CTN Study Reporting Template

CTN STUDY REPORTING TEMPLATE	
STUDY INFORMATION	
CTN or CTNPT Study #: 049	Date: March 22nd, 2024
Study Title/Name: Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario	
Principal Investigator(s): Dr. Roula Kteily-Hawa, Nominated Principal Investigator (Western University); Dr. Josephine Wong, Co-Principal Investigator (Toronto Metropolitan University); Dr. Ahmed Bayoumi, Co-Principal Investigator (St. Michael's Hospital, University of Toronto).	
Phone: 416-809-8443	E-mail: roula.hawa@uwo.ca

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STUDY PROGRESS

CTN Study Reporting Template

1. Please describe study progress during the period of **4-january-2023 to 25-March-2024** (for example, have you met your enrolment targets, have there been any SAEs?):

We have recruited 40 MENA participants for the study. All 40 have been screened via a registration form with referrals from peer leaders. **All 40 participants completed a letter of information and consent and are ready for the intervention.** They received anonymous links to the pre-intervention survey. After which they will complete the HIV literacy module and then start the intervention immediately or wait for 8 weeks for the intervention. We did randomization for all 40 participants since we are running 2 sessions/week.

See detailed breakdown of all tasks completed in the chart below.

Task	Date Started – Date Completed	Additional Information
Study Protocol	January, 2023 - April, 2023	Feedback received from the CTN/UBC stats team. PI Hawa had two meetings with CTN/UBC stats team to work on protocol. Two sets of revisions were made. **See attached.**
Study Survey (sociodemographic questions + scales + pre- and post-HIV literacy module survey)	May, 2023 – June, 2023	**See attached Word document.**
HIV literacy module content development	July, 2023 – Sept., 2023	2 hr module with content and interactive graphics. **You may preview the module at the link HERE.** Password: **HIVSTBBI** (all caps)
Recruitment Flyer	June, 2023	**See attached.**
letter of Information and Consent	June, 2023 – July, 2023	**See attached.**
Ethics submission to St. Michael's hospital (protocol, letter of information and consent, recruitment flyer).	July, 2023 – Sept., 2023	Submission of all documents was made via email. Dr. Bayoumi supported the process. After submitting ethics protocol, we received revisions and attended to them. Process was very slow. We decided to use St. Michael's Hospital Ethics Board since they are used to reviewing randomized controlled trials. Brescia University College is a small affiliate campus of Western and its ethics board does not review RCT studies. With Dr. Bayoumi being a Co-PI on the study, we all agreed that it was a sound decision.
** NEW process for ethics submission to St.	October 1, 2023, Feb. 23rd, 2024	In October, we were notified that St. Michael's Hospital was following a new process for ethics

Michael's hospital (protocol, letter of information and consent, recruitment flyer). New process now via e-submission.		approval. Process at St. Michael's Hospital changed to e-submission. Ethics board asked us to start the process from scratch. We lost 4 months from our project time. Two revisions were made and we submitted all documents. The board was understaffed and the process was very slow as it was dependent on 1 staff member. Ethics review process at St. Michael's Hospital took 7 months which caused a major delay in the study. **See letter of ethics approval.**
CTN Data Safety Committee Presentation	October 5, 2023	PI Hawa met with the committee, presented the project and answered questions.
½ day large team meeting with community partners, ASAAP, AIDS Committee of Ottawa, PIs, Co-Investigators, Knowledge Users.	June 7, 2023	Presentations by PI Hawa and PI Wong. Shared study targets, progress, described the mindfulness intervention sessions. Community advised that an honorarium of $25 for each mindfulness session that is 2 ½ hr long is unacceptable. Team agreed that PI Hawa will try to get additional funding to honour participants' time. Proper compensation is necessary.
Additional funding sought from OHTN. Requested $8,000.	August 19, 2023	PI Hawa reached out to OHTN for additional funding. PI Hawa submitted a proposal with a detailed revised budget to OHTN and asked for $8,000 in additional funding for participant honoraria.
Additional funding approved from OHTN. Amount approved $4,800	Nov 15, 2023	OHTN approved additional funding of $4,800. To have compensation for participants, we needed to pay them $50/session, where each session is 2 ½ - 3hrs long. Given that OHTN gave us 1/2 of what we asked for, we had a deficit of $3,200 in the budget. PI Hawa had to cut down on budget to address the deficit in the budget. While waiting for ethics approval, there was no project coordinator. PI Hawa had to be extra prudent in order to make sure this small CTN grant is sufficient to run a RCT with 40 participants.

HIV literacy module content development/ module design into Rise Articulate 360.	November, 2023 – January, 2024	Content stored securely on Western's OneDrive. The two-hour module is interactive and has voice over and built-in check points to increase HIV 101 and STBBI literacy. **You may preview the module at the link HERE.** Password: **HIVSTBBI** (all caps)
Qualtrics - Study Survey (sociodemographic questions + scales + pre- and post-HIV literacy module survey)	January, 2024 – February, 2024	We have a pre-intervention survey with study scales, pre- and post HIV literacy module on **Qualtrics. See HERE.**
Peer leaders training via Zoom (4 peer leaders, Farsi speaking and Arabic speaking)	February - March, 2024	Peer leaders: Ahmed Ezzeddine, Moe Akel, Hale Nouri, Sal Ben Mahri. Zoom meetings were scheduled to go over study material and consent forms. Study criteria and ethics protocol were discussed with all peer leaders. All peer leaders received honoraria.
Participant Recruitment (targeted via peer leaders)	March 1st – March 25, 2024	We have recruited 40 MENA participants for the study. All 40 have been screened via a registration form with referrals from peer leaders. **All 40 participants completed a letter of information and consent and are ready for the intervention.** They received anonymous links to the pre-intervention survey. After which they will complete HIV literacy module and then start intervention or be in waitlist group. We did randomization for all 40 participants since we are running 2 sessions/week.

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CTN FUNDING

2. Is the CTN providing funding? ☒ Yes ☐ No (if no, proceed to Question 3)

2a. Are the study financial statements attached? ☒ Yes ☐ No (if no, describe why)

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2b. Please describe how the funds provided by the CTN have been used to date and justify why the release of the next instalment is required:

Study intervention will start in early April. Participants have received links to survey and HIV literacy module. After completion of pre-test and HIV literacy module, we can start intervention. All 40 participants have been randomized into intervention group and wait-list group. We need $25,000 funds released ASAP to pay participant honoraria. We are running two cohorts (10 participants/group) from the intervention arm per week and 8 weeks later, we will run 2 cohorts from the waitlist group (10 participants/group). Please see detailed upcoming expenses below.

Upcoming Expenses: CTN Grant

Remaining/Unspent Balance at March 21, 2024: $19,415.28
Funds to be released from CTN: $25,000
Total Available funds for the project: $44,415.28
Expected Expenditures: $49,187
Expected Deficit: - $4,771.72
Additional funding sought from OHTN to go towards participant honoraria: $4,800
Expected deficit: Zero

Breakdown of Upcoming Expenses:
Project Coordinator: (April 1st, 2024 – Dec 31st, 2024)
16 hrs/week x 40 weeks x $28/hr = $17, 920
Benefits (16%): $2,870
Salary for Project Coordinator: $20,787

Consultant: HIV Literacy Module Development and Qualtrics. (Feb 22nd – April, 2024). Consultant Fees: $40/hr for 14 hrs = $560

Mindfulness Intervention Facilitator: (April 6, 2024 – August 4, 2024).
$90/session + 1 hr prep = $120 / session x 8 weeks = $960
Intervention cohort 1: $960 (8 sessions)
Intervention cohort 2: $960 (8 sessions)
Control cohort 1: $960 (8 sessions)
Control cohort 2: $960 (8 sessions)
Fees for Intervention Facilitator: Total: $3,840.

Honoraria for study participants: Intervention Group (April 6, 2024 – August 4, 2024).
$600/participant x 20 participants = $12,000
Honoraria for study participants: Waitlist-Control Group (June 1st, 2024 – October 20th, 2024).
$600/participant x 20 participants = $12,000. Total Honoraria for participants: $24,000

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KNOWLEDGE TRANSLATION ACTIVITIES

3. Please provide a list of publications, presentations, and conference submission details to date (may be provided in a separate attachment). If available, please include the Digital Object Identifiers (DOIs) for publications.

Website:

The CTN funded project is part of a research program led by Dr. Hawa: The **Y**outh **S**exual Health Needs in **M**iddle **E**astern and **N**orth **A**frican Communities in Canada and Globally (YSMENA Program). YSMENA is the first community-based research program in Canada to center the voices of diaspora Middle Eastern and North African (MENA) youth in Canada. We have a website dedicated for the YSMENA program and the CTN funded project is listed on the website. CTN is acknowledged on the website as a funder and all community partners involved in the study are also listed.
https://www.ysmenaprogram.com/cihr-ctn-funded-ysmena

3a. Has the CTN been acknowledged in all publications connected to this study? ☒ Yes ☐ No (if no, describe why)

CTN is acknowledged on our YSMENA website, recruitment flyer, and survey.

4. Please provide details of any publications, presentations, and abstract submissions that are planned for the upcoming year:

Since we are starting the intervention in April, 2024, we will share our findings from the CTN project at the CBRC Summit and CAHR conference.

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5. Please provide details on other knowledge translation activities, such as media interviews, webinars, articles in newsletters, community presentations, etc. to date:

We had community gathering with all partners. A half day large team meeting with community partners, ASAAP, AIDS Committee of Ottawa, PIs, Co-Investigators, Knowledge Users. Presentations by PI Hawa and PI Wong. Shared study targets, progress, mindfulness sessions and their potential impact on vulnerable MENA youth.

COLLABORATIONS

6. Please describe activities conducted with partners and collaborators:

Peer leaders training via Zoom (4 peer leaders, Farsi speaking and Arabic speaking) conducted by PI Hawa. Peer leaders: Ahmed Ezzeddine, Moe Akel, Hale Nouri, Sal Ben Mahri. Zoom meetings were scheduled to go over study material and consent forms. Study criteria and ethics protocol were discussed with all peer leaders. All peer leaders received honoraria.

6a. Have there been any new collaborators, partners, or external funders (not listed in the original submission documents)? ☒ Yes ☐ No

If yes, please name them here: New collaborators: Alliance for South Asian AIDS Prevention (ASAAP)

External funding: OHTN for the amount of $4,800 which will be released once the intervention is started. See details in #1 above.

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STUDY ACTIVITIES FOR UPCOMING YEAR

See details below.

7. Please describe the study plans over the next year(s) (include the end date of the study, both last participant, last visit date, and estimated date of completing the final manuscript):

DATE MARCH – OCTOBER, 2024	** PARTICIPANTS ARE PAID IMMEDIATELY AFTER COMPLETING EACH TASK VIA E-TRANSFER OR DIRECT DEPOSIT	HONORARIA INTERVENTION GROUP (A) COHORTS 1 & 2, N = 20	HONORARIA WAITLIST GROUP (B) COHORTS 1 & 2, N = 20
MARCH 23-31	PRE-INTERVENTION SURVEY (ABOUT 25 MIN LONG) + PRE-HIV LITERACY SURVEY. GROUPS A & B.	$50	$25
MARCH 25 - APRIL 4	HIV LITERACY MODULE (2 HOURS LONG). GROUP A ONLY. Followed by Post-HIV Literacy survey. Online.	$50	
APRIL 6 & APRIL 7	SMART INTERVENTION WEEK 1 (VIA ZOOM) – 2 ½ HOURS	$50	
APRIL 13 & 14	SMART INTERVENTION WEEK 2 (VIA ZOOM) – 2 ½ HOURS	$50	
APRIL 20 & 21	SMART INTERVENTION WEEK 3 (VIA ZOOM) – 2 ½ HOURS	$50	
APRIL 27 & 28	SMART INTERVENTION WEEK 4 (VIA ZOOM)– 2 ½ HOURS	$50	
MAY 4 & 5	SMART INTERVENTION WEEK 5 (VIA ZOOM)– 2 ½ HOURS	$50	
MAY 11 & 12	SMART INTERVENTION WEEK 6 (VIA ZOOM)– 2 ½ HOURS	$50	
MAY 18 & 19	SMART INTERVENTION WEEK 7 (VIA ZOOM)– 2 ½ HOURS	$50	
MAY 25 & 26	SMART INTERVENTION WEEK 8 (VIA ZOOM)– 2 ½ HOURS	$50	
MAY 26	POST-INTERVENTION SURVEY (ABOUT 20-25 MIN LONG)	$25	
MAY 26	PRE-INTERVENTION SURVEY + PRE-HIV LITERACY SURVEY. GROUP B ONLY.		$25
MAY 25 - 30	HIV LITERACY MODULE (2 HOURS LONG). ONLINE. Followed by Post-HIV Literacy survey. Online.		$50
JUNE 1ST & 2ND	SMART INTERVENTION WEEK 1 (VIA ZOOM) – 2 ½ HOURS		$50
JUNE 8 & 9	SMART INTERVENTION WEEK 2 (VIA ZOOM) – 2 ½ HOURS		$50
JUNE 15 & 16	SMART INTERVENTION WEEK 3 (VIA ZOOM) – 2 ½ HOURS		$50
JUNE 22ND AND 23RD	SMART INTERVENTION WEEK 4 (VIA ZOOM)– 2 ½ HOURS		$50
JUNE 29 AND 30	SMART INTERVENTION WEEK 5 (VIA ZOOM)– 2 ½ HOURS		$50
JULY 6 & 7	SMART INTERVENTION WEEK 6 (VIA ZOOM)– 2 ½ HOURS		$50

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JULY 13 & 14	SMART INTERVENTION WEEK 7 (VIA ZOOM)– 2 ½ HOURS		$50
JULY 20 & 21ST	SMART INTERVENTION WEEK 8 (VIA ZOOM)– 2 ½ HOURS		$50
JULY 21ST	POST-INTERVENTION SURVEY (ABOUT 20 MIN LONG) + POST-HIV LITERACY SURVEY. ONLINE.		$25
AUGUST 25 & 26	POST-INTERVENTION SURVEY. 3 MONTHS POST-INTERVENTION. GROUP A ONLY.	$25	
AUGUST 25 & 26	TWO FOCUS GROUP DISCUSSIONS (2 ½ HOURS). ONLINE.	$50	
TOTAL	**TOTAL HONORARIUM /PARTICIPANT (GROUP A)** **TOTAL HONORARIA/20 PARTICIPANTS (GROUP A)**	**$600** **$600 x 20 = $12,000**	
OCTOBER 21 & 22	POST-INTERVENTION SURVEY. 3 MONTHS POST-INTERVENTION. GROUP B ONLY.		$25
OCTOBER 21 & 22	TWO FOCUS GROUP DISCUSSIONS (2 ½ HOURS). ONLINE.		$50
TOTAL	**TOTAL HONORARIUM /PARTICIPANT (GROUP B)** **TOTAL HONORARIA/20 PARTICIPANTS (GROUP B)**		**$600** **$600 x 20 = $12,000**
GRAND TOTAL	**$24,000**		

Interventions and data collection will wrap up by end of October, 2024. Data analysis will take place from November, 2024 – January, 2025. Report writing/manuscript writing will start in November, 2024 and will be completed in February, 2025. We have a February, 2025 planned end date.

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STUDY IMPACT

8. Please describe the anticipated impact and significance of this study:

Despite the need for interventions, evidence-based interventions targeting health issues and minority stress among sexual and gender minority youth are limited. Few studies have evaluated interventions that address mental health risks and promote well-being among sexual and gender minority youth, and none among MENA youth. Mindfulness training has shown benefits for mental and physical health in clinical and community settings. Our community-based, mixed-methods pilot intervention will assess the feasibility and help plan a randomized controlled trial (RCT) comparing Self-Compassion, Mindful Acceptance, and Resilience Transformation (SMART): an 8- week group-based training - with a delayed-treatment waitlist control group. Our pilot study aims to promote the mental well-being, reduce psychological distress (depression, anxiety, and stress) and reduce HIV high risk practices in gay, bisexual and trans MENA youth in Ontario.

In a pilot study, all outcome measures are in a sense exploratory but it is still important to have clarity around what the intended primary and secondary outcomes for the purpose of planning a full RCT, which will be informed by the pilot intervention. The overall purpose of this pilot study is to assess the feasibility of conducting a large study to investigate the benefit of a mindfulness-based intervention to reduce HIV risk and optimize well-being and resilience. Conducting a feasibility study will provide evidence to inform a larger RCT study and will make a substantial contribution to addressing the gap in this area. A larger RCT study would contribute additional information within this context and the generalization of findings will benefit MENA youth groups and other racialized gay, bisexual and trans youth in Ontario and across Canada.

Please use this space to provide any further details you need to report:

See attachments.

March 22, 2024

To: CTN UBC contracts officer

Grant: **CTN Grant**
Principal Investigator: **Roula Hawa, PhD, MSc, MPH, BEd, OCT, PHEc**
Brescia University College Grant/Project Number: **2584**
Total Amount Awarded: **$50,000.00**

Financial Report
For the Period ending March 21, 2024

Funding Received up to Date (Oct 2022 Payment)			**$ 25,000.00**
Less: Expenditures:			
Personnel			
Research Coordinator (Salary & Benefits)	$	2,320.00	
		-	
Total Personnel		**2,320.00**	
Other Expenses			
Two Community Outreach - Stipends		975.00	
Peer Leader Honoraria		900.00	
Open Access Knowledge (Knowledge translation & website)		1,389.72	
		-	
Total Other Expenses		**3,264.72**	
TOTAL Expenditures			**5,584.72**
Remaining/Unspent Balance at March 21, 2024			**$ 19,415.28**

BSzapiel

Barbara Szapiel, CPA, CGA
Controller

Attachments:
- REB 23-179 - Approval - Initial Application (Delegated Review).pdf

Research Ethics Office
Telephone: (416) 864-6060 Ext. 42557
Facsimile: (416) 864-6043
E-mail: researchethics@unityhealth.to

ST. JOSEPH'S • ST. MICHAEL'S • PROVIDENCE
UNITY HEALTH TORONTO

To: Ahmed Bayoumi, Unity Health PI/Network Lead Applicant
From: Unity Health REB
Date: 23-Feb-2024

Dear Ahmed Bayoumi,

RE:

REB number:	23-179
Study title:	Promoting Mental Health and Reducing HIV Risk Behaviours through Self- compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence- informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.
Initial approval date:	23-Feb-2024
Expiration date:	23-Feb-2025
Application type:	Delegated Review

Thank you for your **initial application** submitted on **24-Jul-2023**. The above noted study has been reviewed through a delegated process (not by Full Board review). The views of the Unity Health Toronto Research Ethics Board (REB) have been documented and resolved. Please note that no member of the REB associated with this study was involved in its review or approval.

The REB approves the study as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act (PHIPA), 2004. The REB hereby issues approval for the above named study for a period of 12 months from the date of this letter. Continuation beyond that date will require further review of REB approval.

The following documents have been reviewed and are hereby approved:
**Note: The date listed before the file name is the date the file was uploaded to the eREB.*

Protocol 25-Apr-2023 SMART Protocol.docx *(049 28-JAN-2024)*

Consent Form 29-Jan-2024 Clean_Letter of Information and Consent and survey.docx *(received 29-Jan-2024)*

The following documents have been received and are hereby acknowledged:
**Note: The date listed before the file name is the date the file was uploaded to the eREB.*

Additional Resources	12-Oct-2023 DATA SAFETY AND MONITORING COMMITTEE (DSMC).pdf *(received 12-OCT-2023)*
Participant Facing - Recruitment Materials	16-Oct-2023 Recruitment flyer.docx *(received 16-OCT-2023)*
Consent - Supporting Materials	11-Oct-2023 Focus Interview guide.docx *(received 11-OCT-2023)*
Other - Linking, Screening, Enrollment Logs	11-Oct-2023 Master linking log.docx *(received 11-OCT-2023)*

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB. Please note that shared electronic health systems such as ConnectingOntario, PRO, RM&R, OLIS, HDIRS, eCHN, DPV and IAR do not permit access for research purposes.

For all interventional studies, the study sponsor is required to register the study in a publicly accessible registry prior to enrollment of the first study participant. The study sponsor is also required to ensure that the trial record is updated in a timely manner and the summary results are posted within the required timelines.

All institutional approvals **must** be coordinated and approved through the Office of Research Administration (ORA) prior to initiation of this research. If a Clinical Trial Agreement is required, it must be reviewed and approved by the ORA, prior to commencing any study related activities.

All investigational drug product dispensing must be coordinated through the Research Pharmacy.

The Unity Health REB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at Unity Health Toronto are conducted by Qualified Investigators (as defined in the latter document).

With best wishes,

Michael Szego - Signed: 23-Feb-2024

REB Vice Chair

Brescia REB Notice of APPROVAL # Hawa_20240227	Principal Investigator: Dr. Roula Hawa
Original Date of Approval: February 27, 2024	Expiry Date: February 23, 2025 (as per Unity Health Toronto letter)

February 27, 2024

Dear Dr. Hawa,

Your multijurisdictional study with Drs. Josephine Wong (Co-PI) and Dr. Ahmed Bayoumi (Co-PI) entitled, *Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario*, has been approved by the Brescia REB.

The end date (expiry) for this ethics approval is February 23, 2025. If you require an extension for your study you must notify the Brescia REB.

Please keep in mind there should be no deviation from your *revised* protocol/research plan or Letter of Information and Consent Forms (and other documents submitted) without prior approval from the Brescia REB, unless changes are required to remove any immediate harm, or for *very minor* logistical or administrative items.

You must advise the Brescia REB of any adverse events that occur during the course of your research project. Once the study is complete, please notify me so that it may be documented in your file. Please feel free to contact me at any time with questions.

On behalf of the Brescia Research Ethics Board, I wish you the best of luck with your research!

Sincerely,

Brenda Hartman

Dr. Brenda Hartman
Chair, Brescia Research Ethics Board

Brescia University College
1285 Western Road
London, ON N6G 1H2

Tel: 519.432.8353 x28256
Email: bhartman5@uwo.ca

cc: Dr. Aaron Cecala, Research Officer

PARTICIPANTS NEEDED

Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): A Pilot Study with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario

Principal Investigator: Dr. Roula Hawa, Associate Professor, Brescia University College at Western University

The Youth Sexual Health and Human Immunodeficiency Virus / Sexually Transmitted Infections (HIV/STI) Prevention in Middle Eastern and North African Communities (YSMENA) study is recruiting research participants. This is an invitation to you to participate in a pilot Self- compassion, Mindful Acceptance & Resilience Transformation (SMART) Intervention. Based on concepts and processes rooted in acceptance, commitment to empowerment and social justice, SMART intervention uses mindfulness-based training aimed at enhancing mental health, self-compassion, psychological resilience, and collective empowerment.

- ☑ **Is your background Middle Eastern or North African (Arab and/or West Asian)?**
- ☑ **Are you 21-29 years old and self-identify as a cis gay male, cis male bisexual, or transgender?**
- ☑ **Are you living in Ontario?**
- ☑ **Are you able to read and write English?**
- ☑ **Do you have minimal or no prior experience with mindfulness-based interventions?**
- ☑ **Are you able to take part in the 8-week intervention?**

Then we invite YOU to participate in the SMART mindfulness study!

Your participation in this study is entirely voluntary and confidential.

Eligible participants will be compensated $50 for their time for attending each intervention session (approx. 2 – 2 ½ hrs each) for total of 8 sessions, and $25 for completing each assessment survey.

If you are interested in participating, please fill out a quick form here to determine your eligibility: https://bit.ly/3Fhb4Ty

If you're eligible, a member of the research team will contact you with an anonymous link to the survey.

If you want to learn more, please contact the Research Coordinator at ysmenastudy@gmail.com

The SMART study is funded by the CIHR Canadian HIV Trials Network (CIHR/CTN) CTNPT 049 Pilot Study Funding Program

Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.

The Youth Sexual Health and Human Immunodeficiency Virus / Sexually Transmitted Infections (HIV/STI) Prevention in Middle Eastern and North African Communities (YSMENA) program is conducted to learn more about the experiences of youth who self-identify as members of Middle Eastern and North African (MENA) communities living in Ontario. We want to better understand how your social environments and relationships at home, at school, and/or in the community shape your intersectional identities and how these identities influence your sexual health, resilience and well-being. We also want to learn how we can go about developing effective HIV/STI prevention, sexual health and mental health promotion programs for young people.

YSMENA Study is recruiting research participants. We are looking for 40 young adults living in Ontario who are 21-29 years old, who self-identify as a member of the Middle Eastern and/or North African diaspora community and as cis gender gay men, bisexual, or other men who have sex with men (MSM), or transgender youth. Lesbian/bisexual/queer cis women will not be eligible.

YSMENA study will be piloting a group intervention, **Self-compassion, Mindful Acceptance & Resilience Transformation (SMART)** Intervention. Based on concepts and processes rooted in acceptance, commitment to empowerment and social justice, SMART intervention uses mindfulness-based training aimed at enhancing mental health, self-compassion, psychological resilience, and collective empowerment.

The SMART intervention will be delivered virtually via Zoom by MENA peers or other racialized peer facilitators who are already trained through the Committee for Accessible AIDS Treatment (CAAT) to deliver SMART interventions. **In order to be eligible to participate, you need to commit to attending the group intervention via videoconference for 2 hrs per-week for 8 weeks.**

Your participation in this study is entirely voluntary and confidential. Eligible participants will be compensated $50 for their time for attending each intervention session and $25 for completing each assessment survey starting at baseline**.** Participants will also be offered $50 each to take part in the focus group discussion session.

YSMENA Study Participant Eligibility Assessment Form

1. **Do you identify as Middle Eastern or North African** (Arab and/or West Asian?)

   ○ Yes

   ○ No

2. **Are you 21-29 years old?**

   ○ Yes

   ○ No

3. **Do you self-identify as any of the following: cis gender gay man, bisexual, or other men who have sex with men (MSM), or transgender?**

   ○ Yes

   ○ No

4. **Do you live in Ontario?**

   ○ Yes

   ○ No

5. **Are you able to read and write English?**

   ○ Yes

   ○ No

6. **Do you have minimal or no prior experience with mindfulness-based interventions?**

   ○ Yes

   ○ No

7. **Are you currently enrolled in a mental health intervention?**

   ○ Yes

   ○ No

8. **Have you been enrolled in intensive mental health treatment within the past year?**

   ○ Yes

   ○ No

9. **Do you have reliable internet access and an internet-enabled device with audiovisual**

capabilities?

- ○ Yes
- ○ No

10. Are you able to take part in the 8-week intervention?

- ○ Yes
- ○ No

Letter of Information and Consent

Project Title: Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence- informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth inOntario.

Principal Investigator
Dr. Roula Hawa, Family Studies and Human Development, Brescia University College at Western. Email: roula.hawa@uwo.ca

Co-principal Investigators
- Dr. Josephine Pui-Hing Wong, Toronto Metropolitan University (TMU)
- Dr. Ahmed Bayoumi, St. Michael's Hospital, University of Toronto

Co-investigators and Knowledge Users
- Dr. Priscilla Boakye, Toronto Metropolitan University (TMU)
- Praney Anand, Principal Knowledge User, Alliance for South Asian AIDS Prevention
- Khaled Salam, Principal Knowledge User, AIDS Committee of Ottawa
- Kerolos Saleib, Principal Knowledge User
- Nona Abdallah, Knowledge User
- Ahmad Ezzeddine, Knowledge User
- Noura Hamade, Community Partner, Canadian Arab Institute

Funder
The study is funded by the CIHR Canadian HIV Trials Network (CIHR/CTN) Pilot Study

Conflict of Interest
The study investigators declare no potential conflict of interest, real or perceived.

Invitation to Participate
The Youth Sexual Health and Human Immunodeficiency Virus / Sexually Transmitted Infections (HIV/STI) Prevention in Middle Eastern and North African Communities (YSMENA) study is recruiting research participants. This is an invitation to you to participate in a pilot **Self-compassion, Mindful Acceptance & Resilience Transformation (SMART)** Intervention. Based on concepts and processes rooted in acceptance, commitment to empowerment and social justice, SMART intervention uses mindfulness-based training aimed at enhancing mental health, self-compassion, psychological resilience, and collective empowerment.

Why is this study/project being done?
The overall objective of this project is to pilot SMART, a mindfulness-based group intervention with MENA gay, cis bisexual, or trans youth living in Ontario. The primary objectives are to determine the feasibility and acceptability of SMART intervention and assess the impact of SMART intervention on HIV-risk acts or practices. Secondary objectives are to assess the impact of SMART intervention on mental health and self-compassion. We are also interested in exploring the impact of SMART intervention on HIV literacy, mindfulness and youth resilience.

Study Procedure

The SMART intervention will be delivered virtually via Zoom by MENA peers or other racialized peer facilitators who have been trained by the Committee for Accessible AIDS Treatment (CAAT) for delivering SMART interventions. In order to be eligible to participate, you need to commit to attending the group intervention via videoconference for 2 hrs per-week for 8 weeks.

If you are eligible to participate, you will be randomized to receive SMART intervention or be placed on a waitlist in which you will receive the intervention 8 weeks later. You will be completing the online questionnaires via Qualtrics. We will wait until we have a sufficient sample size to randomize for the first wave of intervention (10 participants per intervention group). Once this is reached, you will be asked to complete the baseline assessment measures, in the form of a questionnaire, online a week before commencing the program.

Study Duration and Participant Responsibilities

Your participation in the SMART study will include:

- 2 weeks prior to the start of the intervention, you will receive a pre-intervention survey that will take approximately 20 minutes. If you are randomly assigned to a waitlist group, you will be completing the pre-intervention survey twice.
- Also, 2 weeks prior to the start of the intervention, you will be asked to complete an HIV literacy module, with pre- and post-module questions. This will take between 1 – 1 ½ hours.
- The SMART intervention is 8 weeks long. These sessions will take place on a weekly basis at an agreed upon set date and time. Each session takes between 2 – 2 ½ hours.
- If you are randomly assigned to a waitlist group, you will start the intervention 8 weeks after the intervention group completes their sessions.
- After completing the 8-week intervention, there will be a follow-up questionnaire that will take approximately 15-20 mins.
- You will complete another follow-up questionnaire 3 months after intervention.
- You will be invited to participate in a focus group discussion 3 months after completion of the intervention. At these focus group sessions, participants are able to provide feedback about their experience in the program, including acceptability and feasibility of the intervention for other MENA youth in Ontario

Total time commitment is approximately 22 weeks for the intervention group and 30 weeks for the waitlist group.

Participants are allowed to be part of other studies as long as they are not part of a similar intervention or study with similar outcomes or objectives.

Privacy and Confidentiality

All personal information you provide to us will be treated with utmost confidentiality. Personal identifiers such as your name and e-mail address will be accessible only to the primary researchers and research staff, and they will be stored separately from the study data. Pseudonyms and codes will be used in place of your identifiable information and subsequently used in all written materials that may come out of this study.

We will not share information about you with individuals outside of the research team. The information shared during the weekly mindfulness sessions will be private. Participants will be encouraged to use pseudonyms for intervention sessions. Since this study involves group activities and discussions, confidentiality can only be kept when all of us agree to keep everything that is

shared confidential. This means respecting people's privacy. We ask that you do not share or disclose any information you learn about others during the mindfulness sessions with anyone outside of the study. There is a code of conduct that is expected to be followed during each intervention session at all times. The original signed informed consent form will be retained in the participant's study files.

The focus group will be recorded and transcribed. Quotes will be used with no identifiers. Your voice from the audio recording of the focus groups will be kept confidential (see section on data storage). All information provided will be kept confidential. Your name will not appear in any report or papers about the study. Data from all participants will be combined when we analyze the data so that no individual and personal information can be identified. Only group findings will be reported in papers and presentations coming out of this research. The research team will keep what you share in the study confidential, except in situations where we are required by law to release the information (e.g., if we learn that a participant may engage in self-harm or harm others, or if someone's life and wellbeing has been threatened). Also, delegated representatives of the Research Ethics Board may require access to your study data.

Limits on Confidentiality

Since group activities involve a number of participants, absolute confidentiality cannot be guaranteed. Confidentiality is kept only when all of us agree to keep everything that is shared in this room confidential and not share any information with anyone outside of the group sharing. To protect your confidentiality, we encourage you to think through and decide what you will and will not share in a group setting. To protect everyone's privacy, we will ask each of you to sign the agreement to confidentiality at the bottom of this consent form. You are also encouraged to use a made-up name while taking part in group discussions to enhance your privacy. Please note that the weekly group meeting is hosted by Zoom, a US company, and as such, is subject to the USA Patriot Act and CLOUD Act. These laws allow government authorities to access the records of host services and internet service providers. By choosing to participate, you understand that your participation in this study may become known to US federal agencies or hackers. To enhance security, our team will only admit registered participants into the Zoom focus group and the Zoom room will be locked to deter hackers. Only the post SMART training focus group will be audio recorded. All recordings will be saved on our designated researcher's computer with password protection. We also encourage participants to participate in the weekly intervention sessions and focus group in a private space, with headphones that would allow you to both participate privately and maintain the privacy of other participants.

What are the risks and harms of participating in this study?

There are minimal risks of taking part in this study. Privacy risks may exist as researchers cannot guarantee the confidentiality of information shared within the intervention group or focus group. You may feel emotional or uncomfortable with some of the discussion topics. All sharing is voluntary. In this consent form, we have provided a list of support services that you may access for additional support if needed. In addition, to reduce risks of compromises in confidentiality, and to ensure we protect your confidentiality and privacy, we will strictly enforce ground rules that emphasize respect for open discussion, confidentiality, and privacy in the sharing of opinions and insights during group activities. There might be some unease in attending an intervention with mixed groups of gay, bisexual and trans MENA youth, given the diverse immigration status, life

histories and length of stay in Canada. Peer co-facilitators, who are representative of all groups, are trained and will create an understanding and awareness among group members, while ensuring respect and ground rules are adhered to at all times. However, the benefits of offering the pilot intervention to all vulnerable groups outweigh the challenges.

Risk Minimization

Risk minimization, management, and assessment procedures have been implemented in the study to minimize and assess potential risks to participants who participate in this intervention study. Participants will be asked to withdraw if they exhibit chronically disruptive behaviour that contradicts the agreed upon ground rules (e.g., swearing, offensive comments towards other participants, bursts of anger, etc.)The research team will follow these steps to ensure participant safety: a) identify a safety person (a trusted friend or buddy that each participant can provide at the beginning of the intervention - much like an emergency contact) with the participant and encourage contact (via the individual or researcher), b) the young adult will be provided with contact details of support services (including nearby emergency departments). The research team will request permission to followup with the young adult via phone or email within 72 h to determine if they need additional support.

To help address some of these potential risks, we are providing you with information and resources below about mental health services as well as sexual and reproductive health services available in Ontario.

Resources

- If you need to speak to someone about your sexual health, please contact Action Canada for Sexual Health & Rights - Call the access line at 1-888-642-2725. The Access Line is a 7-day-a-week toll-free, confidential phone and text line. It is available for questions about sexual health, pregnancy options, abortion, and safer sex. You can access more resources through https://www.actioncanadashr.org/resources, or chat with sexualhealthontario.ca live for answers to your sexual health questions, information and assistance https://sexualhealthontario.ca/en/chat.

- If you need to speak to someone immediately about mental health, please contact Canada's Trans Life Line (call 877-330-6366), Crisis Services Canada (call 1-833-456-4566 or text 45645), or Kids Help Phone (call 1-800-668-6868 or text CONNECT to 686868).

What are the Benefits?

SMART intervention uses mindfulness-based training aimed at enhancing mental health, self-compassion, psychological resilience, and collective empowerment. You may or may not benefit directly from this study. However, your responses will inform effective program development and implementation to support efforts in reducing HIV-related stigmas and promote community wellbeing.

Compensation

You will receive a $50 honourarium to complete the HIV literacy module, and $25 for completing the pre- and post- HIV literacy questions prior to the intervention. You will also be compensated $50 for your time for each intervention session that you attend, for a total of 8 sessions. You will receive $25 for completing each assessment survey (pre-, post- and 3-month

follow-up surveys)**.** As previously indicated, participants randomly assigned to a waitlist group will be completing the pre-intervention survey twice. As such, if you are randomly assigned to a waitlist group, you will be receiving an additional $25 compared to those who are assigned to an intervention group. To keep honouraria equitable to all participants, participants who are randomly assigned to an intervention group will receive $50 for completing their pre-intervention survey. This way, as a compensation for their time, all participants will receive the same amount of honouraria for completing pre and post-intervention surveys, irrespective whether they are randomly assigned to a waitlist group or an intervention group. You will also receive $50 if you agree to take part in the focus group discussion session. As such, if you agree to participate in this study, you be will receiving a **total sum of $625.** All honouraria will be received immediately via e-transfer after completing each of the surveys, after each intervention session attended, and after the focus group discussion.

Data Security, Storage, and Dissemination

All data collected will remain confidential and accessible only to the investigators of this study. Surveys will be saved in Qualtrics and backed up on a secure OneDrive through Western University. The Zoom recording of the focus group will be downloaded onto a password-protected computer and be transcribed into written texts as a password protected document. Once the transcription is completed and we have checked for accuracy, we will delete the Zoom recording. All data will be used only for the purposes of informing policy, practice, and education. The data will be stored on a secure server at Brescia University College and retained for a minimum of 7 years. Your data may be retained indefinitely and could be used for future research purposes (e.g., to answer a new research question).

You will be able to view the results of this research at the end of the study, either from a report on our YSMENA website (www.ysmenaprogram.com) or through our various community partners.

Rights of Participants

Taking part in this study is voluntary. If you decide to take part, you are free to take back your consent and to stop taking part at any time during the study. If you should decide to participate, you may decline to answer certain question(s) on the questionnaires (e.g., by selecting "Prefer not to answer"). If you decide to leave the project, it will not affect anything between you and the researchers or the agencies that collaborate with the project. If you decide to leave the project and do not want us to use your data, please let us know as soon as possible, or within 2 weeks of ending your participation. We will remove and destroy all your data to the best we are able to. We may not be able to remove your data totally if your ideas have been mixed with the ideas of other people in the project and taking away your data may affect their ideas.

If you decide not to continue with the intervention, you may be re-contacted by a member of the research team to ask about reasons for withdrawal and to check in about your need for additional support. The consent to re-contact you is included below.

You will be asked to enter your email at the end of the questionnaires to e-transfer compensation for your time and effort. We have no way of knowing which response is yours based on your email address as your email will be collected and stored separately from your data.

Research Ethics Approvals
This study has been reviewed and approved by the Unity Health Research Ethics Board at St. Michael's Hospital, Brescia University College at Western University Research Ethics Board, and Toronto Metropolitan University Research Ethics Board.

Contacts for Further Information
If you require additional information about this research, you may contact the principal investigator in the Department of Family Studies and Human Development, Professor Roula Hawa, via e-mail at roula.hawa@uwo.ca. If you have questions about your rights as a research participant or the conduct of this study, you may contact St. Michael's Hospital, Unity Health Research Ethics Board Chair.

Consent to Participate
Agreement: by clicking on the 'Agree' button below, you are agreeing that you have:

a) read the information in this agreement and
b) have had a chance to ask any questions about your participation, and
c) have been told that you can change your mind any time and withdraw without consequences.

Note: Participants who choose the 'Decline' option are not eligible to participate.

- ○ Agree
- ○ Decline [*participants who choose the 'Decline' option will not be eligible to participate; a message of 'Thank you' will appear and the online program will close.]

Consent to be Zoom audio-recorded during post-intervention focus group interviews
Agreement: by clicking on the 'Agree' button below, you agree that your participation in a post intervention focus group via Zoom will be audio-recorded for the purpose of research. You have the option in Zoom to choose to join by audio only.
Note: Participants who choose the 'Decline' option are not eligible to participate.

- ○ Agree
- ○ Decline [*participants who choose the 'Decline' option will not be eligible to participate; a message of 'Thank you' will appear and the online program will close.]

Consent to be contacted for taking part in post training focus group
Agreement: by clicking on the 'Agree' button below, you agree to be contacted by the research team so that we can invite you to join a focus group after the training.
Note: Participants who choose the 'Decline' option will not be contacted.

- ○ Agree
- ○ Decline [*participants who choose the 'Decline' option will still be eligible to participate]

Consent to be contacted if you decide to withdraw from the study

Agreement: by clicking on the 'Agree' button below, you agree to be contacted by a member of the research team to ask about reasons for withdrawal and to check in about your need for additional support.
Note: Participants who choose the 'Decline' option will not be contacted.

- ○ Agree
- ○ Decline [*participants who choose the 'Decline' option will still be eligible to participate]

Confidentiality Agreement
Agreement: I understand that during all group activities, participants and facilitators may share personal and confidential information. I agree to respect everyone's privacy, that is, I will not record any part of the focus group discussion and I will not disclose any personal information shared by anyone during the focus group unless I have obtained direct consent from the speaker that it is okay to do so.
Note: Participants who choose the 'Decline' option are not eligible to participate

- ○ Agree
- ○ Decline [*participants who choose the 'Decline' option will not be eligible to participate; a message of 'Thank you' will appear and the online program will close.]

Thank you for participating! We know your time is valuable. Your participation speaks to your commitment to contributing to the well-being of young people. We are going to start with a basic questionnaire to gather sociodemographic information as well as health-related information. This questionnaire is a vital part of your participation. It will take about 15 minutes to complete this questionnaire.

Answering all questions will help us gather important information about MENA youth like you –an under-served youth group. However, your participation in this study is voluntary. As such, you may decide not to answer all questions or any questions or you may stop filling out the questionnaire at any time. All your responses will be kept strictly confidential. Let's start!

Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.

2 weeks before SMART Intervention:

Section 01: Socio-Demographic Questions

Please write your assigned ID #: _____

1. **How old are you?_____**
2. **Place of birth (City and Country)**
   - ○ I was born in _____
   - ○ Don't know
   - ○ Prefer not to answer
3. **How long have you been living in Canada?**
   - ○ I have lived here since birth
   - ○ I have lived here most of my life
   - ○ I have been living in Canada for 10 years or more
   - ○ I have been living in Canada between 4 and 9 years
   - ○ I have been living in Canada between 1 year and 3 years
   - ○ I have been living in Canada less than 1 year
   - ○ Don't know
   - ○ Prefer not to answer
4. **Language(s) you speak i.e., the most common language you use at home and outside. Select <u>ALL</u> that apply.**
   - ○ English
   - ○ French
   - ○ Arabic

- ○ Farsi/Persian
- ○ Afghani
- ○ Armenian
- ○ Kurdish
- ○ Other, please specify _____
- ○ Prefer not to answer

5. Where were your parents (biological/stepparent/guardian/etc.) born?

- ○ Parent/Guardian 01 was born in _____
- ○ Parent/Guardian 02 was born in _____
- ○ Don't know
- ○ Prefer not to answer

6. What do you consider to be your racial and/or ethnic background? Select <u>ALL</u> that apply.

- ○ Arab (e.g., Egyptian, Kuwaiti, Libyan, Moroccan, Saudi, Tunisian)
- ○ North African origins
- ○ West Asian (e.g., Iraqi, Lebanese, Palestinian, Syrian, Iranian, Jordanian, Afghani, Armenian)
- ○ Multiple races / Multiracial / "Mixed"
- ○ Other, please specify _____
- ○ Don't know
- ○ Prefer not to answer

7. Are you personally living with any of the following? Select <u>ALL</u> that apply.

- ○ Learning disability
- ○ Mental health problems (e.g., anxiety, depression)
- ○ Problems with drugs
- ○ Problems with alcohol

- ○ Mobility impairment (e.g., I have difficulty walking/ I cannot walk at all)
- ○ Hearing impairment (e.g., I have difficulty hearing even with hearing aid)
- ○ Speech impairment (e.g., lisp, stutter, cannot speak at all)
- ○ Visual impairment (e.g., I have difficulty seeing even with glasses)
- ○ HIV/AIDS
- ○ I am not living with any of these
- ○ Don't know
- ○ Prefer not to answer

8. With respect to your gender, how do you currently identify?

- ○ Woman (cisgender)
- ○ Man (cisgender)
- ○ Trans man (female to male)
- ○ Trans woman (male to female)
- ○ Intersex
- ○ Genderqueer and/or gender fluid
- ○ Gender non-binary
- ○ Other, my gender is ____
- ○ Prefer not to answer

9. What sexual orientation do you most commonly identify with?

- ○ Heterosexual
- ○ Gay
- ○ Lesbian
- ○ Bisexual

- ○ Pansexual
- ○ Asexual
- ○ Other, my sexual orientation is ____

10. What is your current relationship status?

- ○ Legally married
- ○ Common-law
- ○ In a relationship, living together (but not legally married or common-law)
- ○ In a relationship, not living together
- ○ Single
- ○ Separated / divorced
- ○ Widowed
- ○ Other, please specify ___
- ○ Don’t know
- ○ Prefer not to answer

11. What is your current legal status in Canada?

- ○ Canadian citizen
- ○ Permanent resident / landed immigrant
- ○ Refugee/ protected person
- ○ Refugee claimant/ person in need of protection
- ○ Here with temporary work papers
- ○ Here with humanitarian and compassionate approval
- ○ Here as a visitor
- ○ Here on a student visa

- ◯ Undocumented/ non-status/ immigrant
- ◯ Don’t know
- ◯ Prefer not to answer

12. Which religious affiliation do you identify with?

- ◯ Islam
- ◯ Christianity
- ◯ Judaism ◯ Druze
- ◯ Agnostic (nothing can be known about the existence of God)
- ◯ Atheist (do not believe in the existence of God)
- ◯ No religion
- ◯ Other, please specify _____
- ◯ Prefer not to answer

13. What is the highest level of formal education you have completed?

- ◯ No formal education
- ◯ Some elementary / grade school
- ◯ Completed elementary / grade school
- ◯ Some high school / secondary
- ◯ Completed high school / secondary
- ◯ Some GED (General Education Diploma)
- ◯ Completed GED (General Education Diploma)
- ◯ Some trade / technical training
- ◯ Completed trade / technical training
- ◯ Some undergraduate university

- ○ Completed undergraduate university
- ○ Some post-graduate education
- ○ Completed post-graduate education
- ○ Other, please specify _____
- ○ Don't know
- ○ Prefer not to answer

14. Are you currently employed? Employment includes any work at a job that is paid work and includes people who have a job but are not at work due to maternity leave or illness. Select ALL that apply.

- ○ Yes, I have a paid job, where income tax is deducted
- ○ Yes, I have a paid job, but no income taxes are deducted
- ○ Yes, I am self-employed
- ○ No, I am not currently employed
- ○ Other, please specify _____
- ○ Prefer not to answer

15. In the last year, have you received social assistance or disability assistance? In Ontario, this welfare is known as Ontario Works or Ontario Disability Support Program (ODSP).

- ○ Yes
- ○ No
- ○ Prefer not to answer

16. Do you make money from any of the following sources? Select ALL that apply.

- ○ Pension (including federal Canada Pension Plan Disability Benefits (CPPD), Private Long-Term Disability (LTD), or other sources)
- ○ Sex work/ escorting
- ○ Selling drugs / drugs paraphernalia

- ○ Pan-handling/ 'squeegeeing' / recycling
- ○ Personal savings
- ○ Loan(s) / student Loan(s)
- ○ Parent / friend / relative / partner income
- ○ Honoraria (workshops, training)
- ○ Other, please specify _____
- ○ None of the above
- ○ Don't know
- ○ Prefer not to answer

17. Considering all income sources, how much do you make in a year, before taxes (i.e., personal gross yearly income)?

- ○ Less than $10,000
- ○ $10,000 to $19,999
- ○ $20,000 to $29,999
- ○ $30,000 to $39,999
- ○ $40,000 to $49,999
- ○ $50,000 or more
- ○ Don’t know
- ○ Prefer not to answer

18. What type of place are you currently living in?

- ○ Apartment / condo / house that you own
- ○ Rented house / apartment / condo
- ○ Apartment / condo / house with your parents
- ○ Hotel room / SRO (single room occupancy) hotel

- ○ Shelter – homeless shelter
- ○ Recovery house / transition house / halfway house / safe house
- ○ Homeless - living outdoors, street, parks, car, parkades
- ○ Couch surfing
- ○ Other, please specify _____
- ○ Prefer not to answer

19. What is the postal code for the place where you are currently living or regularly sleep?

- ○ Postal Code: (First 3 digits) _____
- ○ Don't know
- ○ Prefer not to answer

20. How safe do you feel in the place where you are currently living or regularly sleep?

- ○ Extremely safe
- ○ Somewhat safe
- ○ Less than safe
- ○ Not safe at all
- ○ Don't know
- ○ Prefer not to answer

21. Given your total household income, how difficult is it to meet your monthly housing costs (including rent, mortgage, property taxes, heat, electricity, water and/or gas)? Would you say that it is?

- ○ Not at all difficult
- ○ A little difficult
- ○ Fairly difficult
- ○ Very difficult
- ○ Not applicable – do not have monthly housing costs (homeless, shelter, couch surfing)

○ Don't know

○ Prefer not to answer

22. How did you find out about this study? Select <u>ALL</u> that apply.

○ Word of mouth

○ Community-based organizations, specify ___

○ MENA network

○ Social media, please specify _____

○ AIDS service organization(s), please specify _____

○ Other, please specify _____

○ Don't know

○ Prefer not to answer

Pre-HIV module test:

1. HIV, which stands for human immunodeficiency virus, is a virus that attacks the body's:
   a) Circulatory system
   b) Respiratory system
   c) **Immune system**
   d) Skeletal system

2. When HIV enters the body, it targets:
   a) Mitochondria
   b) **CD4 cells**
   c) Stem cells
   d) p25 antigen

3. True or false? HIV can be transmitted by shaking hands, hugging, kissing, coughing, and sneezing.
   True
   False

4. Select all that apply. Which of the following bodily fluids can contain enough HIV to transmit the virus?
   a) **Blood**
   b) **Semen (including pre-cum)**

c) **Rectal fluid**
d) Saliva
e) **Vaginal fluid**
f) **Breastmilk (chest milk)**

5. Select all that apply. Which of the following are highly effective strategies to prevent the sexual transmission of HIV in Canada?
   a) **Condoms**
   b) Microbicides
   c) **PrEP**
   d) **PEP**
   e) **HIV treatment**

6. Select all that apply. How can someone know if they have HIV?
   a) **HIV test**
   b) Appearance of flu-like symptoms
   c) Appearance of a rash
   d) Sudden onset of swollen lymph nodes

7. True or false? The viral load of a person living with HIV is the most important biological factor that can increase or decrease the chance of HIV transmission to an HIV-negative person.
   True
   False

8. Select all that apply. Which of the following activities most commonly transmit HIV in Canada?
   a) **Anal sex**
   b) Tattooing or piercing
   c) **Vaginal (frontal) sex**
   d) **Injection drug use**
   e) Needlestick injury

9. True or false? Using new equipment every time someone injects drugs is a highly effective strategy to prevent HIV, as well as hepatitis B and C.
   True
   False

10. True or false? Most people experience symptoms around the time of HIV infection.
    True
    False

11. True or false? HIV self-testing is available in Canada.
    True
    False

12. True or false? All HIV tests can detect HIV immediately after infection.
    True
    False

13. For better health outcomes, HIV treatment should be started:

a) When symptoms begin to appear
b) **As soon as possible after diagnosis**
c) When the CD4 cell count falls below 500
d) When a person begins to feel ill

14. Select all that apply. How does HIV treatment work?
    a) **It reduces the amount of virus in the body**
    b) It eliminates the virus from the body
    c) It trains the immune system to attack HIV
    d) **It prevents damage to the immune system.**

15. True or false? HIV treatment can be stopped if the person living with HIV is feeling healthy.
    True
    False

16. True or false? With current HIV drugs, many people do not experience side effects.
    True
    False

17. Select all that apply. Benefits of HIV treatment include:
    a) **Improving the health and quality of life of the person living with HIV**
    b) **Preventing damage to the immune system**
    c) **Lowering the chance of developing certain health conditions such as cardiovascular disease and certain types of cancer**
    d) **Preventing the sexual transmission of HIV (if they maintain an undetectable viral load)**

18. When someone living with HIV has an undetectable viral load, their risk of HIV transmission to a sexual partner is reduced by:
    a) **100%**
    b) 95%
    c) 85%
    d) 75%

19. True or false? Over time, a person's overall risk of getting HIV decreases the more they are exposed.
    True
    False

20. Select all that apply. Taking HIV treatment and having an undetectable viral load is a highly effective HIV prevention strategy. In order for this to work, a person with HIV needs to:
    a) **Take their HIV medications consistently and correctly, as prescribed (this is also referred to as high adherence)**
    b) Use condoms consistently and correctly when having sex
    c) **Achieve and maintain an undetectable viral load**
    d) **Be engaged in regular care, including monitoring of viral load and adherence support if needed**

21. What is the most common reason for someone's viral load to become detectable while on HIV treatment?

a) Interactions with other medications
b) Poor diet
c) **Inconsistent adherence**
d) Drug failure

22. Select all that apply. Taking PrEP involves:
    a) **Taking the medication as prescribed**
    b) Using condoms
    c) **Regular testing for HIV and other STIs**
    d) **Monitoring for drug side effects**
    e) **Telling sex partners that you are on PrEP**

23. How often should PrEP be taken (as currently recommended by the Canadian Guidelines)?

- ○ **Everyday**
- ○ Before sex
- ○ Once a month
- ○ Before and after sex
- ○ Weekly
- ○ Don't know
- ○ Prefer not to answer

24. If you are HIV-negative, are you currently taking PrEP? (skip if you are living with HIV)

- ○ Yes
- ○ No
- ○ Don't know
- ○ Prefer not to answer

25. If you are HIV-negative, how likely are you to take PrEP in the future? (skip if you are living with HIV)

- ○ Unlikely
- ○ Somewhat likely
- ○ Likely
- ○ Very likely

- ◯ Don’t know
- ◯ Prefer not to answer

26. If you are not currently taking PrEP and/or not planning to take PrEP in the future, indicate your reasons below. Select <u>ALL</u> that apply (skip if you are living with HIV)

- ◯ I am worried about the side effects of the medication
- ◯ I am in a monogamous relationship
- ◯ I am selective about my sexual partners
- ◯ I am practicing abstinence
- ◯ I am choosing non-penetrative sexual activities
- ◯ I always use condoms
- ◯ I find PrEP to be expensive
- ◯ I do not know where to access PrEP
- ◯ I am worried about stigma for using PrEP
- ◯ Additional reason, please specify _____
- ◯ Prefer not to answer

27. Have you ever heard of PEP (postexposure prophylaxis)?

- ◯ Yes
- ◯ No

28. Where do you get PEP if you needed it? Select <u>ALL</u> that apply.

- ◯ A community clinic
- ◯ My regular doctor / family doctor
- ◯ Emergency room
- ◯ Additional places, please specify _____
- ◯ Don't know

29. What is the longest time after an exposure to HIV that PEP can be started?

- ○ Less than 3 hrs
- ○ Less than 24 hrs (one day)
- ○ Less than 48 hrs (two days)
- ◉ **Up to 72 hrs (three days)**
- ○ Don't know

30. PEP will help prevent other STIs besides HIV.

- ◉ **True**
- ○ False

---------- Participants will complete HIV/STBBI online module now ----------

Post-HIV module survey:

1. HIV, which stands for human immunodeficiency virus, is a virus that attacks the body's:
   a) Circulatory system
   b) Respiratory system
   c) **Immune system**
   d) Skeletal system

2. When HIV enters the body, it targets:
   a) Mitochondria
   b) **CD4 cells**
   c) Stem cells
   d) p25 antigen

3. True or false? HIV can be transmitted by shaking hands, hugging, kissing, coughing, and sneezing.
   True
   False

4. Select all that apply. Which of the following bodily fluids can contain enough HIV to transmit the virus?
   a) **Blood**
   b) **Semen (including pre-cum)**
   c) **Rectal fluid**
   d) Saliva
   e) **Vaginal fluid**
   f) **Breastmilk (chest milk)**

5. Select all that apply. Which of the following are highly effective strategies to prevent the sexual transmission of HIV in Canada?
   a) **Condoms**
   b) Microbicides
   c) **PrEP**
   d) **PEP**
   e) **HIV treatment**

6. Select all that apply. How can someone know if they have HIV?
   a) **HIV test**
   b) Appearance of flu-like symptoms
   c) Appearance of a rash
   d) Sudden onset of swollen lymph nodes

7. True or false? The viral load of a person living with HIV is the most important biological factor that can increase or decrease the chance of HIV transmission to an HIV-negative person.
   True
   False

8. Select all that apply. Which of the following activities most commonly transmit HIV in Canada?
   a) **Anal sex**
   b) Tattooing or piercing
   c) **Vaginal (frontal) sex**
   d) **Injection drug use**
   e) Needlestick injury

9. True or false? Using new equipment every time someone injects drugs is a highly effective strategy to prevent HIV, as well as hepatitis B and C.
   True
   False

10. True or false? Most people experience symptoms around the time of HIV infection.
    True
    False

11. True or false? HIV self-testing is available in Canada.
    True
    False

12. True or false? All HIV tests can detect HIV immediately after infection.
    True
    False

13. For better health outcomes, HIV treatment should be started:
    a) When symptoms begin to appear
    b) **As soon as possible after diagnosis**
    c) When the CD4 cell count falls below 500
    d) When a person begins to feel ill

14. Select all that apply. How does HIV treatment work?
    a) **It reduces the amount of virus in the body**
    b) It eliminates the virus from the body
    c) It trains the immune system to attack HIV
    d) **It prevents damage to the immune system.**

15. True or false? HIV treatment can be stopped if the person living with HIV is feeling healthy.
    True
    False

16. True or false? With current HIV drugs, many people do not experience side effects.
    True
    False

17. Select all that apply. Benefits of HIV treatment include:
    a) **Improving the health and quality of life of the person living with HIV**
    b) **Preventing damage to the immune system**
    c) **Lowering the chance of developing certain health conditions such as cardiovascular disease and certain types of cancer**
    d) **Preventing the sexual transmission of HIV (if they maintain an undetectable viral load)**

18. When someone living with HIV has an undetectable viral load, their risk of HIV transmission to a sexual partner is reduced by:
    a) **100%**
    b) 95%
    c) 85%
    d) 75%

19. True or false? Over time, a person's overall risk of getting HIV decreases the more they are exposed.
    True
    False

20. Select all that apply. Taking HIV treatment and having an undetectable viral load is a highly effective HIV prevention strategy. In order for this to work, a person with HIV needs to:
    a) **Take their HIV medications consistently and correctly, as prescribed (this is also referred to as high adherence)**
    b) Use condoms consistently and correctly when having sex
    c) **Achieve and maintain an undetectable viral load**
    d) **Be engaged in regular care, including monitoring of viral load and adherence support if needed**

21. What is the most common reason for someone's viral load to become detectable while on HIV treatment?
    a) Interactions with other medications
    b) Poor diet
    c) **Inconsistent adherence**
    d) Drug failure

22. Select all that apply. Taking PrEP involves:
    a) **Taking the medication as prescribed**
    b) Using condoms
    c) **Regular testing for HIV and other STIs**
    d) **Monitoring for drug side effects**
    e) **Telling sex partners that you are on PrEP**

23. How often should PrEP be taken (as currently recommended by the Canadian Guidelines)?

- ○ **Everyday**
- ○ Before sex
- ○ Once a month
- ○ Before and after sex
- ○ Weekly
- ○ Don't know
- ○ Prefer not to answer

24. Given the information you have received in the HIV module, how likely are you to take PrEP in the future? (skip if you are living with HIV)

- ○ Unlikely
- ○ Somewhat likely
- ○ Likely
- ○ Very likely
- ○ Don't know
- ○ Prefer not to answer

25. Given the information you have received in the HIV module, if you are not currently taking PrEP and/or not planning to take PrEP in the future, indicate your reasons below. Select <u>ALL</u> that apply. (skip if you are living with HIV)

- ○ I am worried about the side effects of the medication
- ○ I am in a monogamous relationship

- ○ I am selective about my sexual partners
- ○ I am practicing abstinence
- ○ I am choosing non-penetrative sexual activities
- ○ I always use condoms
- ○ I find PrEP to be expensive
- ○ I do not know where to access PrEP
- ○ I am worried about stigma for using PrEP
- ○ Additional reason, please specify _____
- ○ Prefer not to answer
- ○ There are no reasons that would stop me from taking PrEP

26. Have you ever heard of PEP (postexposure prophylaxis)?

- ○ Yes
- ○ No

27. Where do you get PEP if you needed it? Select <u>ALL</u> that apply.

- ○ A community clinic
- ○ My regular doctor / family doctor
- ○ Emergency room
- ○ Additional places, please specify _____
- ○ Don't know

28. What is the longest time after an exposure to HIV that PEP can be started?

- ○ Less than 3 hrs
- ○ Less than 24 hrs (one day)
- ○ Less than 48 hrs (two days)
- ○ **Up to 72 hrs (three days)**
- ○ Don’t know

29. PEP will help prevent other STIs besides HIV.

- **True**
- False

Pre-SMART Intervention Survey:

1. In the past 6 months, have you been involved in any type of intimate relationship, whether it included sex or not?

a) Yes
b) No
c) Don't know
d) Prefer not to answer

2. In the past 6 months, have you had any of these sexual experiences? Select ALL that apply.

- Kissing
- Dry humping
- Vaginal intercourse
- Given or received oral sex (i.e., eating out or blow job)
- Given or received anal sex (i.e., sex in the ass)
- Masturbation (i.e., touched yourself or jerked off)
- Given or received a hand job
- Been fingered or fingered someone else
- Been rimmed or rimmed someone else (i.e., licking someone's asshole)
- Been fisted or fisted someone else
- Used sex toys (e.g., dildo, vibrator, etc.) with someone else
- I have not had any of these experiences
- Don't know
- Prefer not to answer

3. How often have you been objectified or fetishized sexually because you're gay, bi, or trans?

- ○ Never
- ○ Once or twice
- ○ Sometimes
- ○ Many times

4. When you think about using protection with a sex partner (for example, a condom, dental dam,glove, or plastic wrap), how certain are you that you could use protection in the following scenarios? Please rate from 1 – 7. A '7*' means that you're absolutely certain you could do what the question asks; a '1*' means you're absolutely certain that you could not do what the question asks.

I can ask a partner to use a protective barrier	☆ ☆ ☆ ☆ ☆ ☆ ☆
I can ask a partner I haven't been using protective barriers with to start using them	☆ ☆ ☆ ☆ ☆ ☆ ☆
I can refuse sex when I don't have a protective barrier available	☆ ☆ ☆ ☆ ☆ ☆ ☆
I can get a partner to use a protective barrier, even if I'm drunk or high	☆ ☆ ☆ ☆ ☆ ☆ ☆
I can get a partner to use a protective barrier, even if they don't want to	☆ ☆ ☆ ☆ ☆ ☆ ☆

5. Which of the following best describes the type of relationship you have been involved in, in the past 6 months?

Please note: If you've had more than one romantic or intimate relationship in the past 6 months, please think about your relationship with the person you consider your primary partner.
If you think multiple terms apply, please select the one you feel represents your relationship the best (e.g., think about how you would talk about it to others or yourself).

- ○ Married or common-law relationship (husband/wife/spouse/partner relationship)
- ○ Partner relationship but not married or common-law
- ○ Boyfriend/girlfriend relationship
- ○ Dating but not officially in a relationship
- ○ On and off again relationship

- ○ Friend with benefits relationship (i.e., sex/intimacy between friends without monogamy/commitment)
- ○ One-night stand (i.e., a sexual relationship lasting only one time without expectations of further relations, often a stranger such as someone you meet at a bar)
- ○ Casual sexual relationship (i.e., distinct from a one-night stand, with more regular sexual relations but no romantic involvement/commitment, and not necessarily just at night or with a friend)
- ○ Transactional relationship (i.e., refers to sexual relationships where the giving of gifts, money, shelter, drugs, food, clothes, or services in return for sex/intimacy is an important factor)
- ○ Polyamory (i.e., an intimate relationship involving multiple partners, all of whom are aware/consenting)
- ○ Swinging/open relationship (i.e., a committed relationship with non-monogamous behaviour, where singles or partners are allowed to have sex with other people as a recreational or social activity)
- ○ Other, please specify _____
- ○ Don't know
- ○ Prefer not to answer

6. Have you had consensual sex in the past 6 months? This includes any type of sexual intercourse you willingly engaged in, including getting or giving oral sex, vaginal sex, and/or anal sex with people of any gender. This also includes regular partners, casual partners, or paying sex partners/clients.

- ○ Yes
- ○ No
- ○ Don't know
- ○ Prefer not to answer

7. **How many condomless anal and vaginal sex acts have you had in the last 6 months (in the absence of either PrEP or known undetectable viral load of HIV+ primary partners)? _____**

8. Based on where you are or who you are with, do you ever hide or avoid expressing your sexual orientation?

- ○ Never
- ○ Sometimes
- ○ Most of the time
- ○ Always

9. How comfortable are you with the word "gay / bisexual /trans" being used to describe you?

- ○ Very
- ○ Mostly
- ○ Somewhat
- ○ Not at all

10. From which sources have you personally experienced stigma or discrimination as a result of your identity or sexual orientation? Select <u>ALL</u> that apply.

- ○ Friends
- ○ Family
- ○ Romantic partners
- ○ Health care providers
- ○ Gay /bi / trans people
- ○ Employers
- ○ Additional sources, please specify _____
- ○ None of the above

11. Please check the "top three" reasons if you do not want to go for an HIV/STI test.

- ○ Don't know where to go for a test
- ○ Don't see a need
- ○ Afraid of the result

- ○ Afraid of the blood taking
- ○ Afraid of catching an infection
- ○ Fear of stigmatization
- ○ Cultural and language barrier
- ○ Don't think testing is confidential
- ○ Too expensive
- ○ Additional reason, please specify _____

HIV Risk Assessment

HIV Incidence Risk Index (HIRI)

Question	Response	Score
How old are you today (years)?	**18-28 years** **29-40 years**	**8** **5**
How many men have you had sex with in the last 6 months?	**>10 male partners** **6-10 male partners** **0-5 male partners**	**7** **4** **0**
How many of your male sex partners were living with HIV?	**>1 partner living with HIV** **1 partner living with HIV** **0 partners living with HIV**	**8** **4** **0**
In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	**1 or more times** **0 times**	**10** **0**
In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was living with HIV?	**5 or more times** **0-4 times**	**6** **0**
In the last 6 months, have you used methamphetamines such as crystal or speed?	**Yes** **No**	**5** **0**
In the last 6 months, have you used poppers (amyl nitrate)?	**Yes** **No**	**3** **0**

*If the HIRI score is 10 or higher, and a person is HIV negative: Starting HIV PrEP is recommended and should be discussed further between health care provider and client. There may be a higher chance of getting HIV.

Please put the appropriate scoring number based on the above HIRI scale - For example, if your age is between 18-28, then your score is "8"; if you have had sex withmore than 10 male partners, then your score is "7".

I. How old are you today: _____
II. How many men have you had sex with in the last 6 months?: _____
III. How many of your male sex partners were living with HIV?: _____
IV. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?: _____
V. In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was living with HIV?: _____
VI. In the last 6 months, have you used methamphetamines such as crystal or speed?: _____
VII. In the last 6 months, have you used poppers (amyl nitrate)? : _____
VIII. Total: _____

Also, the mental health and well-being, and resilience questions/scales will be administered pre and post SMART intervention

Post-SMART Intervention Survey:

1. Since the SMART intervention, when you think about using protection with a sex partner (for example, a condom, dental dam,glove, or plastic wrap), how certain are you that you could use protection in the following scenarios? Please rate from 1 – 7. A '7*' means that you're absolutely certain you could do what the question asks; a '1*' means you're absolutely certain that you could not do what the question asks.

I can ask a partner to use a protective barrier

I can ask a partner I haven't been using protective barriers with to start using them

I can refuse sex when I don't have a protective barrier available

I can get a partner to use a protective barrier, even if I'm drunk or high

I can get a partner to use a protective barrier, even if they don't want to

2. **Since the SMART intervention, how many condomless anal and vaginal sex acts have you had (in the**

absence of either PrEP or known undetectable viral load of HIV+ primary partners)? _____

3. Based on where you are or who you are with, do you ever hide or avoid expressing your sexual orientation?

- ○ Never
- ○ Sometimes
- ○ Most of the time
- ○ Always

4. How comfortable are you with the word "gay / bisexual /trans" being used to describe you?

- ○ Very
- ○ Mostly
- ○ Somewhat
- ○ Not at all

5. From which sources have you personally experienced stigma or discrimination as a result of your identity or sexual orientation? Select <u>ALL</u> that apply.

- ○ Friends
- ○ Family
- ○ Romantic partners
- ○ Health care providers
- ○ Gay /bi / trans people
- ○ Employers
- ○ Additional sources, please specify _____
- ○ None of the above

6. Given the information you have received from the SMART intervention, please check the "top three" reasons if you do not want to go for an HIV/STI test.

- ○ Don't know where to go for a test
- ○ Don't see a need
- ○ Afraid of the result
- ○ Afraid of the blood taking
- ○ Afraid of catching an infection
- ○ Fear of stigmatization
- ○ Cultural and language barrier
- ○ Don't think testing is confidential
- ○ Too expensive
- ○ Additional reason, please specify _____
- ○ There are no reasons that would stop me from going for an HIV/STI test

HIV Risk Assessment

HIV Incidence Risk Index (HIRI)

Question	Response	Score
How old are you today (years)?	**18-28 years** **29-40 years**	**8** **5**
Since the SMART intervention, how many men have you had sex with?	**>10 male partners** **6-10 male partners** **0-5 male partners**	**7** **4** **0**
How many of your male sex partners were living with HIV?	**>1 partner living with HIV** **1 partner living with HIV** **0 partners living with HIV**	**8** **4** **0**
Since the SMART intervention, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	**1 or more times** **0 times**	**10** **0**
Since the SMART intervention, how many times did you have insertive anal sex (you were the top) with a man who was living with HIV?	**5 or more times** **0-4 times**	**6** **0**
Since the SMART intervention, have you used methamphetamines such as crystal or	**Yes** **No**	**5** **0**

speed?		
Since the SMART intervention, have you used poppers (amylnitrate)?	**Yes** **No**	**3** **0**

*If the HIRI score is 10 or higher, and a person is HIV negative: Starting HIV PrEP is recommended and should be discussed further between health care provider and client. There may be a higher chance of getting HIV.

Please put the appropriate scoring number based on the above HIRI scale - For example, if your age is between 18-28, then your score is "8"; if you have had sex withmore than 10 male partners, then your score is "7".

I. How old are you today: _____
II. How many men have you had sex with in the last 6 months?: _____
III. How many of your male sex partners were living with HIV?: _____
IV. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?: _____
V. In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was living with HIV?: _____
VI. In the last 6 months, have you used methamphetamines such as crystal or speed?: _____
VII. In the last 6 months, have you used poppers (amyl nitrate)?: _____

Total: ___

Also, the mental health and well-being, and resilience questions/scales will be administered pre and post SMART intervention

Section 03. Feasibility and Acceptability Scales (common to both subgroups and administered post-intervention only)

Acceptability of Intervention Measure (AIM)

Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1	2	3	4	5

1. SMART meets my approval. • , *f* „ …
2. SMART is appealing to me. • , *f* „ …
3. I like SMART • , *f* „ …
4. I welcome SMART • , *f* „ …

Feasibility of Intervention Measure (FIM)

Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1	2	3	4	5

1. SMART seems implementable. • , *f* „ …
2. SMART seems possible. • , *f* „ …
3. SMART seems doable. • , *f* „ …
4. SMART seems easy to use. • , *f* „ …

Section 04. Mental Wellbeing

(DASS-21 scale common to both subgroups and administered pre-SMART intervention and post-SMART intervention)

1. We are interested in your emotional and mental health. There are no right or wrong answers. Do not spend too much time on any statement. To what extent do the following statements apply to you over the <u>past week</u>?

Statement	Not at all	Some of the time	A good part of time	Most of the time
1. I found it hard to wind down				
2. I was aware of dryness of my mouth				
3. I couldn't seem to experience any positive feeling at all				
4. I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)				
5. I found it difficult to work up the initiative to do things				
6. I tended to over-react to situations				
7. I experienced trembling (e.g., in the hands)				
8. I felt that I was using a lot of nervous energy				
9. I was worried about situations in which I might panic and make a fool of myself				
10. I felt that I had nothing to look forward to				
11. I found myself getting agitated				
12. I found it difficult to relax				
13. I felt down-hearted and blue				
14. I was intolerant of anything that kept me from getting on with what I was doing				
15. I felt I was close to panic				
16. I was unable to become enthusiastic about anything				
17. I felt I wasn't worth much as a person				
18. I felt that I was rather touchy				
19. I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)				
20. I felt scared without any good reason				
21. I felt that life was meaningless				

Section 05. Self-Compassion Scale Short Form SCS-SF *(common to both subgroups and administered pre-intervention and post-intervention)*

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never Almost always

1 2 3 4 5

_____1. When I fail at something important to me I become consumed by feelings of inadequacy.

_____2. I try to be understanding and patient towards those aspects of my personality I don't like.

_____3. When something painful happens I try to take a balanced view of the situation.

_____4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____5. I try to see my failings as part of the human condition.

_____6. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____7. When something upsets me I try to keep my emotions in balance.

_____8. When I fail at something that's important to me, I tend to feel alone in my failure

_____9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____11. I'm disapproving and judgmental about my own flaws and inadequacies.

_____12. I'm intolerant and impatient towards those aspects of my personality I don't like.

Section 06. Cognitive and Affective Mindfulness Scale– Revised (CAMS-R) *(common to both subgroups and administered pre-intervention and post-intervention)*

Instructions: People have a variety of ways of relating to their thoughts and feelings. For each of the items below, rate how much each of these ways applies to ***yo*u.**

_____1. It is easy for me to concentrate on what I am doing.

_____2. I am preoccupied by the future.

_____3. I can tolerate emotional pain.

_____4. I can accept things I cannot change.

_____5. I can usually describe how I feel at the moment in considerable detail.

_____6. I am easily distracted.

_____7. I am preoccupied by the past.

_____8. It's easy for me to keep track of my thoughts and feelings.

_____9. I try to notice my thoughts without judging them.

_____10. I am able to accept the thoughts and feelings I have.

_____11. I am able to focus on the present moment.

_____12. I am able to pay close attention to one thing for a long period of time.

Section 07. The Adult Resilience Measure-Revised (ARM-R) ***(common to both subgroups and administered pre-intervention and post-intervention)***

Instructions: To what extent do the following statements apply to you? There are no right or wrong answers.

	Not at all	A little	Somewhat	Quite a bit	A lot
1. I cooperate with people around me					
2. Getting and improving qualifications or skills is important to me					
3. I know how to behave in different social situations					
4. My family have usually supported me through life					
5. My family knows a lot about me					
6. If I am hungry, I can get food to eat					
7. People like to spend time with me					
8. I talk to my family/partner about how I feel					
9. I feel supported by my friends					
10. I feel that I belong in my community					
11. My family/partner stands by me during difficult times					
12. My friends stand by me during difficult times					
13. I am treated fairly in my community					
14. I have opportunities to show others that I can act responsibly					
15. I feel secure when I am with my family/partner					
16. I have opportunities to apply my abilities in life (like skills, a job, caring for others)					
17. I enjoy my family's/partner's cultural and family traditions					

Thank you! Your responses have been recorded.

……

Thank you for taking the time to complete the survey. We truly honour your words and time today. You really are the community expert; without you, we would not be able to advocate for change! You are very much appreciated. The information you have shared with us today may help to create intervention programs in the future.

FULL TITLE: Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.

Protocol No. 049

Sponsor:	CIHR/CTN
Principal Investigator(s):	Dr. Roula Hawa, PhD (PI), Dr. Josephine Wong, PhD (Co-PI), Dr, Ahmed Bayoumi, MD (Co-PI)
Sub-Investigators / Collaborators:	Dr. Priscilla Boake (Co-Investigator), Khaled Salam (Principal Knowledge User), Kerolos Saleib (Principal Knowledge User), Jad El Tal (Knowledge User and Collaborator), Nona Abdallah (Knowledge User), Ahmad Ezzeddine (Knowledge User).
Study Support/ Funding:	CIHR/CTN Pilot Study Funding Program
Version No.	CTNPT
Date:	21-12-2022

Compliance Statement

This clinical study will be conducted in accordance with applicable Health Canada regulations, the Tri-Council Policy Statement Version 2 (TCPS2), and the Declaration of Helsinki.

Confidentiality Statement

This clinical study protocol contains information which is of a confidential, trade-secret or proprietary nature. The protocol is for the use of [principal investigator] and [his/her] designated representatives participating in the investigational study. It is not to be disclosed to any other person or party without the prior written approval of [principal investigator].

GUIDANCE NOTE: If Sponsor for the study is an Investigator, Sponsor should be replaced throughout with Sponsor-Investigator (SI).

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INVESTIGATOR AGREEMENT

Protocol Title: Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.

Protocol No.: CTNPT

Version No.: 049

Date: 28-01-2023

This clinical study will be conducted in accordance with applicable Health Canada regulations, the TCPS2, and the Declaration of Helsinki.

I confirm that I have read and understand this protocol and I agree to conduct this clinical study in accordance with the design and specific provisions of the protocol, with the exception of a change intended to eliminate an immediate hazard to participants. Any deviation from the study protocol will be documented in the case report form.

I agree to promptly report to the applicable ethics boards any changes in the research activity and all unanticipated problems involving risks to human participants or others. Additionally, I will not make any changes in the research without prior ethics and sponsor approval, except where necessary to ensure the safety of study participants.

Roula Hawa	RHAWA	21-04-2023
Name	Signature	Date (dd-mmm-yyyy)

ABBREVIATIONS AND DEFINITONS

Acronym / Abbreviation	Definition
SMART	Self-Compassion, Mindful Acceptance, and Resilience Transformation: an 8- week group-based training
MENA	Middle Eastern and North African
RCT	Randomized Controlled Trial
GBT	Gay, bisexual and transgender
Cis, Cis gender	A term for people whose gender identity generally matches the gender assigned for their physical sex.
YSMENA Study	Youth Sexual Health and HIV/STI Prevention in Middle Eastern and North African Communities (YSMENA) Program is the first community-based research program in Canada to center the voices of diaspora MENA youth.
FIM	Feasibility of Intervention Measure (FIM)
AIM	Acceptability of Intervention Measure (AIM)
DASS-21	Depression, Anxiety and Stress Scale. A set of three self-report scales (21 items) designed to measure the emotional states of depression, anxiety, and stress
SCS-SF	Self compassion scale - Measured using the Short Form of the Self Compassion Scale (SCS-SF); scale made of 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification.
CAMS-R	Cognitive and Affective Mindfulness Scale– Revised, a 12-item measure designed to capture a broad conceptualization of mindfulness not specific to any particular type of meditation training
AMR-R	The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social-ecological resilience and is used by researchers and practitioners worldwide.

PROTOCOL SYNOPSIS

Full Title	Promoting Mental Health and Reducing HIV Risk Behaviours through Self-compassion, Mindful Acceptance & Resilience Transformation (SMART): An Evidence-informed Pilot Randomized Trial with Diaspora MENA Gay, Bisexual and Trans Youth in Ontario.
Short Title	SMART Intervention, Middle Eastern and North African Gay Bisexual and Trans Youth
Protocol and Version No.	CTNPT 049
Study Duration	Enrollment period: June 2023 – August, 2023
	Study period: February, 2023 – Feb 2025
Sponsor	CIHR/CTN
Number of Centres	N/A. SMART intervention is a group intervention delivered synchronously via Zoom video communication platform. Participants will be recruited with the support of community partners from across Ontario.
Study Design	This mixed-methods pilot involves two sequential phases: a quantitative component that includes a waitlist randomized controlled trial and a qualitative component that involves focus groups. The waitlist control group will be used as an untreated comparison for the active experimental group to estimate the effect size of the intervention for the primary outcomes. Informed consent will be obtained prior to data collection. Data will be gathered using both quantitative and qualitative tools, which include self-completed surveys and focus groups. Quantitative data will be gathered for participants in the intervention and control groups through self-completed surveys that will be administered online pre- and postintervention and 8 weeks (2 months) postintervention. Qualitative data will be gathered through focus groups that will be conducted for both intervention and control groups at 8 weeks (2 months) postintervention. ***Refer to Fig. 1: Study Design***
Primary Objective	• Assess feasibility and acceptability of SMART intervention • Preliminary quantitative evidence for efficacy.
Secondary Objectives	• Assess the impact of SMART intervention on mental health • Assess the impact of SMART intervention on self compassion

Exploratory Objectives	• Assess the impact of SMART intervention on HIV literacy. • Assess the impact of SMART intervention on Mindfulness.
Sample Size	N =40
Randomization	After eligibility is met for the program, we will wait until we have a sufficient sample size to randomize for the intervention. Once this is reached, participants will be asked to complete the baseline self-completed surveys online before commencing the program. Eligible participants will be randomized to receive SMART intervention or waitlist in a ratio of 1:1. We will wait until we have a sufficient sample size to randomize for the first wave of intervention (10 per condition). Randomization and allocation will be done via the online web-based software Qualtrics. Researchers, participants, and facilitators will not be blind to condition allocation, however, the researcher completing the analysis will be blind. Participants will be offered an honorarium of $25 for attending each intervention session and for completing each assessment survey starting at baseline**.** Participants will be also offered $50 each for taking part in a focus group discussion session. ***Refer to Fig. 1: Study Design***
Study Population / Diagnosis and Main criteria for inclusion	1. self-identified MENA (Arab and/or West Asian); 2. 21-29 years old; 3. gay, cis bisexual, or trans youth; 4. minimal or no prior experience with mindfulness-based interventions; 5. able to speak and read English; 6. have internet access; and 7. able to take part in the 8-week intervention (able to attend at least 70% of the sessions).
Outcome Measures	**<u>Primary:</u>** ○ **HIV-risk acts or practices.** This count outcome is the number of condomless anal and vaginal sex acts in the preceding 8 weeks (in the absence of either PrEP or known undetectable viral load of HIV+ primary partners) ○ **Feasibility and acceptability** (quantitative measures). - Feasibility of Intervention Measure (FIM); and - Acceptability of Intervention Measure (AIM). ○ Also, **feasibility and acceptability** of the intervention will be **assessed qualitatively** using **focus group discussions** to gain a more in-depth understanding and to help triangulate results.

	Secondary: ○ **Depression, anxiety and stress.** The Depression, Anxiety and Stress Scale (DASS-21), a set of three self-report scales (21 items) designed to measure theemotional states of depression, anxiety, and stress. ○ **Self-compassion**. Measured using the Short Form of the Self Compassion Scale (SCS-SF); A total of 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification.
	Exploratory: ○ **HIV literacy.** HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP, PEP, HIV testing, community resources). ○ **Mindfulness.** Cognitive and Affective Mindfulness Scale– Revised (CAMS-R), a 12-item measure designed tocapture a broad conceptualization of mindfulness not specific to any particular type of meditation training. ○ **Resilience.** The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social-ecological resilience and is used by researchers and practitioners worldwide.
Statistical Analysis	**DATA ANALYSES PLAN** • Randomize in clusters of 10. • Measure Inter cluster correlation (ICC). Evaluate the correlation of outcomes within treatment groups Our general approach will use multilevel generalized linear mixed-effect models, with the link function determined bythe type of outcome measure (count, binomial, or continuous). Models will include fixed effects for treatment and random intercepts at the individual and cluster levels; we will also examine for interaction effects between treatment and time in 8-week models. **Quantitative Data Analyses** **Primary Analyses** **Descriptive statistics** will be used to summarize participants' socio-demographics, self-reported health characteristics, and practices. Our analysis will focus on the **difference in the primary outcome** (number of condomless anal and vaginal sex in the preceding 8 weeks, comparing baseline and post-intervention

	[8 week] outcomes) using random effects repeated measures Poisson analysis. Also, for primary analyses, we will **assess feasibility and acceptability of the intervention**. Measures include: o Consent rate o Duration for recruitment o Recruitment rate (% participants recruited) o Retention/success rate/completion rate (completion of intervention sessions). o Attendance/study attrition (able to attend at least 70% of the sessions). **Secondary Analyses** In secondary analyses, we will evaluate the following: 1) ***Number of unprotected sex acts*** over 8 weeks- using repeated measures analyses (baseline and 8 weeks). 2) ***Depression, anxiety and stress.*** Proportion of participants at risk for anxiety, depression, and stress over time using the DASS-21 outcome-specific subscales that assess anxiety, depression, and stress. **Scoring Sheet:** https://maic.qld.gov.au/wp-content/uploads/2016/07/DASS-21.pdf. ***See attached scoring instructions for more details*** ***Self-compassion***. Measured using the Short Form of the Self Compassion Scale (SCS-SF); 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification. **Scoring Sheet:** https://novopsych.com.au/wp-content/uploads/2021/11/SCS-SF-self-compassion-scale-blank-form-pdf.pdf ***See attached scoring instructions for more details*** **Exploratory Analyses** We will use a similar approach to analyzing exploratory outcomes, with the exception that we will not perform hypothesis testing. ***1) HIV literacy.*** HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP, PEP, HIV testing, community resources). Mean scores, Likert scales. No standardized scales. ***2) Mindfulness.*** Cognitive and Affective Mindfulness Scale– Revised (CAMS-R), a 12-item measure designed to capture a broad conceptualization of

	mindfulness not specific to any particular type of meditation training. Items are rated on a 4-point Likert scale from 1 (rarely/not at all) to 4 (almost always). Items 2, 6, and 7 are reverse-scored. After appropriate reversals, sum values for items 1 - 12. Higher values reflect greater mindful qualities. **Scoring sheet:** https://ggsc.berkeley.edu/images/uploads/The_Cognitive_and_Affective_Mindfulness_Scale_–_Revised.pdf ***See attached scoring instructions for more details*** ***Resilience.*** The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social-ecological resilience and is used by researchers and practitioners worldwide. **5-point scoring sheet:** https://cyfar.org/sites/default/files/InstrumentFiles/Resilience_Adult.pdf ***See scoring instructions for more details*** **Qualitative Data Analyses** We will use a computer software program (NVivo) to aid in data management. For data analysis, the team will construct a list of thematic categories based on the research questions. ***More details are found in the data analyses section.***

INTRODUCTION, BACKGROUND, AND STUDY RATIONALE

1.1 Background

Sex and sexual health practices of Middle Eastern and North African (MENA) youth in Canada are under-researched and require attention as the community continues to grow due to immigration. The rise in new HIV infections since 2001 has put the MENA region among the top two regions with the fastest growing rates of HIV infections globally[1], where the spread of HIV is hastened by conflicts, and economic upheavals that upset social stability[2]. A scoping review of the literature focused on youth residing in or originating from the MENA region, conducted by the Nominated Principal Investigator (NPI), Hawa and team in 2022, found that new HIV infections that occurred across the region mostly affected people in key population groups such as sex workers, people who inject drugs, trans youth, and gay and other men who have sex with men, facing homophobia, stigma and discrimination as well as harsh criminalization[3]

These global trends have implications in the Canadian landscape. The 2016 Canadian Census reports that immigrants from Middle Eastern countries (Arabs and West Asians) are expected to increase the most rapidly between 2006 and 2031 and more than triple in the next 25 years [4] . With an influx of newcomer and refugee MENA youth, especially LGBTQ+ youth, many face unemployment, language barriers, limited social support systems, and cultural barriers, increasing their vulnerability to HIV [5] . In Ontario, findings from a mixed-methods, community-based research study, Youth Sexual Health and HIV/STI Prevention in Middle Eastern and North African Communities (YSMENA Study), led by NPI Hawa and conducted between 2019-2021 indicated that diaspora MENA gay and bisexual cis men who have sex with men (MSM) and trans youth deal with unique sexual and mental health challenges, including systemic oppressions and racism when accessing health care or employment, homophobia from cultural communities, and strained familial relationships [6, 7] . In addition, the need for a sense of belonging, marginalized identities, and barriers to accessing mental and sexual health services were identified as factors contributing to sexual and substance use practices that put them at high risk. Despite the lack of culturally-relevant resources, many expressed desires of building self-acceptance and peer support networks.

Findings from the YSMENA study are supported by Canadian and American literature involving LGBTQ youth. For example, minority stress, which refers to the effect of a homophobic social environment within a stress discourse[8] and psychological distress contribute to behavioural health issues such as vulnerability for HIV/STI risk among sexual minority men [9-12] and reduced health service utilization [13,14] . Further, sexual minority men and transgender women are at risk for various behavioural health issues, including high rates of HIV/STI risks[15-17]. A high prevalence of syndemic health issues such as depression and substance use among gay, MSM and trans youth necessitates additional work to understand how “upstream” determinants can be integrated into HIV risk assessments[18,19]

1.2 Study Rationale

Despite the need for interventions, evidence-based interventions targeting health issues and minority stress among sexual and gender minority youth are limited. Few studies have evaluated interventions that address mental health risks and promote well-being among sexual

and gender minority youth, and none among MENA youth. Mindfulness training has shown benefits for mental and physical health in clinical and community settings [20-27] . We are proposing a community-based, mixed-methods pilot intervention to assess the feasibility and help plan a randomized controlled trial (RCT). The proposed study will be a single-blind CONSORT-compliant randomised controlled trial, comparing SMART: an 8- week group-based training - with a delayed-treatment waitlist control group. The study is part of a research program that aims to promote the mental well-being, reduce psychological distress (depression, anxiety, and stress) and reduce HIV high risk practices in gay, bisexual and trans MENA youth in Ontario.

1.3 Potential risks and benefits to human participants

What are the risks and harms of participating in this study?

There might be some challenges in running the intervention with mixed groups of gay, bisexual and trans youth due to their varying health needs. However, benefits of offering the pilot intervention to all vulnerable key populations outweighs the challenges. This can be addressed upfront with co-facilitators and participants to create an understanding and an awareness among group members.

What are the benefits?

SMART intervention uses mindfulness-based training aimed at enhancing mental health, self-compassion, psychological resilience, and collective empowerment. You may not benefit directly from this study. However, the study may provide a benefit for MENA diaspora youth as the information may provide insight to develop innovative community-based, intersectional, and youth-driven HIV/STI prevention strategies.

The overall purpose of this pilot study is to assess the feasibility of conducting a large study to investigate the benefit of a mindfulness-based intervention to reduce HIV risk and optimize well-being and resilience. Our results will be important for planning a future larger scale mindfulness-based study and will contribute additional information within this context. The generalization of findings will benefit MENA youth groups and other racialized gay, bisexual and trans youth in Ontario and across Canada.

2 STUDY OBJECTIVES AND DESIGN

2.1 Overall Study Design

This mixed-methods pilot involves two sequential phases: a quantitative component that includes a waitlist randomized controlled trial and a qualitative component that involves focus groups. The waitlist control group will be used as an untreated comparison for the active experimental group to estimate the effect size of the intervention for the primary outcomes. Informed consent will be obtained prior to data collection.[28] Data will be gathered using both quantitative and qualitative tools, which include self-completed surveys and focus groups. Quantitative data will be gathered for participants in the intervention and control groups through self-completed surveys that will be administered online pre- and postintervention. Both groups will also complete the surveys 8 weeks (2 months) postintervention. Qualitative data will be

gathered through focus groups that will be conducted for both intervention and control groups at 8 weeks (2 months) postintervention. ***Refer to Fig. 1: Study Design***

SMART Intervention

SMART is an evidence-informed intervention that builds on previous community interventions developed by Wong and colleagues to reduce intersecting stigmas and promote collective resilience among racialized people living with HIV and mental health challenges in the Asian, Black and Latinx communities in Toronto[29]. It draws on the Acceptance and Commitment to Empowerment (ACE) model [30] which applies the principles/values of social justice and equity, interdependence, empathy and compassion, and collective empowerment, and mindfulness based psychological processes (e.g., defusion, acceptance, here-and-now, self-as-context, values and committed action) first applied and evaluated in Acceptance and Commitment Therapy [31] . Based on insights and lessons learned from ACE implementation [32, 33] , SMART extends structured mindfulness practices to promote sustainability of behavioural change and resilience. In this project, identity construction, collective resilience, and HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP, PEP, HIV testing, community resources) will be integrated into the entire intervention.

Refer to Table 1 for the 8-week intervention modules.

The SMART intervention will be delivered virtually via Zoom by MENA or other racialized peer facilitators already trained through the Committee for Accessible AIDS Treatment (CAAT). Peer support was found to be a particularly useful model for LGBTQ+ young people [34] . Virtual interventions are a more accessible form of delivery for gay, bisexual and trans young adults since many are excluded from mainstream services, and may experience challenges in accessing services tailored to sexual and gender minority populations, or finding mental health support that is inclusive of their identities and expressions. Moreover, young people often engage with online spaces [35], thus a virtual program may be appealing. Participants need to be able to attend the group intervention via videoconference for 2 hrs per-week for 8 weeks. We will infuse racial, sexual and gender affirmative principles to address minority stress as well as incorporate cultural values relevant to the MENA community in Ontario. We will establish a gay, bisexual and trans **MENA youth advisory group** of 4 youth to ensure that the language used is appropriate for the target groups, and racial, sexual and gender affirmative principles as well as cultural values relevant to the MENA community in Ontario are incorporated. We will also explore change in outcomes from baseline to 20-week follow-up for both intervention and waitlist control groups.

The intervention group will be divided into two cohorts of 10 participants each, running in the same week, to allow more opportunity for participants to share their experiences, mental health stressors, and application of mindfulness-based affirmative intervention strategies during the weekly meetings. The control group will also be divided into two cohorts of 10 participants each and will receive the intervention after the two intervention cohorts are completed.

Fig 1: Study Design

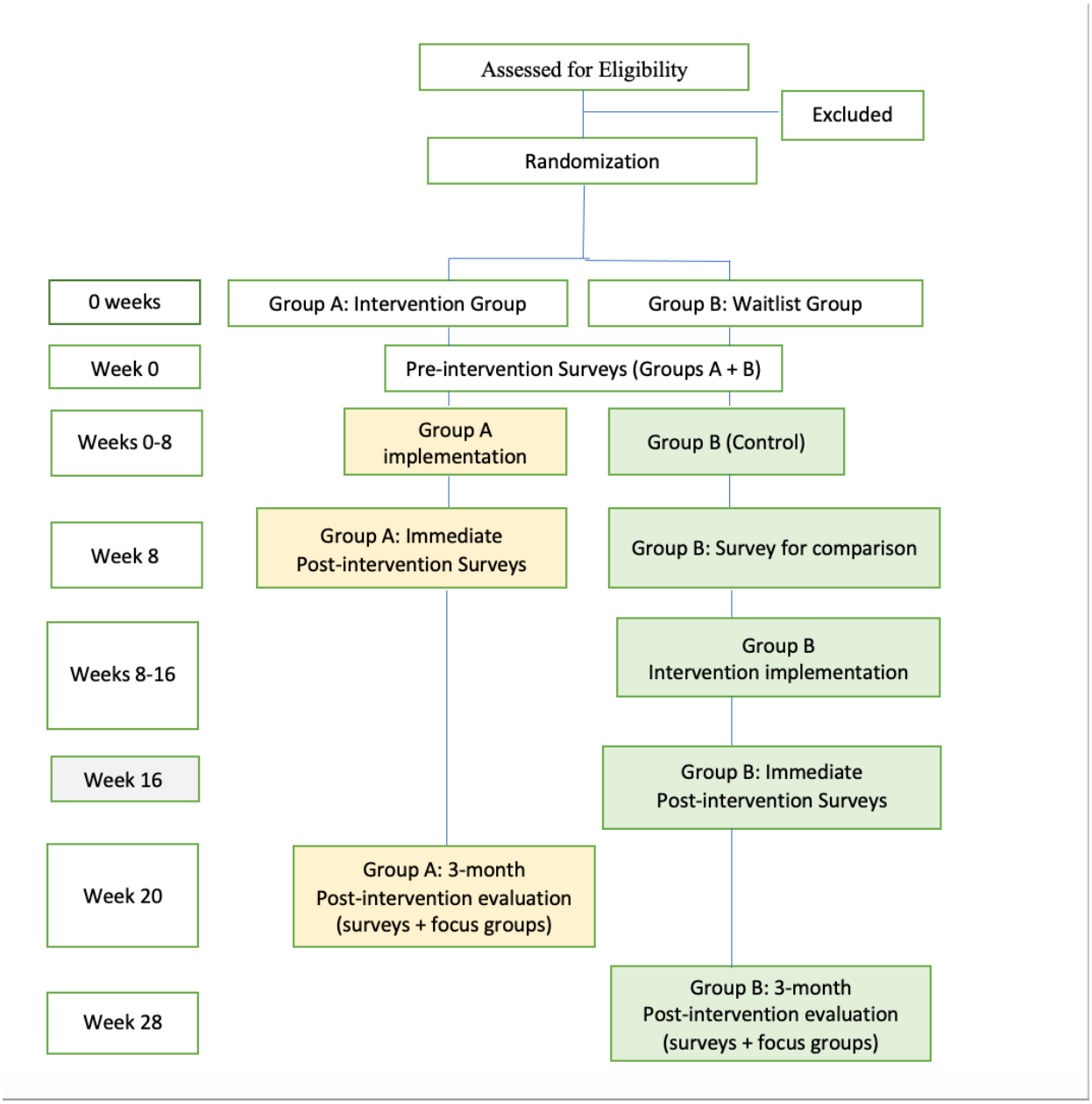


Table 1: Self-compassion, Mindful Acceptance & Resilience Transformation (SMART) Intervention

Self-compassion, Mindful Acceptance & Resilience Transformation (SMART) Intervention

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The SMART Intervention was developed based on concepts and processes in the Acceptance and Commitment to Empowerment (ACE) Model. Based on acceptance and commitment therapy (ACT) and social justice–based group empowerment psychoeducation (GEP), the ACE model aims to enhance psychological resilience and collective empowerment.

At the psychological levels, the processes include: defusion, acceptance, being present, self-as-context, values and committed action. At the collective empowerment level, they include principles/values of social justice, equity, interdependence, compassion, collective empowerment, and process of critical reflection, dialogue, and collaborative learning.

[Reference on ACE model: [33] Fung, K., Cheng, S., Ning, X., Li A., Zhang, J., Liu, J.J.W., … & Wong, J.P. (2021). Mental Health Promotion and Stigma Reduction Among University Students Using the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM) Framework: Protocol for a Mixed Methods Study. *JMIR Research Protocols*, 10(8), e25592, https://www.researchprotocols.org/2021/8/e25592]

Pre-Online Group Sessions

- Two weeks prior to the first session, participants will provide consent and complete a pre-intervention survey. Then participants will receive a list of community resources on mental health relevant to MENA youth, and links to two short videos on Mental Health 101. Each weekly group session is 2.5 hours. Audio recording of guided mindfulness practice will be provided to all participants. They are invited to practice and journal their insights between sessions.

Session 1 - Introduction: Mindfulness and mental health

In this session, participants will:

- be introduced to the SMART program
- identify personal and collective learning goals
- learn about what mindfulness is and how it promotes mental health
- engage in a guided practice -- *Mindfulness Practice: Awareness of breath*
- be engaged in a debriefing of experience, summary and closure

Session 2 - Identities: Who am I?

In this session, participants will:

- share their perspectives on the relationship between social identities, self-concept, and mental health
- learn about the psychological and structural determinants of self-concept and mental health
- engage in a guided practice -- *Mindfulness Practice: Awareness of bodily sensations*
- be engaged in a debriefing of experience, summary and closure

Session 3 – "I have to…": Relating to thoughts

In this session, participants will:

- explore the power of thoughts and how internal struggles affect mental health
- learn defusion techniques/strategies

• engage in a guided practice -- *Mindfulness Practice: Clouds in the sky* • debriefing of experience, summary and closure
Session 4 - Stories and Rules: Power Relations and Mental Health In this session, participants will: • share their perspectives/experiences on how stories and rules operate in their everyday life • learn about the impact of stories and rules on power relations and mental health • learn acceptance techniques/strategies • engage in a guided practice -- *Mindfulness Practice: Loving-Kindness* • be engaged in a debriefing of experience, summary and closure
Session 5 - Beyond Identity: Self-as-context • share the recollection of three moments in the past • explore and distinguish between self-as-content and self-as-context • engage in a guided practice -- *Mindfulness Practice: Being the Observer Self* • be engaged in a debriefing of experience, summary and closure
Session 6 - Interbeing: Three things I did • share three ordinary action / behaviours • explore the web of relationships in an ordinary action • engage in a guided practice -- *Mindfulness Practice: Gratitude and interconnection* • be engaged in a debriefing of experience, summary and closure
Session 7- Value and Choice: Committed action • engage in writing a love letter • learn about value guided committed action as a choice • engage in a guided practice -- *Mindfulness Practice: Value Guided Commitment* • be engaged in a debriefing of experience, summary and closure
Session 8 - Collective practice: Compassion and Resilience • collective sharing / recollection of SMART • reflect on processes and concepts • engage in a guided practice -- *Mindfulness Practice: Compassion and Resilience* • be engaged in a debriefing of experience, summary and closure

2.2 Primary Objective(s)

1. Determine feasibility and acceptability of SMART intervention
2. Assess the impact of SMART intervention on HIV-risk acts or practices.

2.3 Secondary Objective(s)

1. Assess the impact of SMART intervention on mental health
2. Assess the impact of SMART intervention on self compassion

2.4 Exploratory Objectives(s)

1. Assess the impact of SMART intervention on HIV literacy.
2. Assess the impact of SMART intervention on mindfulness.
3. Assess the impact of SMART intervention on resilience.

HYPOTHESIS We hypothesize that participants in the proposed mindfulness-based group intervention with integrated culturally-relevant, GBT affirmative practice will have increased safer sex practices and improved mental health compared to participants in the waitlist control group and that the intervention will be feasible to implement and acceptable to potential participants.

3 SELECTION AND ENROLLMENT OF PARTICIPANTS

3.1 Number of Participants

N = 40 (20 intervention group and 20 waitlist control group).

3.2 Inclusion Criteria

- 21-29 years AND gay, cis bisexual, or trans youth;
- self-identified MENA (Arab and West Asian);
- minimal or no prior experience with mindfulness-based interventions;
- able to speak and read English;
- have internet access; and
- able to take part in the 8-week intervention (able to attend at least 70% of the sessions or a minimum of 5 sessions).

3.3 Exclusion Criteria

- current enrollment in a mental health intervention;
- enrollment in intensive mental health treatment within the past year; or
- self-reported HIV-positive status.

3.4 Enrollment Procedures

The study will be advertised via social media and through peer support, clinical, and advocacy groups for LGBTQIA+ young people, including our project partners. Potential participants will contact the research team via a weblink on the recruitment material. Informed consent to participate will be completed online and consent forms for MENA youth recruited from Ottawa/Gatineau will be translated into French. Screening questionnaires will be completed over the phone before acceptance into the study. Consenting participants will then be contacted by telephone by the research assistant to screen for eligibility, including ensuring the individual is providing informed consent, is able to attend at least 70% of the sessions, and to screen for current enrollment in a mental health intervention; enrollment in intensive mental health treatment within the past year; or self-reported HIV-positive status. After eligibility is met for the program, we will wait until we have a sufficient sample size to randomize for the first wave of

intervention (10 per condition). Once this is reached, participants will be asked to complete the baseline assessment measures online a week before commencing the program.

3.5 Co-enrollment guidelines

Participants are allowed to be part of other studies as long as they are not part of a similar intervention or study with similar outcomes or objectives.

3.6 Strategies for Recruitment

Participants will be recruited through our community partners and through a snowball sampling technique, and randomly assigned to either the intervention or waitlist control group. The intervention group will receive an 8-week intervention with integrated GBT affirmative approaches. The study will be advertised via social media platforms, through our community partner organizations, peer support networks, MENA networks, AIDS Service Organizations, and advocacy groups for LGBTQ+ MENA young people. To capture the diversity among MENA youth, every effort will be made to recruit MENA youth who meet the eligibility criteria from Ottawa/Gatineau with the help of our community partner, AIDS Committee of Ottawa, and from the Greater Toronto Area (GTA), with the help of our knowledge users, Saleib, Abdullah and Ezzeddine who have access to a vast network of MENA gay, bisexual and trans youth across Ontario. Moreover, our partner organization, the Canadian Arab Institute, will help with MENA youth recruitment from the Greater Toronto Area and from across Ontario through their youth Café Yalla Let's Talk.

We will also hire MENA peers as community outreach workers to help with recruitment. Even though we will recruit participants mostly from Ottawa/Gatineau and the GTA, in the areas mostly served by our partner organizations, any MENA youth who live in Ontario and meet the eligibility criteria will be welcome. Potential participants will contact the research team via a weblink on the recruitment material. Informed consent to participate will be completed online, and consent forms for MENA youth recruited from Ottawa/Gatineau will be translated into French.

4 WITHDRAWAL OF PARTICIPANTS

4.1 Withdrawal criteria

Since we are running a group intervention, it may be necessary to replace individuals. For instance, we may withdraw a participant if it is in the participant's best interest according to the Investigator's judgment. Poor attendance (i.e., less than 70% attendance or less than 5 sessions) is one reason. Also, poor mental health that might interfere with the group dynamics would also another reason to ask a participant to withdraw.

5 RANDOMIZATION

After eligibility is met for the program, we will wait until we have a sufficient sample size to randomize for the first wave of intervention (10 per condition). Once this is reached, participants will be asked to complete the baseline assessment measures online a week before commencing the program. Eligible participants will be randomised to receive SMART intervention or waitlist in a ratio of 1:1. Randomization and allocation will be done via the online questionnaire software Qualtrics. Researchers, participants, and facilitators will not be blind to condition allocation, however, the researcher completing the analysis will be blind. For each wave, participants in both conditions will be asked to complete forms at 8 weeks (i.e. after the intervention), and at 16 weeks post-baseline (follow-up 1). Following the first follow-up, waitlist participants will receive the SMART intervention. ***See Table 2:*** **Schedule of Events*.*** Participants will be offered an honorarium of $25 for attending each intervention session and for completing each assessment survey starting at baseline**.** Participants will be also offered $50 each for taking part in a focus group discussion session. ***See Fig. 1.***

6 RISKS AND PRECAUTIONS

The overall purpose of this pilot study is to assess the feasibility of conducting a large study to investigate the benefit of a mindfulness-based intervention to reduce HIV risk and optimize well-being and resilience. Our results will be important for planning a future randomized clinical trial, including estimating effect sizes for sample size calculations, identifying and addressing potential challenges to recruitment and implementation, and refining the intervention to ensure cultural relevance. A larger RCT study would contribute additional information within this context and the generalization of findings will benefit MENA youth groups and other racialized gay, bisexual and trans youth in Ontario and across Canada.

One limitation that needs to be recognized in this proposed pilot study is that using the current waitlist design may result in recall biases in the control group who will do the survey twice before starting the program. Also, having English language proficiency as part of inclusion criteria can be a limitation to this proposed pilot intervention since some Middle Eastern youth are newcomers and would be more comfortable with Arabic or Farsi. Moreover, diaspora youth from the North African region living in Ottawa/Gatineau may be more comfortable with French as opposed to Arabic or English.

Due to limited funds and resources available for this funding opportunity, translating intervention materials and assessment measures into Arabic, Farsi, and French and transcribing them in English is not a viable option. Realizing that inclusion criteria may have excluded newcomers and refugee MENA youth who are at an increased HIV vulnerability and who would have benefitted from the study, we plan to extend the inclusion criteria in the future large RCT to include participants who are not proficient in English. Finally, there might be some challenges in running the intervention with mixed groups of gay, bisexual and trans youth due to their varying sexual health needs. However, benefits of offering the pilot intervention to all vulnerable key populations outweighs the challenges. This can be addressed upfront with co-facilitators to create an awareness.

What are the risks and harms of participating in this study?

There might be some challenges in running the intervention with mixed groups of gay, bisexual and trans youth due to their varying health needs. However, benefits of offering the pilot intervention to all vulnerable key populations outweighs the challenges. This can be addressed upfront with co-facilitators and participants to create an understanding and an awareness among group members.

6.1 Mental Health and Other Support

Resources

Some of the questions we are asking include personal and intimate details about your sexual health and sexual practices, which may make you uncomfortable. We recognize that some questions may trigger a particularly distressing experience; as such, you may choose not to answer particular questions and stop the study at any time. To help address some of this potential risk we are providing you with information and resources below about mental health services as well as sexual and reproductive health services available in Ontario.

A list of mental health resources will be provided to participants. Here is a script for what the participants will receive:

If you need to speak to someone about your sexual health, please contact Action Canada for Sexual Health & Rights - Call the access line at 1-888-642-2725. The Access Line is a 7-day-a-week toll-free, confidential phone and text line. It is available for questions about sexual health, pregnancy options, abortion, and safer sex. You can access more resources through https://www.actioncanadashr.org/resources, or chat with sexualhealthontario.ca live for answers to your sexual health questions, information and assistance https://sexualhealthontario.ca/en/chat.

If you need to speak to someone immediately about mental health, please contact Canada's Trans Life Line (call 877-330-6366), Crisis Services Canada (call 1-833-456-4566 or text 45645), or Kids Help Phone (call 1-800-668-6868 or text CONNECT to 686868).

6.2 Risk Management

1. Surveillance by CTN's Data Safety Monitoring Committee will help address risk management.

2. Risk minimization, management, and assessment procedures have been implemented in the study to minimize and assess potential risks to participants who participate in this intervention study. Participants who may show indications of poor mental health during the study will be asked to withdraw from the intervention. The research team will follow these steps to ensure participant

safety: a) identify a safety person with the participant and encourage contact (via the individual or researcher), b) the young adult will be provided with contact details of support services (including nearby emergency departments). The research team will request permission to follow up with the young adult via phoneor email within 72 h to determine if they need additional support.

7 STUDY PROCEDURES

7.1 Schedule of Events

Table 1: Schedule of Events

	Socio-Demographic & Health Related Questions (S&H)	*Feasibility & Acceptability (FIM & AIM)*	*HIV-Risk Acts or Practices (*number of condomless anal and vaginal sex acts). Measure: S&H	*Depression, Anxiety and Stress (DASS-21)*	*Self Compassion (SCS-SF)*	*Mindfulness (CAMS-R)*	*HIV Literacy* (sexual decision-making, condom use, PrEP, PEP, HIV testing). Measure: S&H	*Resilience AMR-R*
Timepoint								
0 months[1]	*SMART, WAIT*		*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*
Week 8[2]	*SMART, WAIT*	*SMART*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*	*SMART, WAIT*
Week 16[3]	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*
Week 20[4]	*SMART*	*SMART*	*SMART*	*SMART*	*SMART*	*SMART*	*SMART*	*SMART*
Week 28[5]	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*	*WAIT*

[1] Pre-Intervention surveys (S&H + scales) for SMART (active group) and WAIT (delayed waitlist group)
[2] Immediate post-intervention surveys (S&H + scales) for SMART and pre-intervention surveys for WAIT for comparison
[3] Immediate post-intervention surveys (S&H + scales) for WAIT
[4] 3-month post-intervention evaluation for SMART (S&H + scales) + focus groups
[5] 3-month post-intervention evaluation for WAIT (S&H + scales) + focus groups

7.2 Re-contact of Participants after Study Termination

Participants who may not continue with the intervention, may be re-contacted by members of the research team to ask about reasons for attrition. Permission for re-contact will be requested at time of informed consent.

8 STATISTICAL CONSIDERATIONS

8.1 General Study Design

Our general approach will use multilevel generalized linear mixed-effects models (GLMM), with the link function determined by the type of outcome measure (count, binomial, or continuous). Models will include fixed effects for treatment and random intercepts at the individual and group levels; we will also examine for interaction effects between treatment and time in 8-week models.

8.2 Sample Size Considerations/Justification

The choice of statistical analysis plan and associated sample size calculation for evaluating efficacy depend on a number of factors. These include parameter estimates for outcomes in the treatment and control groups, ICC, standard deviation for continuous outcomes, and characteristics of overdispersion for count and binomial outcomes. Our study is a pilot study to aid in planning the full trial, and we plan to recruit 40 patients to inform these choices. Based on previous studies among young adult gay and bisexual men[12], we anticipate our sample size will allow us to estimate outcomes among the treatment and control groups with standard error ~1.5. The use of a GLMM will allow us to estimate the parameters necessary for ICC and overdispersion and will help inform the choice of a statistical modelling plan for the full trial.

Length of time required to complete the enrollment of participants.
Approximately 4 months.

8.3 Data Sets to be Analyzed

The evaluable data set will include all available data from participants who follow the protocol without significant deviation. Criteria for evaluation will be listed in detail in the statistical analysis plan.

8.4 Endpoints/Outcome Measures

All quantitative outcome measures will be administered online, via Qualtrics.

Primary Outcome Measures:

- **HIV-risk acts or practices.** This count outcome is the number of condomless anal and vaginal sex acts in the preceding 8 weeks (in the absence of either PrEP or known undetectable viral load of HIV+ primary partners)

- ***Co-Primary Outcomes: Feasibility and Acceptability (quantitative measures)***
  The first co-primary outcome is feasibility at post-intervention as measured by the Feasibility Intervention Measures (FIM) scale [36]. FIM is a self-report scale with 4 items that measures the implementation outcome in regards to the feasibility of the intervention.

- The second co-primary outcome is acceptability at post-intervention as measured by the Acceptability Intervention Measures (AIM) scale [36]. AIM is a self-report scale with 4 items that that measures the implementation outcome in regards to the acceptability of the intervention.

Also, **feasibility and acceptability** of the intervention will be **assessed qualitatively** using **focus group discussions** to gain a more in-depth understanding and to help triangulate results. Focus group discussions will be audio recorded and transcribed to ensure reliability and rigour in the data analysis. Participants will be randomly selected to complete a videoconference interview with a researcher to discuss their experience of participating in the training program. We will ask about **benefits and drawbacks of videoconferencing** as a means of intervention delivery, as well as their experiences of self-compassion training and other **aspects of intervention feasibility and acceptability.**

Facilitators will be asked similar questions on their experience of delivering the program and their views on the acceptability of the videoconferencing format of the intervention. In total, 20 participants will be interviewed, or as many as needed to reach thematic saturation.

Secondary Outcome Measures:

- **Depression, anxiety and stress.** The Depression, Anxiety and Stress Scale (DASS-21), a set of three self-reports cales (21 items) designed to measure the emotional statesof depression, anxiety, and stress [37]

- **Self-compassion**. Measured using the Short Form of the Self Compassion Scale (SCS-SF); 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification [38]

Exploratory Outcome Measures

- **HIV literacy.** HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP, PEP, HIV testing, community resources)[39]

- **Mindfulness.** Cognitive and Affective Mindfulness Scale– Revised (CAMS-R), a 12-item measure designed tocapture a broad conceptualization of mindfulness not specific to any particular type of meditation training [40]

- **Resilience.** The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social-ecological resilience and is used by researchers and practitioners worldwide [41,42] . These scales have shown good psychometric properties including internal consistency, test-retest reliability, and validity [36-41]

See table 2 for a schedule of events and assessments.

8.5 Analysis of Demographic and Baseline Data

Descriptive statistics will be used to summarize participants' socio-demographics, self-reported health characteristics, and practices. **Important to note:**

8.6 Analysis of Primary Outcome Measures

Our analysis will focus on the difference in the **primary outcome** (number of condomless anal and vaginal sex in the preceding 8 weeks, comparing baseline and post-intervention [8 week] outcomes) using random effects repeated measures Poisson analysis.

Also, for primary analyses, we will assess **feasibility and acceptability** of the intervention. Measures include: FIM and AIM scales [43, 44]

Co-Primary Outcomes: Feasibility and Acceptability (quantitative measures). The first co-primary outcome is feasibility at post-intervention as measured by the Feasibility Intervention Measures (FIM) scale. [36] FIM is a self-report scale with 4 items that measures the implementation outcome in regards to the feasibility of the intervention. Participants with an average FIM score ≥ 4.0 will be considered as "feasible". Participants with an average FIM < 4.0 or those who did not respond to the FIM will be considered as "not feasible".

The second co-primary outcome is acceptability at post-intervention as measured by the Acceptability Intervention Measures (AIM) scale [36]. AIM is a self-report scale with 4 items that that measures the implementation outcome in regards to the acceptability of the intervention. Participants with an average AIM score ≥ 4.0 will be considered as "acceptable". Participants with an average FIM < 4.0 or those who did not respond to the FIM will be considered as "not acceptable". Both FIM and AIM Scales will be administered post-intervention only for both SMART intervention groups and waitlist control.

Other measures for feasibility and acceptability include:

- Consent rate
- Duration for recruitment

- Recruitment rate (% participants recruited)
- Retention/success rate/completion rate (completion of intervention sessions).
- Attendance/study attrition (able to attend at least 70% of the sessions).

8.7 Analysis of Secondary Outcome Measures

In secondary analyses, we will evaluate the following:

1) ***Number of unprotected sex acts*** over 8 weeks- using repeated measures analyses (baseline and 8 weeks).

2) ***Depression, anxiety and stress.*** Proportion of participants at risk for anxiety, depression, and stress over time using the DASS-21 outcome-specific subscales that assess anxiety, depression, and stress (individuals who score at a moderate severity level or above for anxiety, depression, and stress will be considered at risk. The cutoffs for a moderate severity level will be set at 9 for anxiety, 13 for depression, and 18 for stress); 3) self-compassion.

   Scoring Sheet: https://maic.qld.gov.au/wp-content/uploads/2016/07/DASS-21.pdf.
   See attached scoring instructions for more details

3) ***Self-compassion****.* Measured using the Short Form of the Self Compassion Scale (SCS-SF); 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification. The total score is an overall indication of self-compassion, with a higher score indicating more self-compassion. The total score is calculated by summing Self-Care and the inverse of the Self-Disparagement score. Therefore, high levels of Total Self Compassion are characterized by high Self-Care and low Self-Disparagement. “Average Scores” are also presented, which is the sum of all items divided by the number of items.

   Scoring Sheet: https://novopsych.com.au/wp-content/uploads/2021/11/SCS-SF-self-compassion-scale-blank-form-pdf.pdf
   See attached scoring instructions for more details

8.8 Analysis of Exploratory Outcome Measures

We will use a similar approach to analyzing exploratory outcomes, with the exception that we will not perform hypothesis testing.

1) ***HIV literacy.*** HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP, PEP, HIV testing, community resources). Mean scores, Likert scales. No standardized scales.

2) ***Mindfulness.*** Cognitive and Affective Mindfulness Scale– Revised (CAMS-R), a 12-item measure designed to capture a broad conceptualization of mindfulness not specific to any particular type of meditation training. Items are rated on a 4-point Likert scale from 1 (rarely/not at all) to 4 (almost always). Items 2, 6, and 7 are reverse-scored. After appropriate reversals, sum values for items 1 - 12. Higher values reflect greater mindful qualities.

Scoring sheet:
https://ggsc.berkeley.edu/images/uploads/The_Cognitive_and_Affective_Mindfulness_Scale_–_Revised.pdf
See attached scoring instructions for more details

3) ***Resilience.*** The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social-ecological resilience and is used by researchers and practitioners worldwide. Each of the measures is offered in a 3- or 5-point response scale. The 3-point version is scored using options of 'No', 'Sometimes', and 'Yes', while the 5-point version goes includes 'Not at all', 'A little', 'Somewhat', 'Quite a bit', and 'A lot'. The 5-point scale can provide a richer account of variability in responses to the items, but the 3-point scale may be preferable for individuals with comprehension difficulties or in settings where the administration of quantitative measures is not common.

5-point scoring sheet:
https://cyfar.org/sites/default/files/InstrumentFiles/Resilience_Adult.pdf
See attached scoring instructions for more details

Qualitative data analysis

As indicated earlier, **feasibility and acceptability** of the intervention will be **assessed qualitatively** using **focus group discussions** to gain a more in-depth understanding and to help triangulate results. We will use a computer software program (NVivo) to aid in data management.

For data analysis, the team will construct a list of thematic categories based on the research questions. In addition, we will use both inductive and deductive thinking to manually look for broad categories and interpretations that are indigenous (articulated by the participants) and sensitizing (drawn from pre-existing theories and questions) in the transcripts[45].

We will begin with the development of a coding framework informed by questions from the evaluation plan and a systematic approach that involves: (1) familiarizing with the data; (2) generating initial codes; (3) developing a coding tree to guide the coding of transcripts; (4) identifying themes; (5) reviewing, defining and naming themes; 6) analyzing/interpreting the narratives and connecting them to the broader social context ; and (7) producing reports and relevant documents based on the results. These iterative processes will be used by project team members to ensure that **collective insights** are integrated into the data analysis and **consensus** will be reached in understanding the data. Based on a community engagement and capacity building model, data interpretation will involve all members of the research team, i.e., the investigators, the research trainees, and collaborators.

8.9 Planned Subgroup Analyses

Since our potential participants will be mostly Arabic or Farsi speaking, we will conduct Ethnicity analyses.

8.10 Interim Analysis

N/A

8.11 Other Analytical Issues / Considerations

Our analysis plan is to use a GLMM which does not require any specific imputation technique to handle missing data. Patients who do not return for follow-up will still be included with only their baseline measurements. Any factors associated missing outcomes will be adjusted for in the analysis to allow for informative missingness mechanisms. We will contact patients who dropped out of the study in order to document reasons for their withdrawal which will help inform the design of the full trial to alleviate these issues. 8-week outcomes must be measured prior to the implementation of the delayed treatment to maintain a fair comparison of the treatment and control groups.

9 STUDY ETHICAL CONSIDERATIONS

9.1 Ethical Conduct of the study

This study will be conducted in accordance with the applicable regulations of Unity health, St. Michael's Hospital, the Tri-Council Policy Statement Version 2 (TCPS2) and the principles in the Declaration of Helsinki.

9.2 Informed Consent

All participants will be given detailed oral and written information about the study. Consent forms describing in detail the study procedures and risks will be given to each participant and written documentation of informed consent is required prior to starting study procedures. Participants must sign an informed consent document that **has been approved by a St. Michael's, Unity Health, REB prior to any procedures being done specifically for the study**. Each participant should have sufficient opportunity to discuss the study, have all of their questions addressed and consider the information in the consent process prior to agreeing to participate. Participants may withdraw consent at any time during the course of the study without prejudice. The informed consent form will be signed and dated by the participant andthe investigator. *See Appendix for Letter of Information and consent.*

Confidentiality

See Appendix for Letter of Information and consent, including confidentiality. See script below.

All data collected will remain confidential and accessible only to the investigators of this study. Surveys will be saved on a personal computer and backed up on a hard drive. The hard drive used for the backup will also be encrypted for security. The password-protected computer is

kept in a locked office. The data will be stored on a secure server at Brescia University College and retained for a minimum of 7 years. Your data may be retained indefinitely and could be used for future research purposes (e.g., to answer a new research question).

We will not share information about you to individuals outside of the research team. The information collected will be kept private and nothing you share during the weekly mindfulness sessions will be attributed to you by name. Since this study involves group activities and discussions, confidentiality can only be kept when all of us agree to keep everything that is shared confidential. This means respecting people's privacy. We ask that you do not share or disclose any information you learn about others during the mindfulness sessions with anyone outside of the study. The original signed informed consent form will be retained in the participant's study files and a copy will be provided to the participant.

By consenting to participate in this study, you agree that your data can be used beyond the purposes of this present study by either the current or other researchers. Electronic files will be securely destroyed after this time. To ensure confidentiality, any information identifier (email address) will be stored separately from the collected data. The research findings may be shared with academics and practitioners in the field. There will be no identifying information for participants in any reports or venues used for knowledge transfer.

Upon request, and in the presence of the investigator or his/her representative, participant records will be made available to the study sponsor, monitoring groups representative of the study sponsor, representatives of funding groups, and applicable regulatory agencies for the purpose of verification of intervention study procedures and/or data, as is permissible by local regulations.

9.3 Institutional Review Board, Ethics Committee, or Research Ethics Board

An application for ethics approval was submitted to the REB at St. Mike's Hospital. The REB will review all appropriate study documentation to safeguard the rights, safety, and well-being of the participants. Participants will be completing all assessments online and intervention modules are delivered virtually the group via Zoom. A copy of the protocol (including protocol amendments), all versions of informed consent forms, other information to be completed by participants such as survey instruments or questionnaires, and any proposed advertising/ recruitment materials will be reviewed and approved by St. Mike's REB prior to implementation of the study. The investigator will be responsible for obtaining REB/IRB approval of the annual Continuing Review throughout the duration of the study. The investigator will seek prior ethics approval for any protocol deviations except when the change intended to eliminate an immediate hazard to participants. In this case, the protocol deviation will be promptly reported.

10 General Study Conduct Considerations

10.1 Adherence to Protocol

10.1.1 Protocol Amendments

All protocol amendments will be reviewed and approved and if applicable submitted to the applicable regulatory agencies for prior approval or notification. The Investigator must sign and date the amendment prior to implementation. All protocol amendments must also be submitted to the ethics committee.

10.1.2 Protocol Deviations

No deviations from this protocol will be permitted without the prior written approval of the Sponsor, except when the modification is needed to eliminate an immediate hazard or hazards to participants. Any deviations that may affect a participant's informed consent, especially those increasing potential risks, must receive prior approval from the REB unless performed to remove an immediate safety risk to the participants. In this case it will be reported to the REB and the Sponsor immediately thereafter. Any departures from the protocol must be documented.

10.2 Monitoring & Auditing

10.2.1 Data Safety Monitoring Committee

CIHR/CTN has a data safety and monitoring committee.

10.2.2 Early Termination of the Study (N/A)

10.3 Record Keeping

10.3.1 Data Collection

See Table 2: Schedule of Events

10.3.2 Record Retention

10.4 Other Services (if applicable)

We will establish a gay, bisexual and trans **MENA youth advisory group** of 4 youth to ensure that the language used is appropriate for the target groups, and racial, sexual and gender affirmative principles as well as cultural values relevant to the MENA community in Ontario are incorporated.

11 Disclosure and Publication Policy

Our team will work together to come up with a publication policy. Since the study is community-based, we will practice an integrated knowledge translation whereby we involve our community partners in every step of the study. Our partners will be part of community forums, conference presentations and peer-reviewed journal articles

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APPENDICES

See Appendix for questionnaire and standardized scales used.

DATA SAFETY AND MONITORING COMMITTEE (DSMC)

The terms of reference (ToR) outline the DSMC's mandate and responsibilities. The ToR are reviewed and revised, as required.

1. OBJECTIVES

The objectives of the CIHR Canadian HIV Trials Network (CTN)'s DSMC include:

a. Making recommendations to the CTN National Directors about the need to modify or terminate clinical trials accepted by the CTN's Scientific Review Committee (SRC) and Steering Committee (SC); and
b. Reviewing preliminary analyses of CTN study results or new information and recommend changes in protocol, procedures and/or the termination of a study, as required.

2. MANDATE

The DSMC's mandate is:

a. To monitor the conduct and progress of all CTN clinical trials to determine if any trial should be modified or stopped and make recommendations to that effect to the SC;
b. To evaluate accumulating study data for treatment benefit or harm;
c. To recommend protocol changes;
d. To review and approve clinical trial design and methods insofar as these impinge upon the DSMC's functions;
e. To alert clinical trial leaders regarding emerging procedural or ethical issues; and
f. To monitor enrolment to assure that clinical trials proceed in a timely fashion.

3. REPORTING

The DSMC reports to the National Directors if recommending major changes to a trial. The chair transmits the DSMC's recommendations to the National Directors, and, if accepted, to the principal investigators. If the DSMC is recommending minor or no changes to a trial, such a recommendation will be made directly to the principal investigators.

a. If conflict arises between the DSMC, the SC, the principal investigator(s) or the sponsor(s) on any particular Committee recommendation, a meeting will be held to clarify the conflict and work towards consensus;
b. If the DSMC recommends the termination of a trial for reasons other than relative efficacy, the National Directors will be advised and a meeting between the principal investigators and the Committee will be arranged. This will help reduce the likelihood that the DSMC would issue a recommendation without being in possession of all the relevant information;

c. In the event of a split vote on the continuance of a trial, the DSMC will report the outcome to the National Directors and cite the arguments on either side, the National Directors may consult with the SC and determine the next steps;
d. The DSMC may call in consultants when these are deemed useful in helping the members to achieve an adequate understanding of the issues presented by particular clinical trials;
e. All members of the DSMC have full voting privileges;
f. Any member of the DSMC involved in a study as a treating clinician or co-investigator will be excused from DSMC monitoring data for that study. The DSMC may invite other clinicians on an ad hoc basis to replace those Committee members; and
g. Co-investigators who serve as methodologists or statisticians may, as DSMC members, participate fully in discussions, but are to exempt themselves from the deliberation phase of closed meetings if their conflict of interest would likely hinder the Committee's decision process.

4. PROCEDURES

a. The DSMC has a responsibility to review clinical trial protocols presented to the CTN to ensure that the design and methodology of a clinical trial will not hinder the Committee's ability to assess the relative safety and efficacy of the study treatments;
b. The DSMC's review of clinical trial protocols should be done early enough to ensure that its recommended protocol change(s), if any, will not delay or otherwise hinder the CTN's clinical trial evaluation process;
c. Prior to the initiation of a clinical trial, the DSMC will strive to meet with principal investigators, and when necessary with sponsors, to ensure that the DSMC members have a full understanding of the trial's goals and methods, and to ensure that the investigators and sponsors understand the DSMC's operating procedures;
d. The DSMC will aim for consensus on its recommendations, but will not insist on unanimity.

Modification or early termination of a trial:

The following considerations are deemed particularly pertinent to a recommendation for early termination of a trial:

a. A trial may be terminated early if accumulated data indicate that trial participants are being harmed by the treatment;
b. Continuation of a trial is justified only so long as there is no way to choose between the test and control treatments;
c. If accumulated data indicate, to the satisfaction of the DSMC, the superiority of one treatment over another, the trial should be stopped;
d. The costs of a trial are no longer justified once accumulated results allow a reliable discrimination between the treatments;
e. A trial that is no longer likely to produce additional useful information should be stopped;

f. A monitoring committee carries responsibilities not only towards patients currently participating in a trial, but also towards patients scheduled to enter the trial, and to future patients;

g. A monitoring committee may have to advise principal investigators and sponsors to modify a trial protocol, to terminate the trial ahead of schedule, to continue a clinical trial as planned, or even to extend a trial beyond the scheduled point of termination; and

h. A trial may have to be terminated because of excessively slow enrolment combined with the likelihood that enrollment targets will never be reached on time to allow a clinical meaningful completion of the study.

5. CONFIDENTIALITY

The DSMC's activities will require that members of the committee have access to pertinent information, e.g., research protocols, personnel information and other supporting documents. All such documents are confidential and will not be circulated outside the DSMC unless otherwise decided by the Committee. Failure to honour confidentiality is grounds for dismissal from the DSMC. Each Committee member signs and is bound by the CTN Confidentiality Agreement.

6. MEMBERSHIP

DSMC members possess the appropriate range of disciplines needed to assure that the Committee has sufficient expertise to deal with the complexities of the issues it will preside over. The membership should also enjoy sufficient stature among peers to maximize general acceptance of its reasoned judgments.

Members should be:

a. Free from conflicts of interest; and

b. Chosen in such a way as to assure a separation of persons responsible for patient care in the trial from persons responsible for safety and efficacy monitoring.

Committee Composition:

DSMC membership include persons who:

a. Are physicians with expertise in HIV disease, sexually transmitted blood-borne infections (STBBIs) and related health conditions;

b. Are experts on statistical and methodological aspects of HIV clinical trials;

c. Are skilled in identifying ethical and legal implications of clinical trials;

d. Along with one or another of the above areas of expertise, can, by their connection with the HIV-positive community, heighten the sensitivity of the Committee's membership to the experiences, concerns and priorities of those with HIV infection or disease (The Committee requires that one of its members represent the HIV-positive community); and

e. Understand and accept the general principles and procedures of the clinical trial process.

Appointments:

Members are appointed by the National Directors of the CTN at the recommendation of the existing DSMC.

Member Terms:

a. DSMC members will be appointed for five-year terms in alignment with the CTN grant renewal timelines;
b. Members may have their appointment extended beyond five years;
c. To ensure continuity, efforts are made to ensure that the majority of Committee members do not rotate at one time; and
d. Members are required to attend meetings. If a member misses three consecutive meetings without an explanation that is acceptable to the DSMC, the member will be asked to step down from the Committee.

7. GOVERNANCE

The DSMC Chair is appointed by the National Directors for a designated term not to exceed five years. The Chair may be reappointed for additional terms.

Responsibilities of the Chair:

a. Reviewing the agenda and minutes for each meeting;
b. Reporting to SC;
c. Participating in any review of the DSMC undertaken by the Network; and
d. Chairing meetings and delegating responsibilities.

Meeting Frequency:

a. The DSMC meets in person once a year and by teleconference at least once per year; and
b. The DSMC will meet at any other time, either in-person or via teleconference, when important issues arise, such as unexpected adverse events or the occurrence of new external data that could affect the continuance of a clinical trial as planned.

Quorum:

At least two thirds of its members, including the presence of at least two clinicians and at least one member representing the HIV-positive community constitute a quorum.

8. SUPPORT

The CTN provides the DSMC with the required financial and administratice support for its operations. The CTN will provide the following administrative support: meeting coordination/ travel bookings; minutes and other tasks that are required.

9. CONFLICT OF INTEREST GUIDELINES

Members of the DSMC are subject to the CTN Conflict of Interest Guidelines. Members with real or perceived conflicts must absent themselves from discussions of the CTN proposals/studies for which there is conflict.

SMART Program - Post-training Focus Group Interview Guide

1. Introduction:
   - Welcome participants; review purpose of focus group; answer questions (Post Names of SMART Sessions in Chat as a reminder of contents)

2. Explore participants' experiences in participating in the SMART training [These questions explore acceptability]
   - What was your overall experience like?
   - What did you like most about taking part in the SMART training? What did you like the least?
     - Probe – different learning approaches: experiential, group dialogue, mindfulness, self-practice materials, etc.
   - What did you find most useful? What did you find least useful
     - Probe – specific intervention activities and learning materials.

3. Since you completed the SMART training, how have you been able to apply what you learned in your everyday life? [These questions explore effectiveness]
   - In your personal life/personally
     - Probe – self-compassion, self-care, stress reduction, increased connection to community, stigma reduction
   - In your social networks - among peers, friends, family, co-workers, etc.
     - Probe –share stress reduction skills with peers or others, refer peers to community resources
   - In the community –
     - Probe – increased participation in community activities; address mental health and related issues, etc.

4. What are some barriers to participating in SMART?

5. What are some facilitators to participating in SMART? i.e., what worked for you?

6. How can the SMART training program be improved?
     - Probe—length, contents, approaches, day/time
     - Probe – how do you address facilitators and barriers to participate?

Invite participants for additional comments.

MASTER LINKING LOG – SMART Intervention Study

Participant Name	Email Address	Telephone Number	Unique ID