

BMJ Open Usability of dual HIV/syphilis self-testing among men who have sex with men in China: study protocol for a three-arm randomised controlled trial

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ABSTRACT

Introduction HIV self-testing (HIVST) provides a key measure for the early detection of HIV infection in men who have sex with men (MSM). However, dual HIV/syphilis self-testing in the MSM population has not been studied. We describe a randomised controlled trial to evaluate the effect of dual HIV/syphilis self-testing on the testing frequency among MSM in China.

Methods and analysis This randomised controlled trial will be implemented in Guangxi, China. 330 MSM, including 255 frequent testers and 75 less frequent testers, will be recruited and randomly assigned in a 1:1:1 ratio into one of three arms: a site-based testing arm, a single HIVST arm and a dual HIV/syphilis self-testing arm. Participants in the single HIVST arm and dual HIV/syphilis self-testing arm will receive two free finger-prick-based HIVST or HIV/syphilis self-testing kits at enrolment. The data will be collected at five separate times: baseline, 3 months, 6 months, 9 months and 12 months. The primary outcome is the mean frequency of HIV testing used by MSM after intervention comparing each group during the study period. The secondary outcome includes changes in sex behaviours (eg, number of male sex partners and the proportion of consistent condom use) and the mean number of HIV tests used by the social network members over the study period.

Ethics and dissemination The study protocol was reviewed and approved by the Medical Ethics Committee of Guangxi Medical University, China (20210173). The study results will be disseminated through conferences and academic journals.

Trial registration number ChiCTR2100050898.

INTRODUCTION

In 2020, 1.5 million people became newly infected with HIV worldwide, of which men who have sex with men (MSM) accounted for 23%.¹ The risk of acquiring HIV is 25 times higher among gay men and other MSM than the general population.¹ In China, the HIV prevalence and incidence among MSM are increasing and have reached 8.0% and 5.7 per 100 person-years, respectively.^{2,3} Notably, MSM are one of the key populations for HIV

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A parallel, open-label and three-arm randomised controlled trial will conduct to address the effect of dual HIV/syphilis self-testing on the testing frequency among men who have sex with men.
- ⇒ Recruiting less frequent testers in each group closer to a real-world setting.
- ⇒ The principal limitations are self-reported data may increase the likelihood of social desirability bias as measures of impact.

infection.⁴ It is estimated that more than 8 million Chinese men are sexually active MSM, of whom 2.5 million are at high risk of infection.⁵

To end AIDS, the Joint United Nations Programme on HIV/AIDS set up the 95-95-95 goal by 2025: 95% of people living with HIV (PLWH) know their status, 95% of PLWH who know their status initiate treatment and 95% of people living on treatment are virally suppressed.⁶ However, approximately 6.1 million (16%) PLWH did not know that they were living with HIV around the World in 2020.¹ It was estimated that 20% of PLWH were unaware of their HIV status in China.⁷ Regular HIV testing is an effective way to detect potential infections among other key populations, such as MSM⁸⁻¹⁰ In China, the HIV screening rate was estimated at approximately 53% among MSM.⁵ Although the Chinese Center for Disease Control and Prevention (CDC) has clear recommendations on the frequency of HIV testing for MSM, few MSM perform repeated testing as recommended.^{10,11} In 2019, data from a meta-analysis showed that approximately half of MSM have not been tested for HIV among Chinese students MSM.¹² Studies have shown that MSM know that their own HIV infection status can reduce high-risk sexual behaviour,

thereby reducing their HIV transmission rate.^{13–16} HIV self-testing (HIVST) offers an outstanding opportunity to further expand HIV testing coverage, identify PLWH but unaware of the infection and link more cases to care.¹⁷

At the same time, the transmission routes of syphilis and HIV are similar. Syphilis infection increases the risk of MSM being infected with HIV, promotes the spread of HIV and even changes the progression of the two diseases.¹⁸ The WHO recommends providing dual HIV/syphilis rapid testing to screen high-risk populations to reduce undiagnosed and untreated morbidity and mortality.¹⁹ The dual testing rate among MSM in China remains very low.^{20–21} The results showed that approximately one-third of MSM have not been tested for HIV and syphilis.^{20–22} Therefore, it is necessary to carry out dual HIV/syphilis self-testing in MSM. Previous research showed that it is acceptable for the tester to use the same blood sample for double testing without collecting additional specimens.^{23–24} HIVST can also promote partner testing through the secondary distribution of test kits²⁵; that is, an individual who is provided multiple self-test kits can distribute them to sexual partners or others in their social network.²⁶ Peers within the key HIV-infected population play an important role in facilitating HIV prevention in that population, for example, by promoting the uptake of HIV testing and linkage to care.^{27–28} There is an evidence that providing free HIVST kits significantly increases testing frequency among Chinese MSM and effectively enlarges HIV testing coverage by enhancing partner HIV testing through the distribution of kits within their sexual networks.²⁹

However, there is very little evidence of the impact of the distribution of dual HIV/syphilis self-testing kits on the frequency of HIV testing. To that end, we will recruit 330 MSM to evaluate the effect of self-testing on the testing frequency, determine whether dual self-testing is more effective for HIV testing frequency among the MSM as well as prospectively assess the secondary distribution of HIVST kits. This study aims to address the above research gaps in a well-designed, randomised controlled trial.

METHODS/DESIGN

This is a parallel, open-label, three-arm randomised controlled trial. Participants will be recruited in Guangxi. The HIV/AIDS epidemic in Guangxi is rising among MSM.³⁰ We define MSM who had at least two HIV tests in the last year as frequent testers and those who tested less than two times or had never tested as less frequent testers. Frequent and less frequent testers will be simply randomly assigned to one of three groups in a 1:1:1 ratio: site-based testing group, single HIVST group and dual HIV/syphilis self-testing group. The study design is shown in figure 1.

Study setting and recruitment

All MSM participants will be recruited by community-based organisations (CBOs) and social media such as

WeChat (Tencent, Shenzhen, China), an immediate messaging platform in China and Blued (Danlan, Beijing, China), a social network app for MSM. The study recruitment information will be released on WeChat public accounts of CBOs. The advertisement will include the study introduction, content, procedures, etc. Potential participants can contact the investigators via WeChat and make an appointment with local CBOs. Local CBOs staff will provide HIV/syphilis tests and counsel for MSM. If the participants who meet the inclusion criteria of the study, the researchers will obtain informed consent and conduct their baseline questionnaire process by face to face or on-line. After completing the screening procedure, the participants can scan the quick response (QR) code of the study by mobile phone to verify their unique identities.

Sample size

The target sample size was calculated based on the frequency of HIV testing of MSM using the software PASS V.15.0 (NCSS). We assumed that the frequency of HIV testing was higher in intervention groups than the control group and the variances of both intervention groups were equal. The mean and SD of the control group (1.40 and 1.13) and those of the intervention group (2.18 and 1.77) were used as the expected power in this study.³¹ Based on this assumption, with an alpha of 0.05, a power of 0.90, 99 MSM are needed per arm. Given a lost to follow-up rate of 0.10, we estimate conservatively that a total of 330 MSM, 110 in each arm, would be sufficient to power in the study. Based on the preliminary study results from members of the research team, frequent testers make up approximately 77.3% of MSM. We will recruit 255 frequent and 75 less frequent testers.

Inclusion and exclusion criteria

Individuals interested in the study who meet the following basic eligibility criteria will be scheduled for the informed consent process and baseline survey. Individuals will be eligible if they: (1) are born biologically male; (2) ever had anal sex with a man; (3) aged 18 years or older; (4) HIV and syphilis seronegative by rapid screening testing; (5) are willing to provide personal information; (6) are willing to participate in a 1-year follow-up survey; (7) are willing to use the self-testing kits for testing and feedback the results; and (8) live in Guangxi, China and do not leave Guangxi in the next 12 months. Participants were excluded if they: (1) had an obvious mental illness or intellectual disability or (2) had language and communication barriers and could not cooperate to complete the study.

Randomisation and blinding

After a screening visit that will assess eligibility, the researchers will ask participants the number of HIV tests in the past year. Then, they will be divided into frequent testers and less frequent testers. All frequently and less frequently tested participants will be numbered

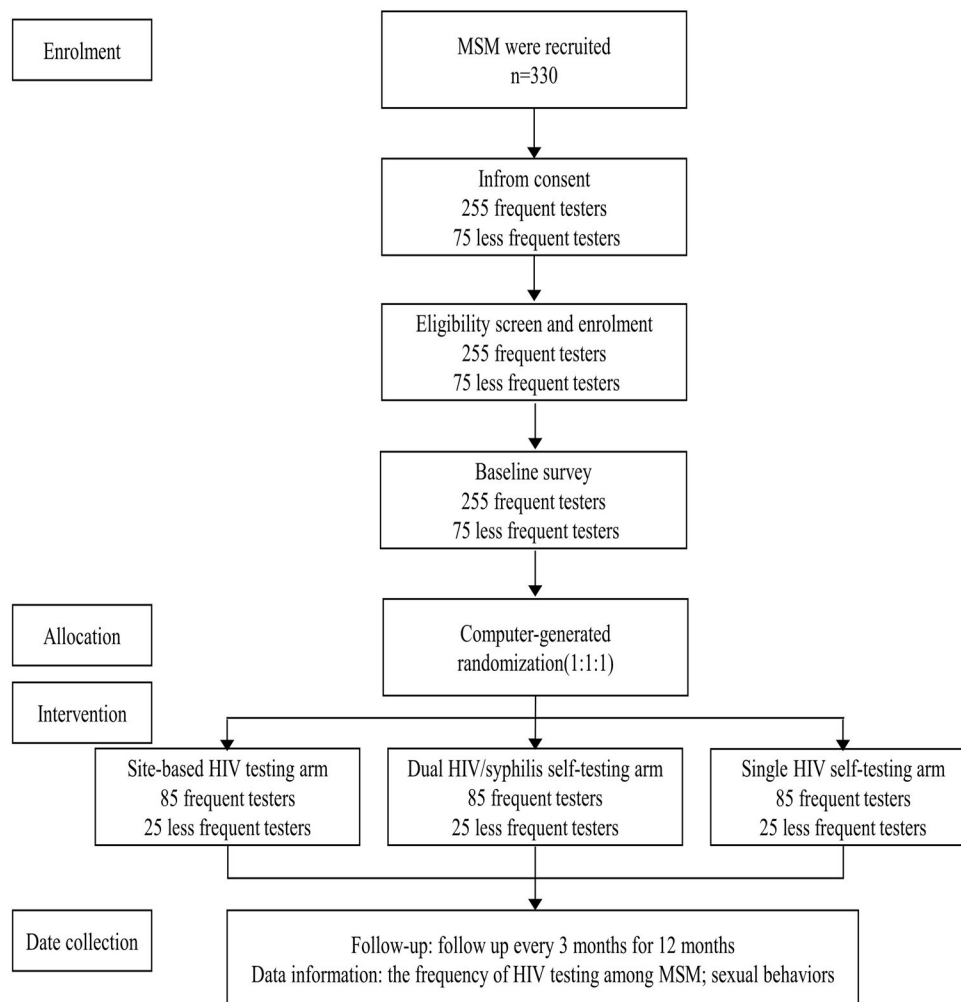


Figure 1 Study design. MSM, men who have sex with men.

according to the order of entry. Then, frequent testers and less frequent testers will be simple-randomly assigned to one of the following three groups in a 1:1:1 ratio: control groups, single HIVST group and dual HIV/syphilis group, respectively. The randomised number of frequently and less frequently tested participants will be generated by the computer software SPSS V.29.0 (IBM). The grouping result of each random number is sealed and numbered in a special envelope. After the participants pass the screening, they open the envelopes in turn to obtain the grouping results.

The data analyst will not be involved in any interventions and will be blinded to group allocation. As researchers

and participants were not able to mask group assignment, this is an open study.

Control group

Participants in the control group can take HIV testing in hospitals, CDCs and CBOs or use HIVST kits from others. We will issue exclusive online virtual cards with the unique ID number and QR code to the participants of the site-based group through WeChat every 3 months after enrolment. By scanning the QR code in the virtual card, the participants can upload the results of the HIV test. HIV testing results can be either from site-based testing or self-testing.

Intervention

Intervention group

When participants are assigned to the intervention group, we will send a standard self-testing operation video via WeChat and 2 HIVST kits or HIV/syphilis self-testing kits to evaluate the effectiveness of self-testing in improving HIV testing frequency every 3 months. We will encourage our participants to test using kits and encourage them to distribute the kits to members within their social network

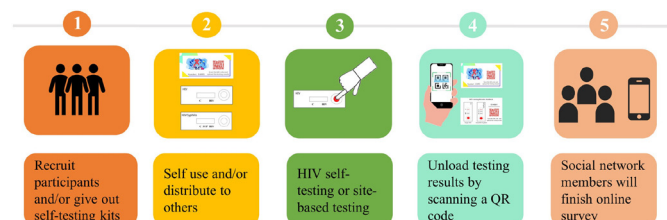


Figure 2 Social network distribution. QR, quick response.

HIV testing Results feedback

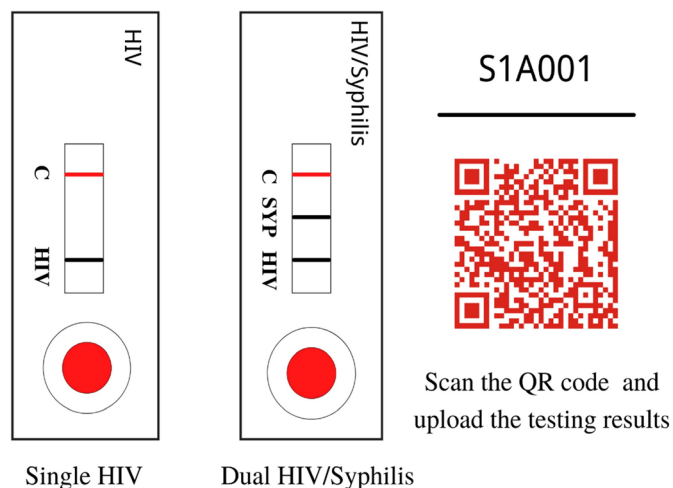


Figure 3 Uploading system of HIV testing results. OR, quick response.

(figure 2). If they run out of kits and feedback all the testing results within 3 months, they can apply for additional kits. To ensure that we can protect participants' privacy and use information in a way that they are comfortable with, these kits will be sent off by mail in private packages and not mention anything about HIV/AIDS.

HIV and dual HIV/syphilis self-testing kits

We will use Alere Determine HIV 1/2 and SD Bioline HIV/syphilis Duo rapid test kits. For Alere Determine HIV 1/2, the fourth generation HIV 1/2 rapid assay (Alere Medical, Japan), the specificity and sensitivity are 99.75% and 100%, respectively.³² For SD Bioline HIV/syphilis duo, the specificity and sensitivity of HIV-1/2 are 99.67% and 99.91%, and the specificity and sensitivity of syphilis are 99.72% and 99.67%, respectively.³³ The tester needs to wait a minimum of 15 min (up to 60 min) to read the result.

Result feedback

Participants will feedback the results through a QR code (figure 3).

Each self-testing kit has a unique ID number of participants during the follow-up period every 3 months. After receiving the self-testing kits, the participants can use them for HIV testing or donate the self-test kits to their comrades, friends or sexual partners for testing. Each self-testing kit, whether used by the research subject or their comrades, friends or sexual partners, needs to report the results instantaneously to the researchers after detection. When feeding back the self-testing results, the participants need to synchronously send the unique ID number of the used kit to the researcher. When someone other than the participant feedbacks the result, we will ask about their relationship with the participant.

Outcome measures

The primary outcome is the mean frequency of HIV testing used by MSM after intervention comparing each group, including self-testing and site-based tests in 12 months. The secondary outcome includes the change in sexual behaviours (eg, number of male sex partners, the proportion of consistent condom use) and the mean number of HIV tests used by their social network members reported by participants during the 12 months comparing the control group and intervention group.

Data collection

Participants in the control and intervention groups will receive and complete the questionnaires via WeChat or phone survey five times at baseline, 3-month, 6-month, 9-month and 12-month follow-ups. In an attempt to make each MSM participant feel as comfortable as possible, the research staff will interview them in a private place.

Baseline survey

All eligible participants will complete a baseline survey at MSM CBOs at enrolment. The baseline survey collects information: (1) sociodemographic characteristics, including age, biological sex, residence status, marital status, highest education, monthly income, sexual orientation, etc; (2) sexual behaviours, including sexual history with men and/or women, role during sex with men, condom use, number and type of sex partners, group sex, one-night stand, etc and (3) site-based testing or self-testing history of HIV testing information, self-reported risk perception for HIV infection, the number of HIV testing in the last 1 year, reasons of HIV testing, whether had done HIVST, etc.

Follow-up

All participants will complete a follow-up survey online through WeChat or phone survey every 3 months after entering the groups, thus completing a total of four follow-ups. The follow-up surveys will collect information on HIV and/or syphilis testing in the past 3 months, sexual behaviours in the past 3 months and their experience using self-testing kits. HIV and/or syphilis testing information includes testing frequency, testing results, number of tests and other testing methods; sexual behaviours include sexual history with men and/or women, role during sex with men, condom use, number and type of sex partners, group sex and one-night stand; and using self-testing kit information includes the number of self-testing kits used for self-testing and the number delivered to members of society. After the social network members of the participants upload the results, they complete a short questionnaire online. We will collect information on sociodemographic and HIV testing history.

If the participants or their social network members using HIV are diagnosed with syphilis, we will provide them with STD referral services. If the participants or their social network members have positive results using HIVST kits, we will also do as above.

Table 1 Timeline of the study

Study period	Enrolment		Allocation		Postallocation		Close-out
	September 2021– February 2022	September 2021– February 2022	T1*	T2†	T3‡	T4§	March–August 2023
Enrolment:							
Recruitment	×						
Informed consent	×						
Eligibility screen	×						
Allocation		×					
Interventions:							
Single HIV self-testing			×	×	×	×	
Dual HIV/syphilis self-testing			×	×	×	×	
Site-based testing			×	×	×	×	
Assessments							
Baseline questionnaire	×						
Follow-up questionnaire			×	×	×	×	
Analyse data							×
*T1: 1–3 months after enrolment.							
†T2: 3–6 months after enrolment.							
‡T3: 6–9 months after enrolment.							
§T4: 9–12 months after enrolment.							

The research staff will contact participants for follow-up appointments during the follow-up window. For those who fail to make an appointment or fail to attend the follow-up visit within the agreed time, the research staff will contact them again through various contact methods. To achieve a higher cohort retention rate, participants who complete five surveys (baseline and four follow-up surveys) will receive additional compensation that is provided to participants for their time spent after filling out the questionnaires (¥100 for baseline, 3-month and 6-month follow-ups, ¥80 for 9-month and 12-month follow-ups). Invited testers will complete the online survey by Sojump (Changsha Haoxing Information Technology, China) when uploading test results.

Data management

The recruiting staff will record the study number, group number, and phone number for use during the follow-up period in the records. All baseline and follow-up data collected from participants will be entered directly into computers via EpiData V.3.1 (EpiData Association, Odense, Denmark). To improve the data quality of the research, we will set up a verification mechanism. When a questionnaire has been completed, we will check it first. If it has only one logical error, we will verify with the participant. The research staff will also conduct a double check for the data. The survey data of social network members and photographs of testing results will be recorded directly in the online database by Sojump. The database system automatically saves the data to ensure its security, integrity, and consistency. The study researchers

must enter username and password to gain access to the information.

Data analysis

The data will be analysed by SPSS V.29.0. The intention to treat will be used in the all statistical analyses. The socio-demographic characteristics, sexual behaviour characteristics and HIV testing-related variables will be summarised using descriptive statistics, including mean, SD, count, percentage, etc.

To estimate the effect of self-testing on HIV testing frequency among MSM, we will use generalised linear mixed model to compare the results between the three groups at 3, 6, 9 and 12 months follow-up. Intervention will be considered a fixed effect.

For the secondary outcomes, we will use the similar method to compare differences in the proportions of male partners of MSM and have male sex partners without condoms, the number of men who are social network members of MSM participants taking HIV testing during the follow-up period, etc. The baseline characteristics of MSM who lost to follow-up will be compared with those who completed at least one follow-up survey in the observed period. We will also carry out a subgroup analysis based on frequent and less frequent testers. Two-sided tests with $p < 0.05$ were considered statistically significant.

Missing data plan

Participants will complete four follow-up surveys until the end of the study. If there were missing data, we recorded the reasons and number of missing data points. If there

is missing for <10% of participants in the follow-up, we will use a complete-case approach. If there is missing for ≥10% of participants in the follow-up, multiple imputation method will be used for imputing the missing values.

Study schedule

The study will span approximately 2 years from 1 September 2021 to 31 August 2023 (table 1). The researchers will recruit participants in the first 6 months. The intervention and data collection will continue for 1 year. We will analyse data and publish the paper at the end of the 6 months.

Patient and public involvement

Between 1 August 2021 and 20 August 2021, 30 MSM were enrolled in the pretest study. These included 25 frequent and 5 less frequent testers. The results indicated the participants preferred finger-prick-based testing kits (20 of 30 (66.7%)), ever used HIVST kits (13 of 30 (43.3%)) and were willing to distribute self-testing kits to social network members (29 of 30 (96.7%)). We have collected all of this information, which can help us to design a better study. They had no role in study design, recruitment and conduction. All participants can drop out at any time after assessing the burden of the intervention. The results will be disseminated to the study population and public after study completion.

ETHICS AND DISSEMINATION

The study was reviewed and approved by the Medical Ethics Committee of Guangxi Medical University, China (No. 20210173). The informed consent forms will be obtained from all participants before taking part in the study. This informed consent form describes what is the object of the research and what personal information will be collected. The results of the study will be disseminated through academic journals and conferences.

Trial registration

The study has been registered with the Chinese Clinical Trial Registry (trial ID: ChiCTR2100050898).

DISCUSSION

The HIV infection rate of MSM is increasing annually in China. HIV testing is critical to control the HIV/AIDS epidemic, especially MSM. However, the HIV testing rate is low. A serial cross-sectional study found that the HIV prevalence was high, and 16.2% (168/1036) of MSM who had never been tested for HIV were diagnosed with HIV.³⁴

HIVST provides a key measure for the early detection of HIV infection. It can reduce barriers to testing and potentially be delivered at low cost, and it can also serve those who cannot or will not access traditional HIV testing services.³⁵ An RCT showed that HIVST significantly increased regular HIV testing among participants.³⁶ Because the outbreak of COVID-19, attendance at facility-based HIV testing has become more difficult because

of clinic closures, challenges with social distancing and related difficulties.³⁷ In 2020, the Global Fund to Fight AIDS reported that, according to data collected at 502 health facilities in 32 African and Asian countries, HIV testing declined by 41%.¹ HIVST and supplementation with internet-based support is a convenient and confidential option for HIV testing, allowing people to take an HIV test and learn the outcome in their own home or at other private locations.³⁸ Moreover, on mailing and applying the test kit, support consultations during testing, uploading of testing outcomes and follow-ups can be conducted over the internet.^{39 40} However, dual HIV/syphilis self-testing is not truly being spread across the population.⁴¹

One of the major strengths of this study is the use of the social network to enlarge HIV testing coverage. HIVST, through internet recruitment and the distribution of tests by mail, could be a promising new strategy to reach more at-risk persons. We will encourage our participants to distribute self-testing kits to their sex partners or other people. However, to the best of our knowledge, there is no evidence to implement a single HIV or dual HIV/syphilis self-testing intervention and measure its effect on HIV testing coverage among MSM in China. The effect of dual HIV/syphilis self-testing interventions on HIV testing coverage and testing frequency in MSM in China has not been established. Therefore, the results of this study will provide opportunities for HIV testing scale-up and testing frequency.

This study has some limitations that should be considered. First, although the sample size calculation was conducted based on previous studies, the study findings will need to be confirmed with a larger number of participants, not just MSM. Second, to reach the sample size, it may take a long time to recruit MSM who meet the criteria, especially recruiting less frequent testers. Therefore, we will use as many methods as possible to recruit MSM, such as gay apps, WeChat or QQ chat groups, and CBOs. Third, all information we collected will be self-reported in our study, which may introduce social desirability bias. To reduce the likelihood of bias, we will guarantee the confidentiality of the results of the questionnaire to the participants.

This article presents the design and protocol of a randomised controlled trial investigating the effectiveness of a single HIV or dual HIV/syphilis self-testing intervention on increasing HIV testing frequency among MSM in China. If successful, the results of this innovative study will be expected to provide evidence and novel insights into the field of HIVST.

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Contributors HZ, MW and YZ contributed equally to this paper. PC, CN, HZ, MW and YZ conceived and designed the experiment. ST, HH, WT, JinM and JieM performed the study and experiments. JZ provided the plan for statistical analysis.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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