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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

Registration date
15/12/2021

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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
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Sponsor information

Organisation
Malaysian Aids Council

Funder(s)

Funder type
Charity

Funder Name
Global Fund to Fight AIDS, Tuberculosis and Malaria

Alternative Name(s)
Global Fund, The Global Fund, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Fonds mondial de lutte contre le sida, la tuberculose et le paludisme, Fonds mondial, Le Fonds mondial, Globalen Fonds, Der Globalen Fonds, 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

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?
Funder report results			11/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.1	08/03/2022	08/03/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes