

The development of an online intervention to reduce HIV/STI risk and drug use-related harms among stimulant-using men who have sex with men (MSM) in Malaysia

Submission date 22/10/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/07/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The study aims to develop a community-based, online intervention to address the mental health and sexual health needs among stimulant-using MSM in Malaysia. Recreational drug use in the sexual context ("chemsex") is driving the HIV epidemic among MSM in Malaysia and yet community-based, harm-reduction services are not available for MSM who wish to reduce their drug use or support their recovery from drug abuse. In this study, participants will be able to receive peer counselling on drug use and sexual risk reduction, access interactive online education materials to support their recovery, at their own privacy and convenient time. This randomized controlled trial will provide feasibility, acceptability, and efficacy of a community-led online intervention to reduce harms associated with stimulant use among MSM in Malaysia. Specifically, this online intervention will address HIV/STI/Hepatitis risk and a range of adverse mental health conditions such as depression, suicidality, and harms related to methamphetamine overdose and methamphetamine-induced psychosis.

Who can participate?

Men aged at least 18 years who eEngaged in chemsex with other men (defined as using crystal methamphetamine, GBL/GHB, or ecstasy/MDMA) in the past 12 months

What does the study involve?

Participants will be randomly allocated to two groups:

Group A will receive the developed intervention tool comprising a Brief Intervention (FRAME Model). An online meeting will be arranged with a trained, peer counsellor to discuss drug use behaviour and to provide support and motivation to change. After the brief counseling, participant will then be directed to the Chemsex Care Plan, a self-directed interactive program that participants can access anytime at their convenience and will provide participants access to online materials (videos, infographics, etc) to educate stimulant-using MSM on reducing risky drug-use behaviour, as well as goal-setting. Participant will be asked to complete a brief survey at 6-week and 12-week follow-up to assess the drug use behavior and motivation to change.

Group B will receive a self-help toolkit from the World Health Organization for cutting down and stopping drug use. Participant is encouraged to use the toolkit to manage their drug use for 12 weeks. Similar to Group A, they will then be asked to complete a follow-up survey after 6 weeks and 12 weeks. After the end of the study, they will be given access to the Chemsex Care Plan.

What are the possible benefits and risks of participating?

Possible benefits

All participants will be provided with the online education and psychosocial support listed within the study, which will provide them assistance in managing/reducing drug use, risky sexual behavior, as well as improving mental health. Participants will also be given referred to HIV prevention services under the Malaysian AIDS Council to reduce their risk for HIV/STI/Hep C infection. They will also be referred to access substance abuse treatment services available in Malaysia as they wish.

Possible risks

Some questions asked might be sensitive in nature, and may cause discomfort or distress while answering. This may also occur during sessions with counselor or caseworker. Participation itself might cause a risk, as the nature of the study can be considered sensitive.

Where is the study run from?

This study is an online intervention by Malaysian Aids Council and Centre of Excellence for Research in AIDS (CERiA), University of Malaya.

When is the study starting and how long is it expected to run for?

December 2020 to June 2022

Who is funding the study?

The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Sustainability of HIV Services for Key Populations in Asia Program (SKPA) and the Malaysian AIDS Council.

Who is the main contact?

1. Dr Lim Sin How, howie.ceria@gmail.com
2. Associate Prof Dr Anne Yee, annyee17@um.edu.my

Study website

<https://chemfunsupport.online/>

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

UPUM/2020-MAC.588

Study information

Scientific Title

Development of an online intervention to reduce HIV/STI risk and drug use-related harms among stimulant-using MSM in Malaysia

Study objectives

The development of the online intervention will address the worsening HIV epidemic in a subpopulation of MSM in Malaysia. This pilot study will collect the feasibility, acceptability, and preliminary efficacy of ASSIST-Brief Intervention and Chemsex Care Plan to reduce harms related to drug use and sexual risk among MSM.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/09/2020, UMMC Medical Research Ethics Committee (2nd floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya 59100 Kuala Lumpur, Malaysia; +60 3 7949 3209, ummc-mrec@ummc.edu.my), ref: 202092-9036

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

<https://chemfunsupport.online/consent>

Health condition(s) or problem(s) studied

Online intervention to reduce HIV/STI risk and drug use-related harms among stimulant-using MSM in Malaysia

Interventions

The study aims to develop a community-based, online intervention to address the mental health and sexual health needs among stimulant-using MSM in Malaysia. Participants will be able to receive peer counselling on drug use and sexual risk reduction, access interactive online education materials to support their recovery, at their own privacy and convenient time. The psychosocial interventions selected for the study (ASSIST-Brief Intervention and Chemsex Care Plan) are rooted in motivational interviewing which is client-oriented and aims to enhance participants' motivation in changing drug use and risky sexual behaviors, and helps participants establish and meet their goals in reducing both behaviors.

The study will be a behavioral intervention trial, whereby eligible participants will be recruited and go through a baseline screening for demographic and health status assessment. After that, they will then be randomly assigned into one of the two groups:

(i) Group A will receive the developed intervention tool comprising a Brief Intervention (FRAME Model). An online meeting will be arranged with a trained, peer counsellor to discuss drug use behaviour and to provide support and motivation to change. After the brief counseling, participant will then be directed to the Chemsex Care Plan, a self-directed interactive program that participants can access anytime at their convenience and will provide participants access to online materials (videos, infographics, etc) to educate stimulant-using MSM on reducing risky drug-use behaviour, as well as goal-setting. Participant will be asked to complete a brief survey at 6-week and 12-week follow-up to assess the drug use behavior and motivation to change.

(ii) Group B will receive a self-help toolkit from the World Health Organization for cutting down and stopping drug use. Participant is encouraged to use the toolkit to manage their drug use for 12 weeks. Similar to Group A, they will then be asked to complete a follow-up survey after 6 weeks and 12 weeks. After the end of the study, they will be given access to the Chemsex Care Plan.

Randomization:

Computer-generated (www.randomization.com)

Participants who agree to the follow-up study are sent a link and a password (unique password for each participant) to log onto the study website. Those logging on are randomized in 1:1 ratio with no stratification to receive their respective materials.

Intervention Type

Behavioural

Primary outcome measure

Stimulant use severity is measured using e-ASSIST (eASSIST; measured at baseline and 12-week follow-up)

Secondary outcome measures

Measured at baseline, 6-week, and 12-week follow-up:

1. Number of days stimulants used in the last 30 days
2. Depression, Anxiety, and Stress Scale - 21 Items (DASS-21)

Overall study start date

01/12/2020

Completion date

30/06/2022

Eligibility

Key inclusion criteria

1. Being biologically male
2. Aged at least 18 years
3. Engaged in chemsex with other men (defined as using crystal methamphetamine, GBL/GHB, or ecstasy/MDMA) in the past 12 months
4. Capable of understanding and reading English or Malay
5. Willing to be contactable by messaging service for follow-up online surveys

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

226

Total final enrolment

154

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/2021

Date of final enrolment

07/03/2022

Locations

Countries of recruitment

Malaysia

Study participating centre

Centre of Excellence For Research in AIDS, University of Malaya
Level 17, Wisma R&D.
Universiti Malaya

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Sponsor information

Organisation

Malaysian Aids Council

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Sponsor type

Other

Website

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Funder(s)

Funder type

Charity

Funder Name

Global Fund to Fight AIDS, Tuberculosis and Malaria

Alternative Name(s)

Global Fund, Fonds mondial, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Fonds mondial de lutte contre le sida, la tuberculose et le paludisme, The Global Fund, Le Fonds mondial, GFATM

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

Funder Name

Sustainability of HIV Services for Key Populations in Asia Program (SKPA)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1	08/03/2022	08/03/2022	No	No
Funder report results			11/07/2023	No	No