

Effectiveness evaluation of a comprehensive HIV intervention based on Internet and community engagement among MSM populations in China: a prospective multicenter cluster randomized controlled trial

Zhen Jiang

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Chen-Long Lv

State Key Laboratory of Pathogen and Biosecurity, Academy of Military Medical Science

Fan Lv

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Li-Li Dai

Beijing Youan Hospital, Capital Medical University.

Wei Ma

Shandong University

Jie Wu

The First Affiliated Hospital, Zhejiang University School of Medicine.

Wei Luo

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Kangmai Liu

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Keming Rou

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Zhen Xie

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Zihuang Chen

Danlan (Beijing) Media Co.

Fei Yu

Danlan (Beijing) Media Co.

Zhaobing Cao

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Tingli Dong

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Jie Xu

xujie@chinaaids.cn

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

Liqun Fang

State Key Laboratory of Pathogen and Biosecurity, Academy of Military Medical Science

Zunyou Wu

National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine

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Abstract

Background

The integration of Internet- and community-based interventions against HIV transmission represents a promising avenue. This study aims to assess their practical effectiveness among men who have sex with men (MSM) in China.

Methods

A cluster randomized controlled trial was conducted among MSM in 20 selected cities across China from February 1, 2019 to June 30, 2021. An Internet-based HIV appointment testing platform, integrated with offline HIV screening services, was developed and implemented in 10 intervention cities.

Findings

A total of 5788 and 2965 participants were enrolled from 10 intervention and 10 control cities, respectively, of which 171 and 96 individuals tested positive for HIV infection at the conclusion of the trial. Intervention group exhibited higher testing frequencies (43·81% tested more than twice vs. 39·66%, $p < 0·05$) and lower self-assessment HIV risk scores (11·12 vs. 11·20, $p < 0·05$) compared to control group. Modeling analysis revealed that the interventions significantly increased testing frequency among participants who reported having no sexual partners, being uncertain about their sexual partners' HIV status and having never used condoms during heterosexual behaviors during recent six months. Additionally, the intervention reduced risk scores among residents who had not engaged in anal intercourse in the past six months and had never previously undergone HIV testing.

Interpretation

Our findings suggest that these interventions have a significant impact on two indicators associated with HIV infection risk. Future research should prioritize long-term evaluations of these interventions' effects on HIV incidence and explore effective strategies and measures for scaling up comprehensive intervention programs.

Trial registration

The trial has been registered in www.chictr.org.cn, number ChiCTR1900020921 on Jan.22,2019.

Introduction

Men who have sex with men (MSM) have consistently played a key role in the HIV epidemic both globally and within China.¹ The proportion of new HIV infections attributable to MSM transmission ranged from 21·4% to 28·25% annually between 2013 and 2018 in China.² To control the HIV epidemic among MSM, China has been dedicated to community-based interventions during the past decades. Significant improvements in community intervention packages have been driven by two key developments: the enhanced functionality of MSM community-based-organizations (CBOs) and the establishment of new cooperation mechanisms among CBOs, hospitals, and CDCs.^{3–5}

In recent years, the use of mobile applications for seeking sex partners has become increasingly prevalent among MSM globally.^{6,7} The internet platforms offer avenues to promote awareness, encourage safer sex practices, and facilitate referrals to HIV/STI screening and prevention interventions through mobile and Internet technologies.⁸ Evidence suggests that HIV interventions through mobile or digital health approaches are both feasible and acceptable, with preliminary data indicating efficacy and promising trends in HIV prevention and treatment outcomes.^{9–11} Multilevel interventions that integrate digital health strategies have significantly improved engagement of Chinese MSM in the HIV care continuum.^{12,13} Social media platforms and sex-seeking apps targeting MSM represent an efficient approach to actively engaging this population in public health HIV interventions.¹⁴

In 2019, we initiated the Project “Clustered randomized trials of HIV infectious agent controlling among MSM population” across twenty cities (ten for the intervention group and ten for the control group) in six eastern provinces: Guangdong, Shandong, Jiangsu, Zhejiang, Hebei, and Fujian provinces. The project aims to promote comprehensive HIV care through integrated Internet- and community-based HIV interventions. This report details the implementation process and evaluates the effectiveness of this multicenter cluster randomized controlled trial (RCT). The trial has been registered in www.chictr.org.cn, number ChiCTR1900020921 on Jan.22,2019.

Methods

Study design

We adopt a multicenter cluster RCT design with one intervention arm and one control arm, using cities as cluster units. A total of 20 clusters were chosen from six provinces along China’s eastern coastal region. The selection criteria included cities with an urban population between one and five million and those reporting more than 90 newly diagnosed HIV cases among MSM during 2015–19. The selected 20 cities were paired on a 1:1 basis, taking into account their geographical location and the coverage rates of antiretroviral treatment for HIV infections among MSM(Figure 1). Within each pair, cities were randomly assigned to either the intervention group or the control group. Participants in the control cities received standard care according to local protocols, while the intervention group implemented a series of measures, including promoting testing culture within the MSM community, enhancing mental health

support, facilitating HIV testing appointments through social media platforms, ensuring early diagnosis and rapid treatment, and providing post-exposure prophylaxis (PEP).

Participants, Cohort establishment and follow-up

To recruit and follow up participants, we developed an HIV testing appointment platform named “HAPPY TESTING” on the largest MSM social media platform, Blued, in each city pair. This platform linked online recruitment with offline HIV testing services (HTS), for MSM with fixed-point voluntary counseling and testing services provided by CBOs or local CDCs (appendix p 4). Participants were required to be at least 18 years old, report engaging in anal sex with men within the past year, voluntarily participate in the study, and provide online informed consent. Individuals who did not engage in male-to-male sexual behavior in the past 12 months, did not use MSM dating apps, or refused to participate in the study and sign the informed consent were excluded (appendix p 2).

Eligible participants completed online surveys and subsequently scheduled in-person appointments for HIV testing (appendix pp 2–3 and 5). We informed participants about the data collection procedures and provided them opportunities to ask questions and opt out of the study. If participants consented to data sharing, all study data were maintained in strict confidence. No financial compensation was provided for participation in order to obtain informed consent. Participants who scheduled HIV testing via the appointment platform at least twice during the recruitment period formed the research cohort.

Statistical analysis

The intraclass correlation coefficient (ICC) was used to evaluate the consistency of demographic characteristics for the cohort, with a higher ICC indicating better reliability and validity of the cohort data.¹⁵ We used the incidence density, defined as the number of positive HIV individuals tested within a specific group divided by the total follow-up time of all tests in that group, to describe the intensity of new HIV infections in the population.

To examine the impact of intervention measures on various outcomes before or during the COVID-19 pandemic, we introduced a binary categorical variable (appendix p 3): first testing during the COVID-19 pandemic (yes/no), which was incorporated into both descriptive and modelling analyses. To maximize the utilization of participants’ HIV risk behavior self-assessment information in subsequent models, we imputed items with missing rates (denoted as “unknown”) below 25%. Random forest was applied for the imputation process, with the missing variables serving as the outcome variables.¹⁶

The negative binomial regression was applied to assess the impact of intervention measures on the testing frequency among participants. The follow-up time was computed from the date of cohort recruitment with an initial negative HIV test to the date of the first positive testing or the last follow-up examination. Individual models were also constructed for the interaction between the follow-up group and each of the other 19 variables, with the main effects of the remaining variables considered as

potential covariates, aiming to compare the heterogeneity of intervention effects across different populations. The gross domestic product (GDP) per capita, population density, HIV epidemic among MSM in 2015 (proportion of HIV-positive reports among MSM to urban population), and HIV testing coverage from 2015 to 2018 (proportion of MSM who have undergone HIV testing to the urban population) at city level were considered in the modeling analysis, in order to adjust for the impacts of the regional discrepancy.

In addition, we conducted both generalized linear models (GLMs) and Cox regression models to separately examine the associations of HIV risk self-assessment scores and the risk of HIV infection with the intervention measures, adhering to the previously outlined modeling procedures. Furthermore, we conducted sensitivity analyses by repeating the modeling procedures using the original un-imputed dataset which contained complete information of all variables (6580 participants, consist of 4315 in the intervention group and 2265 in the control group) to assess the robustness of our findings. All statistical analyses were performed using R software (version 4.3.2) and SAS software (version 9.4).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between February 1, 2019 and June 30, 2021, a total of 5788 participants in the intervention group and 2965 participants in the control group were recruited for online HIV screening tests (Fig. 1). Specifically, in the intervention group, 3582 participants were recruited before January 20, 2020, and 2206 after this date. In the control group, the corresponding numbers were 2033 and 932. By the end of the trial, a total of 171 cases in the intervention group and 96 cases in the control group were identified as having suspected HIV infection, resulting in suspected HIV seroconversion rates of 2·95% and 3·24%, respectively.

Among the intervention group, higher proportions of younger, highly educated individuals with non-local domicile were recruited for the HIV screening test (Table 1). Furthermore, higher proportions of students, office workers and commercial service while lower proportions of workers and freelance workers were observed in the intervention group than the control group. The intervention group had a higher proportion of individuals with incomes above 5000 or below 3000, relatively, married or cohabiting, and divorced or widowed individuals accounted for more in the control group. Regarding the HIV risk behaviors during recent six months, higher proportions of individuals with sexual role of 0 or 1, no group sexuality, no heterosexual or commercial homosexual behaviour, having STIs and using addictive substances were seen in the intervention cities by compared to the control cities. In addition, there were more individuals who had never undergone HIV test before and took their first test for HIV screening during the COVID-19 pandemic in the intervention group. Analysis of the temporal changes in the number of testing persons

revealed a sharp decline around January 20, 2020, followed by a gradual return to the original level (appendix p 6). Similarly, the number of new HIV infections demonstrated comparable temporal dynamics. Overall, apart from certain changes observed in the occupation (average ICC was 0·389) and sexual orientation (average ICC was 0·486), the other demographic characteristics (average ICC ranged from 0·637 to 0·978) of the participants maintained good consistency across the multiple information collections during the follow-up (appendix p 7).

Table 1

Comparison of baseline information between the intervention group and the control group.

Demographic features	Intervention	Control	<i>p</i> value
Age, years (median, IQR)	27 (22, 34)	30 (24, 39)	< 0·001
18–24 (n, %)	2258 (39·01)	797 (26·88)	< 0·001
25–34 (n, %)	2182 (37·70)	1152 (38·85)	
35–44 (n, %)	820 (14·17)	609 (20·54)	
≥ 45 (n, %)	528 (9·12)	407 (13·73)	
Domicile (n, %)			0·006
Local	3948 (68·21)	2109 (71·13)	
Non-local	1840 (31·79)	856 (28·87)	
Education (n, %)			< 0·001
High educated	1949 (33·67)	703 (23·71)	
Medium educated	2986 (51·59)	1638 (55·24)	
Low educated	853 (14·74)	624 (21·05)	
Occupation (n, %)			< 0·001
Office workers	1665 (28·77)	803 (27·08)	
Commercial service	904 (15·62)	415 (14·00)	
Workers	527 (9·11)	457 (15·41)	
Students	857 (14·81)	283 (9·54)	
Freelance workers	1177 (20·34)	676 (22·80)	
Others	658 (11·37)	331 (11·16)	
Income, yuan (n, %)			< 0·001
>5000	2128 (36·77)	1011 (34·10)	
3001–5000	1963 (33·92)	1217 (41·05)	
1501–3000	694 (11·99)	350 (11·80)	
≤1500	1003 (17·33)	387 (13·05)	
Sexual orientation (n, %)			0·334

Demographic features	Intervention	Control	<i>p</i> value
Homosexuality	3315 (57.27)	1689 (56.96)	
Bisexuality	1781 (30.77)	947 (31.94)	
Unknown	692 (11.96)	329 (11.10)	
Marital status (n, %)			< 0.001
Married or cohabitation	1380 (23.84)	1040 (35.08)	
Unmarried	4104 (70.91)	1723 (58.11)	
Divorce or widowhood	304 (5.25)	202 (6.81)	
HIV risk behavior			
Anal and/or oral sex with men (n, %)			0.236
No	784 (13.55)	374 (12.61)	
Yes	5004 (86.45)	2591 (87.39)	
Number of sexual partners during recent six months (n, %)			0.603
0	427 (7.38)	215 (7.25)	
1	2171 (37.51)	1112 (37.50)	
≥2	2406 (41.57)	1264 (42.63)	
Unknown	784 (13.55)	374 (12.61)	
Status of sexual partners during recent six months (n, %)			0.824
Without HIV infected sexual partners	2449 (42.31)	1262 (42.56)	
Unclear HIV infection of sexual partners	1994 (34.45)	1044 (35.21)	
With treated HIV infected sexual partners	103 (1.78)	55 (1.85)	
With untreated HIV infected sexual partners	31 (0.54)	15 (0.51)	
Unknown	1211 (20.92)	589 (19.87)	
Use of condom during anal intercourse during recent six months (n, %)			0.204
Every time	2582 (44.61)	1365 (46.04)	
Sometimes	1511 (26.11)	800 (26.98)	
Never	222 (3.84)	100 (3.37)	
No anal intercourse	1046 (18.07)	485 (16.36)	

Demographic features	Intervention	Control	<i>p</i> value
Unknown	427 (7.38)	215 (7.25)	
Sexual role during recent six months (n, %)			< 0.001
0	1034 (17.86)	503 (16.97)	
0 & 1	1716 (29.65)	1033 (34.84)	
1	1565 (27.04)	729 (24.59)	
Unknown	1473 (25.45)	700 (23.61)	
Group sexuality during recent six months (n, %)			0.030
Never	1918 (33.14)	955 (32.21)	
Sometimes	477 (8.24)	301 (10.15)	
Often	69 (1.19)	36 (1.21)	
Unknown	3324 (57.43)	1673 (56.42)	
Commercial homosexual behaviour during recent six months (n, %)			0.001
No	5337 (92.21)	2672 (90.12)	
Yes	451 (7.79)	293 (9.88)	
Use of condom during heterosexual behavior during recent six months (n, %)			< 0.001
Every time	2073 (35.82)	1199 (40.44)	
Sometimes	997 (17.23)	587 (19.80)	
Never	496 (8.57)	288 (9.71)	
No heterosexual behavior	2222 (38.39)	891 (30.05)	
Sexually transmitted infections during recent six months (n, %)			0.010
No	5513 (95.25)	2860 (96.46)	
Yes	275 (4.75)	105 (3.54)	
Use of addictive substances during recent six months (n, %)			0.016
No	4787 (82.71)	2513 (84.76)	
Yes	1001 (17.29)	452 (15.24)	
Sexual activity after drinking alcohol during recent six months (n, %)			0.094
No	4640 (80.17)	2422 (81.69)	

Demographic features	Intervention	Control	<i>p</i> value
Yes	1148 (19·83)	543 (18·31)	
The information of HIV screening			
First HIV testing for lifetime (n, %)			
No	4246 (73·36)	2261 (76·26)	0·004
Yes	1542 (26·64)	704 (23·74)	
First testing during the COVID-19 pandemic (n, %)			< 0·001
No	3581 (61·87)	2031 (68·50)	
Yes	2207 (38·13)	934 (31·50)	

Of the twenty selected cities, intervention and control city pairs were situated within the same province or in adjacent provinces (Fig. 2A). Among them, the median numbers of participants in the intervention group and control group were 381 (ranged from 290 to 1109) and 327 (ranged from 94 to 549). During the follow-up period, there were 9 cities with the HIV seroconversion rates higher than 3%. The testing frequency for each participant ranged from 2 to 20 times. Specifically, 57·59% of participants were tested twice, 13·55% were tested three times, and 9·17% were tested four times (Fig. 2B). The median HIV risk scores in the intervention cities varied between 9 and 11·820, whereas in the control cities, it ranged from 10·525 to 13·215 (Fig. 2C).

Compared to the control cities, the participants in the intervention cities exhibited higher testing frequency (43·81% of participants in the intervention group tested more than twice, 39·66% of participants in the control group tested more than twice, $p < 0·001$), and lower HIV risk self-assessment scores (the median score of the intervention group was 11·12, the median score of the control group was 11·20, $p = 0·021$) (Fig. 3A and B). However, no significant difference in the HIV seroconversion rate (2·95% in the intervention group, 3·24% in the control group, $p = 0·507$) and in the HIV incidence density (3·49% in the intervention group, 3·35% in the control group, $p = 0·748$) were found between the two groups (Fig. 3C and D). Through further stratified comparison, it was found that higher HIV risk self-assessment scores were observed either in the control group or the infected group than those of their respective reference group, if the differences between groups were significant (appendix p 8). Furthermore, the implementation of intervention measures exerted a notable positive influence on individuals in avoiding the selection of sexual partners with HIV infections and consistently using condoms during heterosexual behaviour (appendix p 9).

Based on the univariate negative binomial regression analysis, higher testing frequency were observed to be significantly associated with the intervention measures (Table 2). The individuals aged 35 and above tended to have a lower testing frequency, whereas those who were non-local or bisexual showed a higher

testing frequency. The individuals who had engaged in anal intercourse were more inclined to undergo multiple times of HIV test, while the opposite was true for those with untreated HIV infected sexual partners during recent six months. Additionally, higher testing frequency were observed in the individuals with first HIV testing during the COVID-19 pandemic. The results aligned with those derived from the sensitivity analysis (appendix pp 10–11). Furthermore, through interaction analyses, we identified the significant impact of intervention measures on testing frequency across various subgroups, encompassing most levels within all candidate variables (Fig. 4). These effects consistently demonstrated that intervention measures promoted an increase in testing frequency within the corresponding subgroups, which were further corroborated in sensitivity analysis conducted using the un-imputed dataset (appendix p 12). In the interaction analyses on demographic characteristics, the intervention measures had a particularly prominent effect on increasing the testing frequency among subgroups such as individuals aged 18 to 24 years, non-local residents, and students. Similarly, with the assistance of intervention measures, the testing frequency were also elevated visibly among subgroups with zero sexual partner, sexual role of 0, and those who were unclear the HIV infections of their sexual partners and never used condoms during heterosexual behaviour during recent six months.

Table 2

Negative binomial regression analysis of influencing factors associated with testing frequency.

Variables	Univariate analysis		Multivariate analysis	
	β	<i>p</i> value	β	<i>p</i> value
Follow-up group				
Control	Ref	—	Ref	—
Intervention	0.265	< 0.001	0.240	< 0.001
Demographic features				
Age, years				
18–24	Ref	—	Ref	—
25–34	−0.089	0.014	−0.060	0.152
35–44	−0.198	< 0.001	−0.170	0.003
≥ 45	−0.259	< 0.001	−0.236	< 0.001
Domicile				
Local	Ref	—	Ref	—
Non-local	0.110	0.002	0.084	0.017
Education				
High educated	Ref	—	Ref	—
Medium educated	−0.080	0.023	−0.039	0.304
Low educated	−0.063	0.178	0.037	0.501
Occupation				
Office workers	Ref	—	Ref	—
Commercial service	−0.045	0.355	−0.068	0.172
Workers	−0.037	0.494	−0.016	0.783
Students	0.142	0.007	0.093	0.214
Freelance workers	−0.042	0.342	−0.028	0.529
Others	0.003	0.953	0.007	0.901
Income, yuan				
>5000	Ref	—	Ref	—

Variables	Univariate analysis		Multivariate analysis	
	β	<i>p</i> value	β	<i>p</i> value
3001–5000	0.037	0.302	0.046	0.216
1501–3000	0.009	0.859	−0.010	0.852
≤1500	0.097	0.045	−0.039	0.554
Sexual orientation				
Homosexuality	Ref	–	Ref	–
Bisexuality	0.045	0.186	0.079	0.032
Unknown	−0.009	0.859	0.026	0.626
Marital status				
Married or cohabitation	Ref	–	Ref	–
Unmarried	0.113	0.001	−0.016	0.719
Divorce or widowhood	0.082	0.227	0.100	0.143
HIV risk behavior				
Anal and/or oral sex with men				
No	Ref	–	Ref	–
Yes	0.122	0.014	0.146	0.045
Number of sexual partners during recent six months				
0	Ref	–	Ref	–
1	0.001	0.987	−0.031	0.584
≥2	0.065	0.181	0.017	0.780
Status of sexual partners during recent six months				
Without HIV infected sexual partners	Ref	–	Ref	–
Unclear HIV infection of sexual partners	−0.002	0.957	−0.003	0.927
With treated HIV infected sexual partners	−0.001	0.990	−0.001	0.996
With untreated HIV infected sexual partners	−0.747	0.022	−0.768	0.018
Use of condom during anal intercourse during recent six months				
Every time	Ref	–	Ref	–

Variables	Univariate analysis		Multivariate analysis	
	β	<i>p</i> value	β	<i>p</i> value
Sometimes	−0.029	0.438	0.011	0.795
Never	−0.097	0.254	−0.010	0.908
No anal intercourse	−0.070	0.091	0.038	0.562
Sexual role during recent six months				
0	Ref	—	Ref	—
0 & 1	−0.032	0.425	−0.023	0.583
1	−0.065	0.108	−0.039	0.368
Commercial homosexual behaviour during recent six months				
No	Ref	—		
Yes	0.024	0.661		
Use of condom during heterosexual behavior during recent six months				
Every time	Ref	—	Ref	—
Sometimes	−0.061	0.169	−0.078	0.135
Never	−0.136	0.020	−0.118	0.065
No heterosexual behavior	−0.021	0.555	−0.058	0.148
Sexually transmitted infections during recent six months				
No	Ref	—		
Yes	0.083	0.263		
Use of addictive substances during recent six months				
No	Ref	—	Ref	—
Yes	0.054	0.187	0.013	0.756
Sexual activity after drinking alcohol during recent six months				
No	Ref	—		
Yes	−0.005	0.897		
The information of HIV screening				
First HIV testing for lifetime				

Variables	Univariate analysis		Multivariate analysis	
	β	<i>p</i> value	β	<i>p</i> value
No	Ref	–	Ref	–
Yes	–0·050	0·179	–0·074	0·056
First testing during the COVID-19 pandemic				
No	Ref	–	Ref	–
Yes	0·139	< 0·001	0·118	0·001

In the GLM analysis for HIV risk self-assessment scores, six variables were identified as significant based on the multivariate model (appendix p 13). Specially, intervention measures showed a significant effect on lowering the individual risk scores. Individuals aged no less than 25, medium educated, earning between 1501 and 3000, and those who were homosexual and had never undergone HIV testing before, all demonstrated higher risk scores. Sensitivity analysis further revealed that students exhibited higher risk scores (appendix p 14). Through modeling analysis for interaction, we found that the intervention measures remarkably reduced the risk scores among populations such as local residents, those with zero sexual partner, and those who were not engaged in anal intercourse and had never undergone HIV testing before (appendix p 15). Consistent with the primary analysis, the sensitivity analysis also confirmed the effectiveness of intervention measures in reducing the risk scores among individuals who consistently used condoms during heterosexual behaviour during recent six months and those who underwent their first testing prior to the COVID-19 pandemic (appendix p 16).

Based on the Cox regression, seven and three variables were significantly associated with the risk of HIV infection in the univariate and multivariate analysis, respectively (appendix pp 17–18). The individuals aged no less than 45 and who played sexual roles as 1 during recent six months, displayed lower risk of HIV infection, while the individuals who sometimes used condom during anal intercourse had a higher risk compared to those who used them consistently. Notably, sensitivity analysis also uncovered that individuals with two or more sexual partners during recent six months were at high risk of HIV infection (appendix pp 19–20). In the Cox models of interaction, no significant impact of the intervention measures on the risk of HIV infection was observed across various populations, except for those with a sexual role of 0 during recent six months, probably due to our relatively short study period, during which the effects of the intervention measures had not yet manifested (appendix pp 21–22). Notably, HIV risk scores showed a significantly positive association with the risk of HIV infection, while lower testing frequency was significantly associated with higher risk of HIV infection, with this correlation being particularly pronounced in the intervention group (appendix p 23).

Discussion

In this RCT study, a repeated testing cohort was established through the dual platform recruitment, comprising 8753 participants who initially tested negative and underwent retesting between February 1, 2019 and June 30, 2021, across 20 cities in eastern China. By the end of the trial, a total of 171 cases (2·95%) in the intervention group and 96 cases (3·24%) in the control group were identified with suspicious HIV infection.

Compared to the control cities, individuals in the intervention cities exhibited a higher frequency of HIV testing and lower self-assessed HIV risk scores. However, no statistically significant differences were observed in the HIV seroconversion rates or HIV incidence density between the two groups. Given the time needed to detect meaningful differences in HIV infection incidence,¹⁷ our analysis also includes a wider range of behavioural indicators closely linked with reduced HIV to improve confidence that a distal improvement in incident infections is likely. Further interaction analysis revealed that the intervention measures were particularly effective in consistently increasing testing frequency and reducing risk scores among specific subgroups. This finding further underscores the urgent need for targeted and effective interventions to address the unmet needs of HIV testing among MSMs.¹⁸

Our data confirm that the integrated HIV care promoted increased HIV testing.¹⁹ Higher testing frequency was also observed among participants who had engaged in anal intercourse. Improving awareness of pre-exposure prophylaxis (PrEP) through increasing access to PrEP-related health education and strengthened perception of HIV infection risk may yield positive outcomes among subpopulations exhibiting both high-risk behaviors and frequent HIV testing.²⁰ The findings underscore the urgent need for an integrated HIV service continuum that combines scaled-up HIV testing with PrEP/PEP, aiming to establish both biological and behavioral protective measures to further maximize the benefits of internet- and community-based interventions.

Furthermore, our research indicates differences in risk assessment scores between infected and uninfected individuals, suggesting that the HIV risk self-assessment tool holds significant potential for population-level risk monitoring and assessment. However, it should be noted that the consistency of sexual orientation data, closely associated with HIV transmission risk, is lower across multiple self-assessment questionnaires when compared to demographic and sociological indicators. This may imply that respondents tend to provide more inconsistent or random answers when reporting sensitive information online. As certain changes are deemed reasonable within the risk self-assessment section, a consistency test could not be conducted. However, it remains to be further verified whether the sensitivity of certain issues might influence respondents' answers, thereby potentially affecting the authenticity of the crowd-based monitoring in the risk self-assessment process to some extent.

During the COVID-19 pandemic, MSM were globally reported to have fewer sexual partners, along with reduced access to HIV testing and care, compared to pre-pandemic levels.²¹ In China, strict non-pharmaceutical interventions (NPIs) against the COVID-19 epidemic were implemented between January and May 2020. Studies have indicated that following a relaxation of these strict NPIs in China, MSM have experienced a rebound in HIV risk behavior scores and an increase in the uptake of HIV testing.²² Within

our project, a significant decline in the number of individuals undergoing testing was observed between January and April 2020. Testing levels gradually returned to pre-pandemic levels after May 20, 2020, with a corresponding trend seen in the number of new HIV infections. This fluctuation in testing frequency accurately reflects changes in HIV testing accessibility before and after the implementation of the strict NPIs. The pandemic disrupted HTS partly due to individuals avoiding healthcare facilities to minimize exposure risk, as well as public health departments reallocating certain sexual health resources toward COVID-19-related response efforts.^{21,23}

The proportion of participants who were first tested at different phases of the COVID-19 pandemic varied significantly between groups, with a greater number of individuals in the intervention group being tested after January 20, 2020. In comparison with real-world data, several scenario analyses were conducted to assess the potential impact of the pandemic on HIV incidence. These analyses examined scenarios in which services affected by the pandemic, including HIV testing, care engagement, PrEP uptake, and retention, were compared against a counterfactual scenario in which no changes due to the pandemic occurred.^{24,25} In the absence of behaviour changes, however, the combined effects of a six-month reduction in condom use, HIV testing, viral suppression, PrEP initiations, PrEP adherence, and ART initiations are predicted to increase new HIV infections by median 10.5% (5.8 to 16.5) over 1 year, and by median 3.5% (2.1 to 5.4) over 5 years.²⁶ The interplay of positive factors (e.g., reduced sexual partners, advanced health awareness) and negative factors (e.g., disrupted health services) complicates the attribution of changes in HIV incidence.

There are several limitations in this study. First, to evaluate and compare the intervention effects, online and offline HIV screening testing platform, as well as self-risk assessment tools, were established to facilitate cohort follow-up and data collection in both the intervention and control cities. However, these measures themselves may have exerted a health promotion effect on the target populations in both arms, thus potentially attenuating the observed differences between the intervention and control groups.^{27–31} Second, the inherent risk of observation bias should be considered when interpreting the results of this study. Specifically, a follow-up period of 29 months may not have been sufficient to capture meaningful differences between intervention and control groups, even though the intervention measures significantly reduced the HIV-related behavioral risks of the population, compared to the control cities. Furthermore, loss to follow-up has been increasing over time, a trend potentially exacerbated during COVID19-pandemic. This may introduce bias and lead to a potentially inaccurate estimation of differences in suspicious infection rates. Although these findings warrant further in-depth investigation, such analyses fall beyond the scope of the current study. A third limitation is that, as the observation period of this study ended before the conclusion of the COVID-19 pandemic, the data are insufficient to determine whether new infections rebounded in its aftermath. The fourth limitation is that, although cities implementing integrated interventions demonstrated higher levels of HIV testing compared to control cities, the scale-up of a fixed number of offline HIV testing sites in most cities may not be sufficient to meet the needs of the large MSM population. Future distribution of both online

appointment systems and offline HIV testing services should focus on improving accessibility, equity, and convenience, particularly for MSM in rural and remote regions.

Abbreviations

AIDS: Acquired Immunodeficiency Syndrome

ART: Antiretroviral Therapy

CBO: Community-Based Organization

CDC: Centers for Disease Control and Prevention

COVID-19: Coronavirus Disease 2019

GDP: Gross Domestic Product

GLM: Generalized Linear Model

HIV: Human Immunodeficiency Virus

HTS: HIV Testing Services

ICC: Intra-cluster Correlation Coefficient

MSM: Men Who Have Sex with Men

NPIs: Non-pharmaceutical Interventions

PEP: Post-Exposure Prophylaxis

PrEP: Pre-Exposure Prophylaxis

RCT: Cluster Randomized Controlled Trial

STD: Sexually Transmitted Disease

VCT: Voluntary Counselling and Testing

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention & Chinese Academy of Preventive Medicine (Approval No.: X180629516). Inform

consent prior to enrolment was obtained electronically from all participants, and the consent obtained from all participants was informed consent.

Consent for publication

Not applicable. No identifiable individual person's data, images, or clinical details are presented in this manuscript.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to restrictions by the data provider, which were used under license for the current study, but are available upon reasonable request to both corresponding authors and with permission from the data providers (JX and ZJ).

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributors

Z-YW, JX, ZJ, LF, L-LD, WM, JW, WL, K-ML, K-MR, ZX, Z-HC, FY, conceived, designed, and supervised the study. Z-YW, JX, and ZJ formulated the protocols, guidelines, and standard operating protocols of the active surveillance. ZJ, Z-HC, FY, Z-BC, T-LD and MSM subproject research team of the 13th Five-Year National Science and Technology Major Project "Precision-Guided HIV Intervention Technologies Research among High-Risk Groups" collected the data. ZJ, Z-BC, T-LD cleaned the data. ZJ and C-LL analyzed the data. ZJ, L-QF, and C-LL wrote the drafts of the manuscript. JX, ZJ, and L-QF interpreted the findings. JX, ZJ, L-QF, LF, L-LD, WM, HW, WL, K-ML, K-MR, ZX, Z-HC, FY, Z-BC, and T-LD commented on and revised the drafts of the manuscript. The corresponding authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. All the authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol. The trial investigators had access to the data, but the sponsors did not.

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Figures

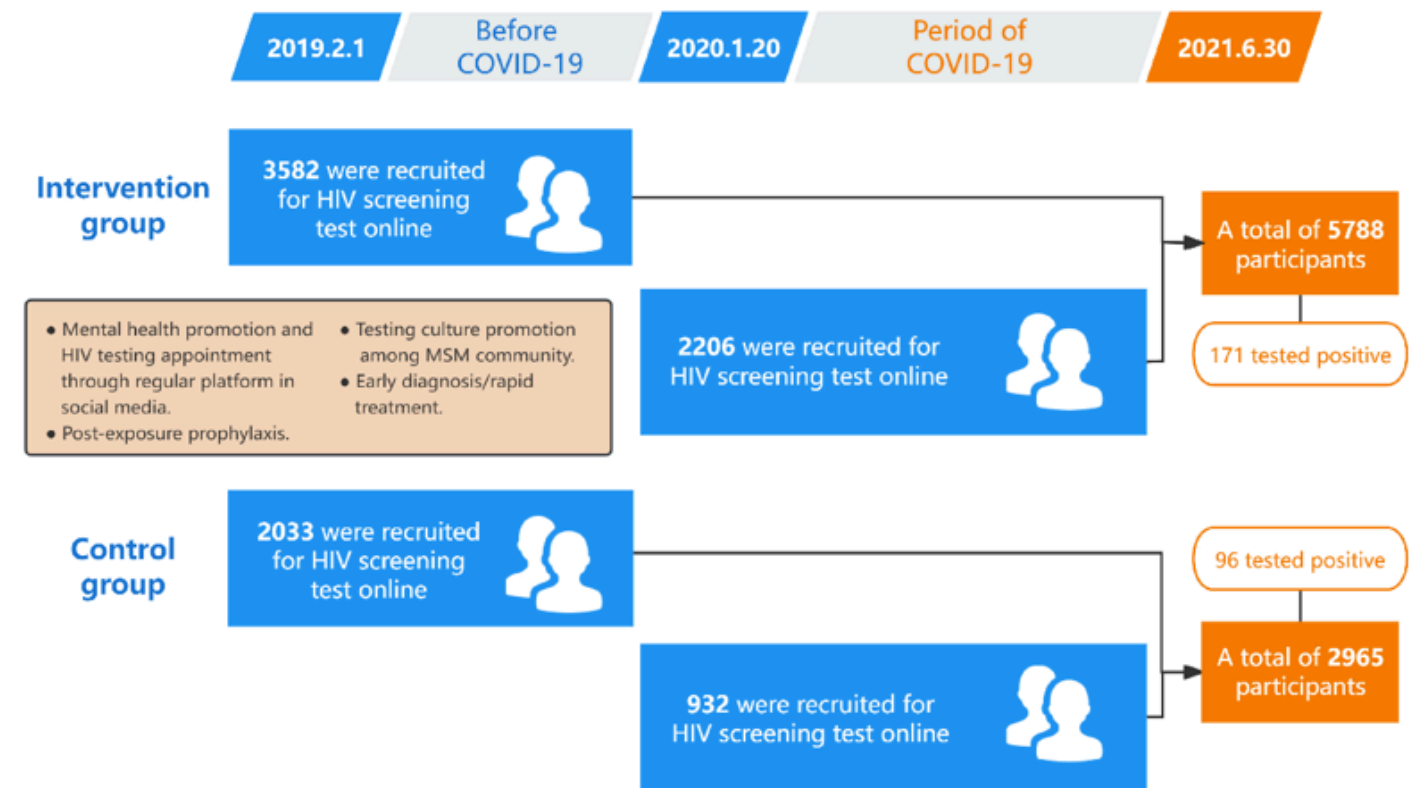


Figure 1

The framework of the cohort follow-up study.

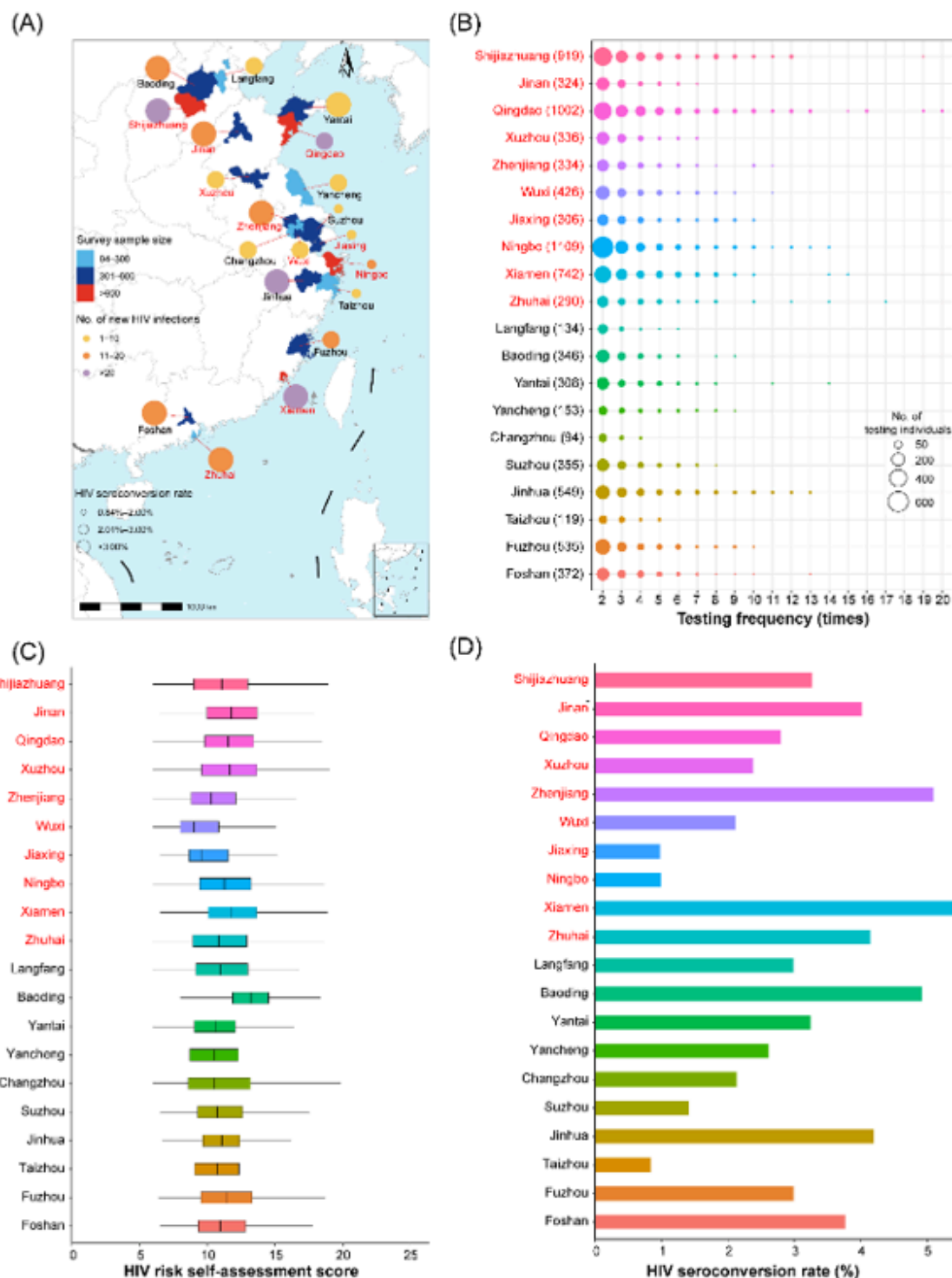


Figure 2

Geographical distribution and comparison of HIV outcomes and testing patterns across cities within the MSM cohort. (A) Geographical distribution of the HIV outcomes. (B) Distribution of testing frequency across cities. (C) Distribution of HIV risk self-assessment scores across cities. (D) HIV seroconversion rates across cities. Cities belonging to the intervention group and control group are labeled in red and black, respectively.

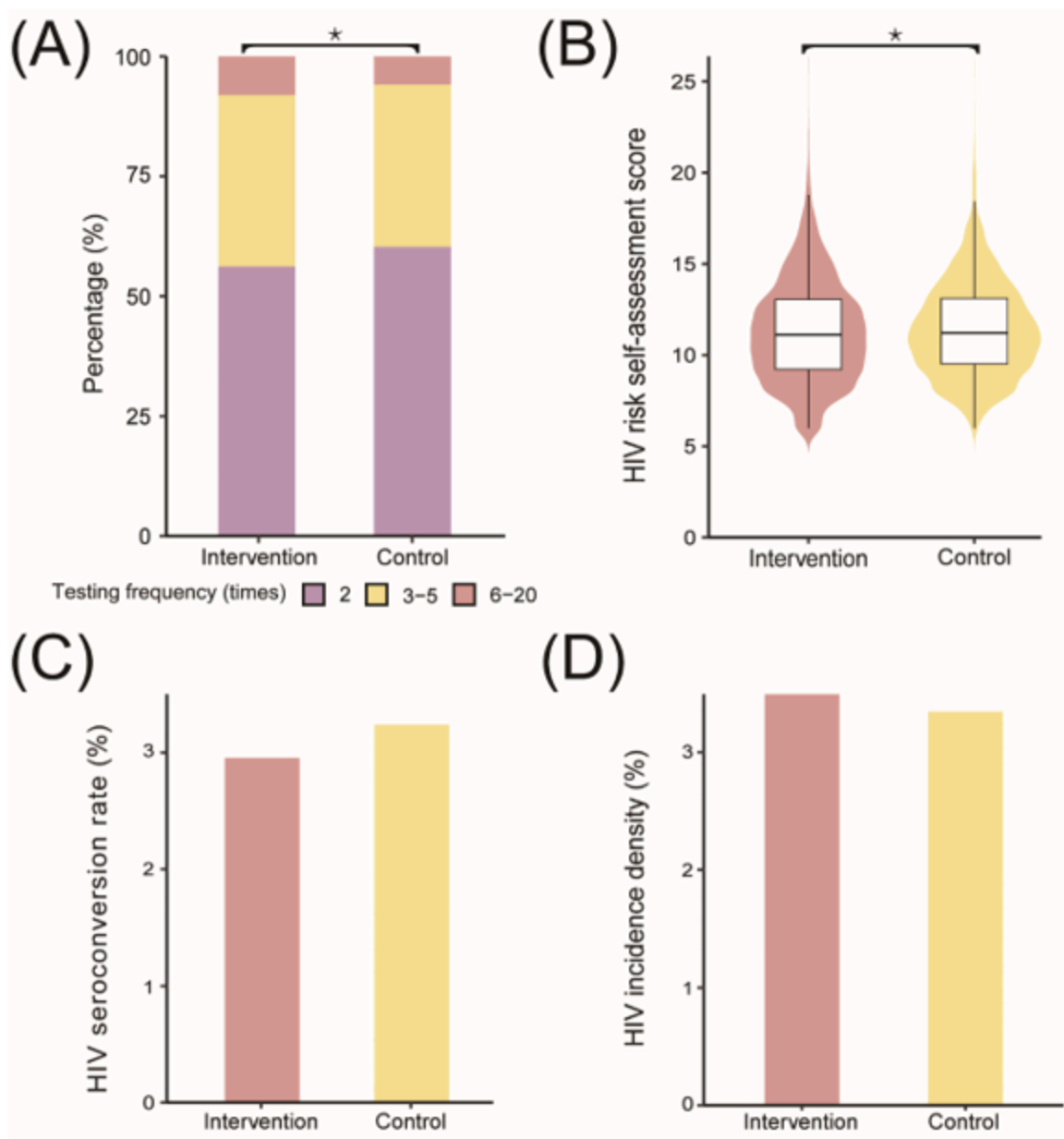


Figure 3

Comparison of different outcomes between the intervention group and the control group. (A) Testing frequency. (B) HIV risk self-assessment scores. (C) HIV seroconversion rates. (D) HIV incidence density. Significant differences between the two groups are indicated by asterisks placed above the corresponding panels.

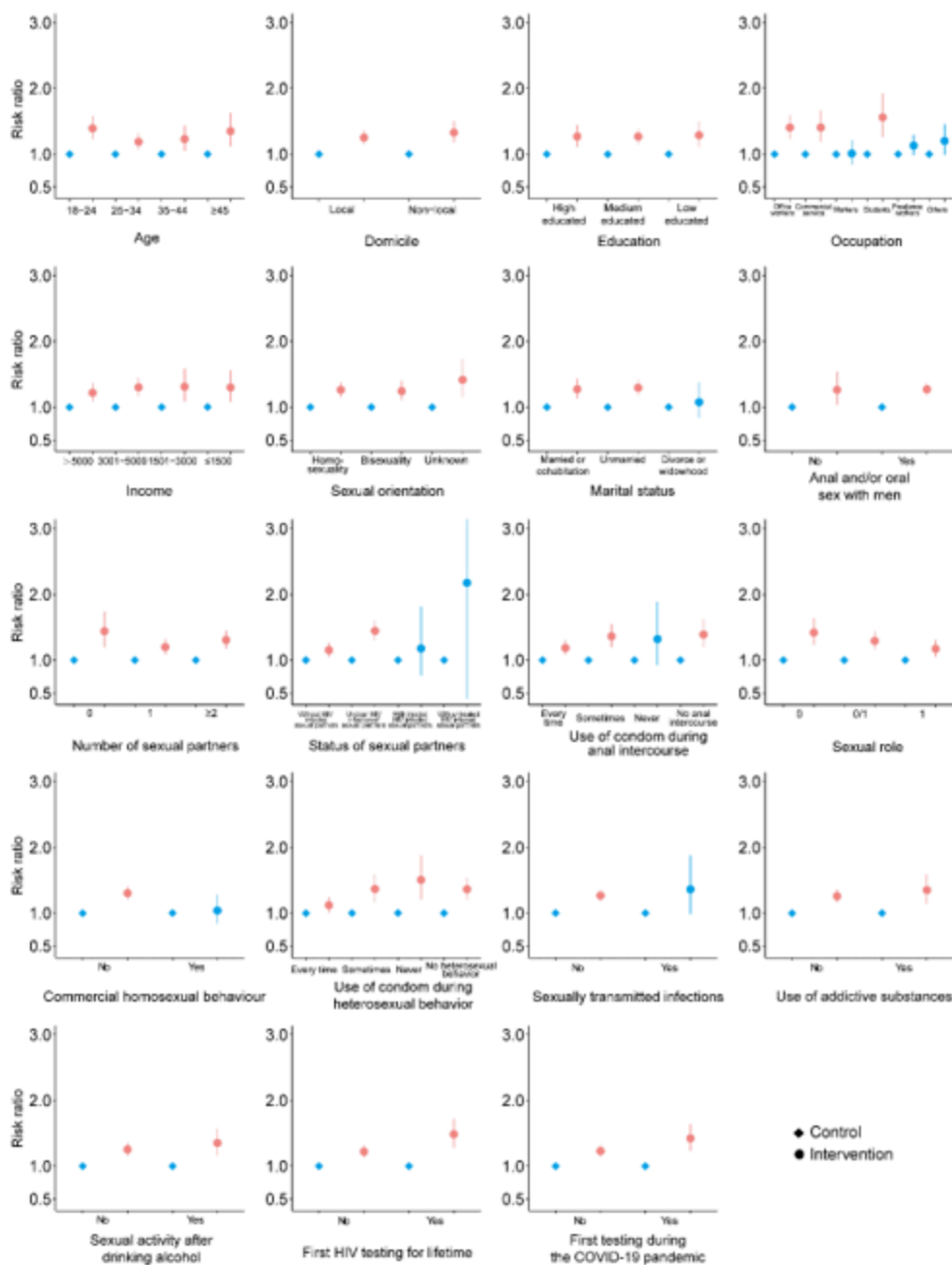


Figure 4

The impact of the intervention measures on testing frequency across different subgroups. The intervention groups marked in red within each subgroup indicate significant intervention effects compared to the control group.

Supplementary Files

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