

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

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
22/10/2025	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
22/10/2025	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
22/10/2025	Other	<input checked="" type="checkbox"/> 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 Chinese.

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

ClinicalTrials.gov (NCT)

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,
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes