceived self-efficacy, and perceived subjective norm were found within the intervention group, but not within the control group (p = 0.274–0.789). Statistically significant decrease in perceived barriers was observed in both groups (intervention: p < 0.001; control: p = 0.002) (Tables 1, 3).

## Testing the Mediation Hypotheses

Adjusted for the potential confounders assessed at the baseline survey, the within-group changes in the scores of HBM/TPB scales (the Perceived Benefit Scale, the Perceived Barrier Scale, the Perceived Self-Efficacy Scale, and the Perceived Subjective Norm Scale) were significantly associated with the randomization status (p < 0.05; data not tabulated) and uptake of VMMC (p < 0.01; Table 4).

The associations between the randomization status and VMMC uptake became statistically non-significant (p = 0.736) after controlled for changes in perceived barriers, the changes in perceived barrier remained strongly associated with the VMMC uptake in the model. The same results occurred when perceived self-efficacy was controlled in the model. The results suggested changes in perceived barriers and perceived self-efficacy fully mediated the intervention effect. The association between randomization status and VMMC uptake was weakened (from p = 0.002 to p = 0.062) when change in perceived benefit was controlled in the model, with change in perceived benefit remained statistically significant in the model (p < 0.001). A partial mediation effect existed (Table 4).

## Post-surgical Experiences

In the follow-up survey conducted at Month 6, 70% of the 20 circumcised participants (n = 14) reported no surgical complication. Minor complications included edema (n = 2), inflammation (n = 3), and oozing of blood (n = 1); one-third (2/6) of those self-reported having complications of VMMC had sought medical consultation.

At Month 6, 19 (95%) of the circumcised participants were sexually active. Regarding risk compensation, 42.1% of the sexually active circumcised participants (n = 19) reported reduced frequency of condom use with RP after taking up VMMC; one and two had had sexual intercourse with NRP and FSW after taking up VMMC. One participant reported reduced frequency of condom use with NRP after taking up VMMC, while no participant reported reduced frequency of condom use with FSW.

## Process Evaluation of Health Promotion for VMMC

Among those in the intervention group that participated in the process evaluation (n = 76), 84.2% and 71.0% believed

that the content of the health promotion video was clear and attractive, respectively. Over 80% (84.2%) were satisfied/very satisfied with the brief consultation session.

Among those in the control group that completed the process evaluation (n = 84), 73.8% and 52.4% believed the content of the health promotion booklet was clear and attractive, respectively. The intervention group was more likely than the control group to believe that the health promotion has increased their understanding of VMMC (80.3% versus 54.8%, $p < 0.001$) and willingness to take up VMMC (65.8% versus 39.3%, $p < 0.001$).

## Discussion

The growing amount of evidence of biomedical HIV interventions has changed HIV prevention strategies substantially. Of these biomedical interventions, VMMC is probably the most practical one for MSTDP in China, because as compared to other biomedical approaches (e.g., pre-exposure prophylaxis), VMMC is one-off and involves a reasonable cost (about 1/4 of the median monthly income of urban residents in China) [32].

Compared to the simple information-based intervention (provision of a health promotion booklet), the present setting-based and theory-based intervention brought a significant increase in VMMC uptake among MSTDP over the 6-month follow-up period. The ARR observed in our study (11.9%) was comparable to some other effective interventions promoting VMMC (7.1–16.0%) [19–23]. The present intervention has several strengths over the other interventions and has higher sustainability. First, this intervention was one-off and only a relatively small amount of manpower on top of the routine consultation, while the other effective interventions took multiple sessions to complete, and the length and complexity limited their feasibility and sustainability [18, 21–23]. Second, our video clip is reusable in other STD clinics with a minimum cost for maintenance. With simple training, the doctors/nurses can perform the brief counseling easily. Third, it takes only 20 min to complete and makes use of the waiting time, so it adds little stress to the medical system, and it can readily be fit into the routine practice of STD clinics. Fourth, unlike the other studies that either provided VMMC for free [18, 21–23] or offered monetary incentive upon VMMC uptake [19, 20], no additional funding is required for the present intervention, as the users paid for the VMMC at market rate without any subsidy. Lastly, since the intervention made use of the STD clinic settings to recruit participants, the cost of outreaching can be saved. Cost-effective analysis is required to support the intervention further. For the first time, health workers in China was provided an evidence-based intervention for promoting VMMC targeting heterosexual MSTDP. Given the aforementioned strengths, this intervention can be easily integrated into the existing services provided by STD clinics and scaled up with little extra cost. It would increase coverage of VMMC among MSTDP in China and hence create positive impact on the national HIV/STD epidemics.

The intervention also caused between-group differences in perceptions related to HBM/TPB that were used to develop the intervention. The results of the mediation analysis explained some plausible mechanism that led to the observed behavioral change. The behavioral change may be caused by increase in perceived self-efficacy and reduction in perceived barriers. Our study extended the applicability of these behavioral theories.

The results reminded us that prevention of risk compensation should be an essential part of VMMC promotion, as 40% of the circumcised participants reported reduced frequency of condom use with RP after taking up VMMC. Since some STDs (e.g., syphilis) can become asymptomatic but infectious after treatment, they are of high risk of spreading STDs to their RPs. Perceived risk reduction offered by VMMC might initiate risk compensation [33]. Post-VMMC counseling should be given by the clinicians to prospective VMMC users, emphasizing protective effects of VMMC is partial and certainly lower than consistent condom use.

Although our study has the strengths of the RCT design, targeting high-risk population, being supported by results of formative studies, being theory-based, good process evaluation results and making use of STD clinic settings, it has some limitations. First of all, the primary and secondary outcomes, as well as risk compensation behaviors relied on self-report and were therefore subject to reporting bias. In China, there is no history of routine VMMC in the Han majority population. Male circumcision is performed as a ritual passage to adulthood only in some Muslim minorities which account for < 2% of the total population [34]. To our knowledge, no cultural studies discussed VMMC in China. The lack of academic interest in the cultural meanings of VMMC may reflect a state of neutrality—VMMC is neither seen as beneficial nor inappropriate. Therefore, reporting bias for the primary outcome might be small. Second, like most RCTs, the participants were recruited by convenient sampling and selection bias might exist. The RCT design ensured good internal validity. However, caution should be exercised when generalizing the results to other Chinese cities. Third, attrition bias might also exist. However, since no significant difference was found in the measured baseline characteristics between the drop-outs and non-drop-outs, we expected such bias would be small. Moreover, we did not measure perceived cue to action, another constructs of the HBM. Although all of them received recommendation from the clinicians, variance still existed as they might still have

**Table 2** Comparing baseline characteristics between drop-outs and non-drop-outs

| | Intervention group | | | Control group | | |
|---|---|---|---|---|---|---|
| | Non-drop-outs (n = 76) (%) | Drop-outs (n = 32) (%) | p value | Non-drop-outs (n = 84) (%) | Drop-outs (n = 52) (%) | p value |
| Socio-demographic variables | | | | | | |
| Age group | | | | | | |
| 18–30 years | 31.6 | 28.1 | | 33.3 | 28.8 | |
| 31–40 years | 32.9 | 43.8 | | 33.3 | 36.5 | |
| 41–50 years | 28.9 | 15.6 | | 27.4 | 25.0 | |
| > 50 years | 6.6 | 12.5 | 0.338 | 6.0 | 9.6 | 0.812 |
| Registered permanent residents | | | | | | |
| No | 71.1 | 56.3 | | 60.7 | 61.5 | |
| Yes | 28.9 | 43.8 | 0.136 | 39.3 | 38.5 | 0.924 |
| Marital status | | | | | | |
| Single | 21.1 | 15.6 | | 16.7 | 9.6 | |
| Married or cohabited with a woman | 71.1 | 78.1 | | 75.0 | 78.8 | |
| Divorced, separated or widowed | 7.9 | 6.3 | 0.749 | 8.3 | 11.5 | 0.461 |
| Highest education level attained | | | | | | |
| Junior high or lower | 35.5 | 18.8 | | 23.8 | 19.2 | |
| Senior high (or equivalent) | 26.3 | 21.9 | | 31.0 | 32.7 | |
| College | 11.8 | 25.0 | | 16.7 | 19.2 | |
| University and above | 26.3 | 34.4 | 0.155 | 28.6 | 28.8 | 0.928 |
| Monthly personal income (RMB) | | | | | | |
| < 3000 | 18.4 | 12.5 | | 11.9 | 11.5 | |
| 3000–4999 | 22.4 | 18.8 | | 26.2 | 17.3 | |
| 5000–9999 | 39.5 | 37.5 | | 33.3 | 34.6 | |
| ≥ 10,000 | 19.7 | 31.3 | 0.588 | 28.6 | 36.5 | 0.620 |
| Study site | | | | | | |
| Guangzhou | 51.3 | 62.5 | | 56.0 | 46.2 | |
| Shenzhen | 17.1 | 15.6 | | 17.9 | 34.6 | |
| Jiangmen | 31.6 | 21.9 | 0.526 | 26.2 | 19.2 | 0.083 |
| HIV/STD-related service utilization in the last 6 months | | | | | | |
| HIV antibody testing | | | | | | |
| No | 71.1 | 53.1 | | 69.0 | 76.9 | |
| Yes | 28.9 | 46.9 | 0.116 | 31.0 | 23.1 | 0.320 |
| Other HIV/STD-related prevention service | | | | | | |
| No | 44.7 | 43.8 | | 46.4 | 30.8 | |
| Yes | 55.3 | 56.3 | 0.925 | 53.6 | 69.2 | 0.103 |
| STD history of the participants | | | | | | |
| Type of current STD infection | | | | | | |
| Syphilis | 32.9 | 25.0 | | 23.8 | 23.1 | |
| Genital warts | 47.4 | 50.0 | | 42.9 | 48.1 | |
| Genital herpes | 10.5 | 12.5 | | 15.5 | 13.5 | |
| Gonorrhea | 5.3 | 6.3 | | 10.7 | 9.6 | |
| NGU | 3.9 | 6.3 | 0.929 | 7.1 | 5.8 | 0.981 |
| Time since STD diagnosis | | | | | | |
| < 1 month | 53.9 | 50.0 | | 48.8 | 59.6 | |
| 1–3 months | 17.1 | 28.1 | | 21.4 | 23.1 | |
| 4–6 months | 14.5 | 9.4 | | 20.2 | 5.8 | |
| > 6 months | 14.5 | 12.5 | 0.588 | 9.5 | 11.5 | 0.142 |
| Presence of STD-related symptoms | | | | | | |

**Table 2** (continued)

| | Intervention group | | | Control group | | |
|---|---|---|---|---|---|---|
| | Non-drop-outs (n = 76) (%) | Drop-outs (n = 32) (%) | p value | Non-drop-outs (n = 84) (%) | Drop-outs (n = 52) (%) | p value |
| No | 27.6 | 18.8 | | 26.2 | 19.2 | |
| Yes | 72.4 | 81.2 | 0.330 | 73.8 | 80.8 | 0.352 |
| On STD treatment | | | | | | |
| No | 21.1 | 9.4 | | 26.2 | 15.4 | |
| Yes | 78.9 | 90.6 | 0.146 | 73.8 | 84.6 | 0.140 |
| Sexual behaviors since exhibiting STD symptoms or receiving an STD diagnosis | | | | | | |
| Condomless sexual intercourse with female regular sex partners (RP) | | | | | | |
| Had not had sex with RP since STD diagnosis | 43.4 | 34.4 | | 36.9 | 48.1 | |
| No | 31.6 | 28.1 | | 32.1 | 23.1 | |
| Yes | 25.0 | 37.5 | 0.414 | 31.0 | 28.8 | 0.379 |
| Condomless sexual intercourse with non-regular female sex partners (NRP) | | | | | | |
| Had not had sex with NRP since STD diagnosis | 75.0 | 75.0 | | 69.0 | 76.9 | |
| No | 18.4 | 18.8 | | 16.7 | 13.5 | |
| Yes | 6.6 | 6.3 | 0.997 | 14.3 | 9.6 | 0.591 |
| Condomless sexual intercourse with female sex workers (FSW) | | | | | | |
| Had not had sex with FSW since STD diagnosis | 77.6 | 81.3 | | 81.0 | 84.6 | |
| No | 17,1 | 15.6 | | 9.5 | 9.6 | |
| Yes | 5.3 | 3.1 | 0.865 | 9.5 | 5.8 | 0.736 |
| Perceptions related to voluntary medical male circumcision (VMMC) | | | | | | |
| Perceptions based on the health belief model (HBM) | | | | | | |
| Perceived benefit of VMMC (% agree/strongly agree) | | | | | | |
| VMMC would reduce the risk of HIV infection | 26.3 | 31.3 | 0.601 | 31.0 | 36.5 | 0.501 |
| VMMC would reduce the risk of STD infection | 44.7 | 46.9 | 0.839 | 42.9 | 55.8 | 0.143 |
| VMMC would increase sexual pleasure | 35.5 | 40.6 | 0.616 | 40.5 | 46.2 | 0.515 |
| VMMC would reduce female sex partner's risk of STD infection | 55.3 | 43.8 | 0.274 | 56.0 | 48.1 | 0.371 |
| VMMC would increase female sex partner's sexual pleasure | 27.6 | 25.0 | 0.778 | 27.4 | 38.5 | 0.177 |
| Perceived benefit scale (mean/SD) | 16.7 (2.8) | 16.8 (2.7) | 0.890 | 16.6 (2.9) | 17.0 (3.1) | 0.425 |
| Perceived barrier of taking up VMMC (% agree/strongly agree) | | | | | | |
| VMMC is expensive for me | 14.5 | 12.5 | 0.787 | 11.9 | 15.4 | 0.561 |
| VMMC would cause pain on penis | 51.3 | 46.9 | 0.673 | 46.4 | 38.5 | 0.362 |
| VMMC would result in severe surgical complications (e.g., bleeding, edema or inflammation) | 44.7 | 40.6 | 0.694 | 38.1 | 32.7 | 0.524 |
| VMMC would result in erectile dysfunction | 13.2 | 15.6 | 0.735 | 14.3 | 15.8 | 0.860 |
| I am embarrassed to take up VMMC | 26.3 | 40.6 | 0.140 | 26.2 | 32.7 | 0.415 |
| Perceived barrier scale (mean/SD) | 14.3 (2.3) | 14.8 (2.6) | 0.306 | 13.8 (2.7) | 14.5 (3.2) | 0.219 |
| Perceived self-efficacy of taking up VMMC (% agree/strongly agree) | | | | | | |
| I am confident that I can take up VMMC if desired | 77.6 | 78.1 | 0.955 | 75.0 | 75.0 | 1.000 |
| Whether to take up VMMC or not is completely under my control | 80.3 | 84.4 | 0.615 | 86.9 | 82.7 | 0.500 |
| I am confident that I can take up VMMC in the next 6 months | 23.7 | 21.9 | 0.839 | 20.2 | 26.9 | 0.366 |
| I have sufficient resources enabling me to take up VMMC in the next 6 months | 26.3 | 34.4 | 0.398 | 26.2 | 28.8 | 0.735 |
| Perceived Self-efficacy scale (mean/SD) | 13.7 (3.0) | 14.0 (2.8) | 0.600 | 13.4 (2.9) | 13.4 (2.7) | 0.994 |
| Perceptions based on the theory of planned behavior (TPB) | | | | | | |
| Perceived subjective norm related to VMMC uptake (% agree/strongly agree) | | | | | | |
| Some doctors would support you taking up VMMC | 59.2 | 53.1 | 0.559 | 57.1 | 50.0 | 0.416 |

**Table 2** (continued)

| | Intervention group | | | Control group | | |
|---|---|---|---|---|---|---|
| | Non-drop-outs (n = 76) (%) | Drop-outs (n = 32) (%) | p value | Non-drop-outs (n = 84) (%) | Drop-outs (n = 52) (%) | p value |
| Your peers would support you taking up VMMC | 43.4 | 21.4 | 0.137 | 39.3 | 32.7 | 0.438 |
| Your female sex partners would support you taking up VMMC | 48.7 | 50.0 | 0.901 | 46.4 | 48.1 | 0.852 |
| Perceived subjective norm scale (mean/SD) | 10.3 (2.7) | 9.7 (2.1) | 0.239 | 10.3 (2.5) | 10.0 (2.5) | 0.465 |

p values were obtained by using Chi square test (categorical variables) and two-sample t-test (continuous variables)

**Table 3** Comparisons of primary outcome and secondary outcomes between the intervention group and the control group

| | Intervention (%) | Control (%) | RR (95% CI) | ARR (95% CI) | NNT (95% CI) | p value[a] |
|---|---|---|---|---|---|---|
| Primary outcome | | | | | | |
| Uptake of voluntary male medical circumcision (VMMC) during the 6-month follow-up period | 14.8 (16/108) | 2.9 (4/136) | **5.03 (1.73, 14.62)** | **11.9 (4.6, 19.2)** | **8.4 (5.2, 21.8)** | **0.001** |
| | Intervention (n = 108) mean (SD) | | | Control (n = 136) mean (SD) | | p value[b] |
| Secondary outcomes | | | | | | |
| Perceived benefit scale | | | | | | |
| Baseline | 16.7 (2.8) | | | 16.7 (2.9) | | 0.989 |
| Month 6 | 18.8 (3.4) | | | 17.1 (3.0) | | **< 0.001** |
| p value[c] | **< 0.001** | | | 0.274 | | |
| Perceived barrier scale | | | | | | |
| Baseline | 14.5 (2.4) | | | 14.1 (2.4) | | 0.278 |
| Month 6 | 12.2 (3.7) | | | 13.2 (3.4) | | **0.026** |
| p value[c] | **< 0.001** | | | **0.002** | | |
| Perceived self-efficacy scale | | | | | | |
| Baseline | 13.7 (3.0) | | | 13.4 (2.9) | | 0.280 |
| Month 6 | 15.0 (3.4) | | | 13.4 (2.9) | | **< 0.001** |
| p value[c] | **< 0.001** | | | 0.789 | | |
| Perceived subjective norm scale | | | | | | |
| Baseline | 10.1 (2.6) | | | 10.2 (2.5) | | 0.948 |
| Month 6 | 10.7 (2.3) | | | 10.0 (2.4) | | **0.022** |
| p value[c] | **0.015** | | | 0.519 | | |

*RR* relative risk is the ratio of the event rate in the intervention group divided by the event rate in the control group, *ARR* absolute risk reduction is the arithmetic difference between the event rate in the intervention group and the event rate in the control group, *NNT* number needed to treat is the number of participants that needed to be intervened for on to benefit compared with a control in a clinical trail

[a]p values were obtained by using Chi square test

[b]p values were obtained by using two-sample *t* test

[c]p values were obtained by using paired *t* test

RR (95% CI), ARR (95% CI), NNT (95% CI) and p values were bold for variables with $p < 0.05$ in between-group and within-group comparisons

chance to receive cues to action from media, other healthcare providers, and internal cues (e.g., STD symptoms). Furthermore, evaluating the intervention sessions observed by audio/video taping was considered to be the gold standard to access fidelity. We however, were not able to do so as our participants were MSTDP and the studied questions covered sensitive topics such as their STD status and sexual behaviors.

**Table 4** Test for independent effect of changes in scale scores (Month 6 vs. baseline) on the association between intervention status and uptake of VMMC during the follow up period (n = 244)

| Model | Variables | B | S.E. | AOR (95% CI) | p value |
|---|---|---|---|---|---|
| 1 | Intervention status | 2.28 | 0.73 | 9.77 (2.53, 40.59) | 0.002 |
| 2A | Change in score of the perceived benefit scale | 0.66 | 0.17 | 1.93 (1.40, 2.67) | < 0.001 |
| 3A | Intervention status | 1.90 | 1.02 | 6.69 (0.91, 49.08) | 0.062 |
| | Change in score of the perceived benefit scale | 0.58 | 0.16 | 1.79 (1.32, 2.43) | < 0.001 |
| 2B | Change in score of the perceived barrier scale | − 2.06 | 0.73 | 0.13 (0.03, 0.54) | 0.005 |
| 3B | Intervention status | 0.50 | 1.49 | 1.66 (0.09, 30.94) | 0.736 |
| | Change in score of the perceived barrier scale | − 2.00 | 0.76 | 0.14 (0.03, 0.60) | 0.009 |
| 2C | Change in score of the perceived self-efficacy scale | 2.07 | 0.68 | 7.90 (2.07, 30.15) | 0.003 |
| 3C | Intervention status | 0.86 | 0.66 | 2.36 (0.65, 8.58) | 0.191 |
| | Change in score of the perceived self-efficacy scale | 0.52 | 0.11 | 1.69 (1.36, 2.09) | < 0.001 |
| 2D | Change in score of the subjective norm scale | 0.63 | 0.15 | 1.87 (1.39, 2.53) | < 0.001 |
| 3D | Intervention status | 2.00 | 0.82 | 7.35 (1.49, 36.34) | 0.014 |
| | Change in score of the subjective norm scale | 0.59 | 0.17 | 1.81 (1.31, 2.51) | < 0.001 |

*AOR* adjusted odds ratios, odds ratios adjusted for potential confounders measured at baseline (socio-demographics, HIV/STD related service utilization, STD history and sexual behaviors since exhibiting STD symptoms or receiving an STD diagnosis)

## Conclusion

In sum, the RCT findings showed that the brief theory-based and setting-based VMMC promotion was effective in increasing uptake of VMMC among MSTDP in China. Findings of this study should be disseminated to Centers for STD Control at provincial and national level. Larger scale implementation research project involving more STD clinics with similar settings both inside and outside Guangdong Province should be considered in future. Adaption of this brief intervention should be made in order to integrate it with the routine services of STD clinics. Cost-effectiveness analysis should also be conducted.

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## Compliance with Ethical Standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Research Involving Human Participants** All procedures performed in studies involving human participants were in accordance with the ethical standards of the Ethics Committee of Guangdong Provincial Dermatology Hospital, Guangzhou, China and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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