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Developing and testing an eHealth intervention to reduce sexual risks among men who have sex with men

Submission date 22/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 22/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 22/10/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Men who have sex with men (MSM) remain disproportionately affected by HIV and other sexually transmitted infections (STIs). In many regions, including Hong Kong, disparities in and the limited availability of pre-exposure prophylaxis (PrEP) contribute to continuing vulnerability. In addition, issues such as risk compensation related to PrEP use and the increasing prevalence of chemsex further complicate HIV and STI prevention among MSM.

Although several systematic reviews have shown that eHealth interventions can effectively improve sexual health among MSM, only a limited number of randomised controlled trials (RCTs) have been conducted in Chinese settings. Most previous trials were carried out in the United States and Europe, largely involving White, African American, or Latino participants. Moreover, many of these studies took place before PrEP became widely available and before chemsex emerged as a notable concern. As a result, some of the existing interventions may no longer be fully relevant to the current needs and realities of MSM communities. To address these gaps, there is a need to develop a culturally appropriate eHealth intervention specifically tailored to Chinese MSM. Such an approach can promote sexual health and support HIV/STI prevention in a way that reflects the local context. Importantly, an effective eHealth intervention could also be adopted by government and non-governmental organisations working with MSM populations. The aim of this study is therefore to develop an eHealth intervention using a participatory design approach and to evaluate its effectiveness in reducing sexual risk behaviours among MSM through an RCT.

Who can participate?

Individuals can take part in this study if they are cisgender men who have sex with men (MSM), are aged 18 years or above, are HIV-negative, have been sexually active within the past 12 months, and are able to communicate in Chines.

What does the study involve?

Chinese (MSM) will be invited to take part in this study. Participants will be randomly assigned to one of two groups: an intervention group (177 participants) or a control group (177 participants).

Those in the intervention group will take part in a web-based programme designed to promote safer sexual practices. The programme includes content that encourages consistent condom use and regular HIV and STI testing, presents these behaviours as normal and positive, and supports participants in feeling more confident about using and negotiating condom use. The materials will be tailored to each participant based on their initial assessment, such as condom use habits and use of HIV PrEP.

Participants in the control group will receive web-based information about mental health, without any sexual health content.

Participants in both groups will be evaluated at baseline and three and six months after baseline.

What are the possible benefits and risks of participating?
One possible benefit is that participants can enhance their sexual health knowledge. There is no significant risk in the study.

Where is the study run from?
School of Nursing, University of Hong Kong.

When is the study starting and how long is it expected to run for?
Participant recruitment is expected to begin in November 2025, and the study is expected to run until July 2026.

Who is funding the study?
Research Grants Council (General Research Fund), Hong Kong

Who is the main contact?
Professor Edmond Pui Hang Choi
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Developing and testing an eHealth intervention to reduce sexual risks among men who have sex with men: a randomized controlled trial

Study objectives
The objectives of this study are to develop an eHealth intervention using a participatory design approach and to evaluate its effectiveness in reducing sexual risk behaviours among men who have sex with men through a randomised controlled trial.

It is hypothesised that participants receiving the eHealth intervention will be more likely to report higher condom use consistency, more positive attitudes towards condom use, greater condom use self-efficacy, more frequent HIV and STI testing, and a lower likelihood of engaging in chemsex or group sex compared with men in the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/03/2022, Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (Room 901, 9/F, Administration Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong, -, Hong Kong; +852 2255 4086; hkwirb@ha.org.hk), ref: UW 22-146

Study design
Two-arm parallel-group assessor-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Safer sex to prevent sexually transmitted infections (STIs).

Interventions
Chinese men who have sex with men will be recruited and randomly allocated to either the intervention group (n = 177) or the control group (n = 177).

Participants in the intervention group will receive a web-based intervention containing content designed to:

-Encourage positive attitudes towards consistent condom use and regular HIV/STI testing, and negative attitudes towards chemsex and group sex;
-Promote condom use and regular HIV/STI testing as normative behaviours; and
-Enhance perceived self-efficacy regarding condom use, negotiation, and HIV/STI testing.

Tailored content and recommendations will be provided based on participants' baseline assessments (e.g., condom use practices and use of HIV pre-exposure prophylaxis).

The control group will receive web-based information on mental health (without sexual health components).

Participants in both groups will be assessed at baseline, and at 3 and 6 months after baseline.

Participants will be randomly assigned to either the intervention or control group through computer-generated block randomisation (block size = 4) using a 1:1 allocation ratio, with no stratification applied.

Intervention Type
Behavioural

Primary outcome(s)
Frequency of condomless anal sex measured using self-report, in the preceding 3 months (at baseline), at 3 months, and 6 months follow up

Key secondary outcome(s))
1. Self-efficacy in condom use measured using the validated traditional Chinese version of the Condom Self-Efficacy Scale at baseline, 3-month follow-up and 6-month follow-up
2. Attitudes towards condom use is measured by the UCLA Multidimensional Condom Attitudes Scale at baseline, 3-month follow-up and 6-month follow-up
3. Frequency of HIV and testing measured using self-report, in the preceding 3 months (at baseline), at 3 months, and 6 months follow up
4. Frequency of other STI testing measured using self-report, in the preceding 3 months (at baseline), at 3 months, and 6 months follow up
5. Frequency of group sex measured using self-report, in the preceding 3 months (at baseline), at 3 months, and 6 months follow up
6. Frequency of chemsex measured using self-report, in the preceding 3 months (at baseline), at 3 months, and 6 months follow up

Completion date
30/07/2026

Eligibility

Key inclusion criteria
1. Men who have sex with men
2. Cisgender
3. Aged 18 years or above
4. HIV-negative

5. Sexually active (defined as having engaged in sexual behaviour in the past 12 months)
6. Able to read and understand Chinese

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
03/11/2025

Date of final enrolment
30/01/2026

Locations

Countries of recruitment
Hong Kong

Study participating centre
School of Nursing, The University of Hong Kong
5/F, HKUMed Academic Building,
3 Sassoon Road,
Pokfulam
Hong Kong
Hong Kong
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Sponsor information

Organisation
University of Hong Kong

ROR
https://ror.org/02zhqgq86

Funder(s)

Funder type
Research council

Funder Name
The Research Grants Council (RGC) of Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request from Professor Edmond Pui Hang CHOI (email: h0714919@connect.hku.hk)

IPD sharing plan summary
Available on request