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

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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. • Assess the impact of SMART intervention on Resilience.
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 $50 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. 21-39 years old; 3. gay, cis bisexual, or trans/gender diverse 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>** 1) **HIV-risk acts or practices.** - This count outcome is the number of condomless anal and vaginal sex acts in thepreceding 8 weeks (in the absence of either PrEP or known undetectable viral load of HIV+ primary partners) - HIV Risk Index (HIRI) [19] 2) **Feasibility and acceptability** (quantitative measures). - Feasibility of Intervention Measure (FIM) - Acceptability of Intervention Measure (AIM). - Different measures (Consent rate; duration for recruitment; recruitment rate; retention/success rate/completion rate; attendance/study attrition)

	3) 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: 1) **Depression, anxiety and stress.** The Depression, Anxiety and Stress Scale (DASS-21), a set of three self-report scales (21 items) designed to measure the emotional states of depression, anxiety, and stress. 2) **Self-compassion**. Measured using the Short Form ofthe Self Compassion Scale (SCS-SF); A total of 6 subcomponents: self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification.
	Exploratory: 1) **HIV literacy.** HIV literacy (sexual decision-making, high risk conditions/behaviours, condom use, PrEP,PEP, HIV testing, community resources). Assessed only pre-and post-intervention. 2) **Mindfulness.** Cognitive and Affective MindfulnessScale– Revised (CAMS-R), a 12-item measure designed to capture a broad conceptualization of mindfulness not specific to any particular type of meditation training. 3) **Resilience.** The Adult Resilience Measure-Revised (ARM-R), a 17 item self-report measure of social- ecological resilience and is used by researchers andpractitioners worldwide.
Statistical Analysis	**DATA ANALYSES PLAN** • Randomize in clusters of 10. • Measure Inter cluster correlation (ICC). Evaluate thecorrelation of outcomes within treatment groups Our general approach will use multilevel generalized linear mixed-effect models, 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 cluster levels; we will also examine for interaction effects between treatment and time in 8-week models. **Quantitative Data Analyses** **Primary Analyses** 1) **Descriptive statistics** will be used to summarize participants'socio-demographics, self-reported health characteristics, and practices.

	2) 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.

	Quantitative Data Analyses cont'd **Primary Analyses** 3) HIRI is an HIV-risk screening tool to identify optimal candidates for PrEP use among men who have sex with men and trans/gender diverse youth. HIV risk measured by HIRI score. HIRI score of ≥ 10 indicates a higher chance of acquiring HIV. [19] Ref: Wilton J, Kain T, Fowler S, Hart TA, Grennan T, Maxwell J, Tan DH. Use of an HIV-risk screening tool to identify optimal candidates for PrEP scale-up among men who have sex with men in Toronto, Canada: disconnect between objective and subjective HIV risk. Journal of the International AIDS Society. 2016 Jan;19(1):20777. https://pmc.ncbi.nlm.nih.gov/articles/PMC4911732/ 4) **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. 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 < 4.0or 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. AIM is a self-report scale with 4 items 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.

5) Also, for primary analyses, we will **assess feasibility and acceptability of the intervention**. Measures include:
   - Consent rate
   - Duration for recruitment
   - Recruitment rate (% participants recruited)
   - Retention/success rate/completion rate (completion ofintervention sessions).
   - Attendance/study attrition (able to attend at least 70%of the sessions).

Secondary Analyses

In secondary analyses, we will evaluate the following:

1) ***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

2) ***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 andlow Self-Disparagement. "Average Scores" are also presented, which is the sum of all items divided by the number of items. For scoring,
   see **Scoring Sheet.**

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 MindfulnessScale– 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 the3-point scale may be preferable for individuals with comprehension difficulties or in settings where the administration of quantitative measures is not common. ***For scoring, see ARM-R*** User Manual https://resilienceresearch.org/wp-content/uploads/2022/03/CYRM-ARM-user-manual-V2.5.pdf **<u>Qualitative Data Analyses</u>** 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 randomized 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

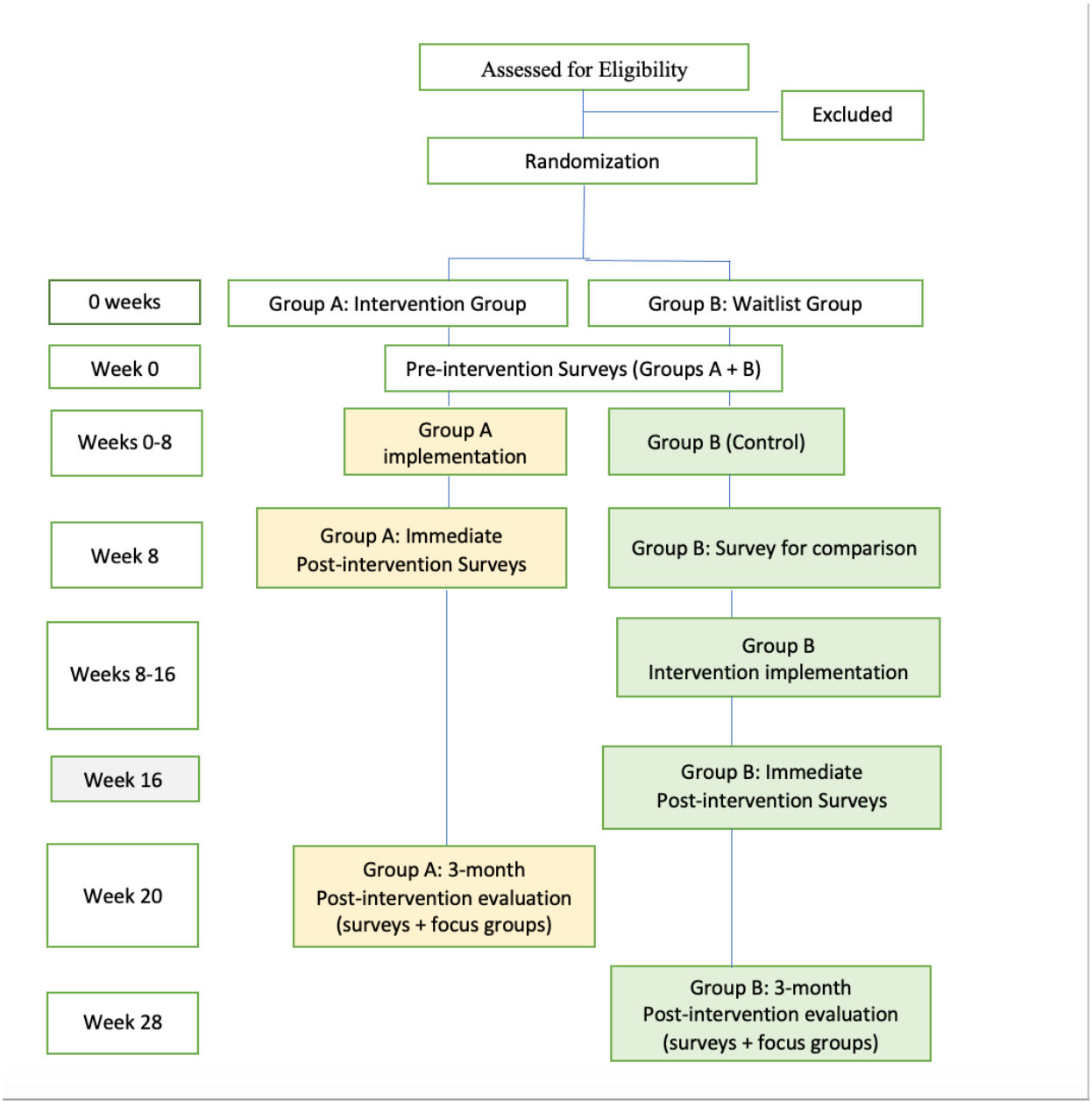


Table 1: Self-compassion, Mindful Acceptance & Resilience Transformation (SMART) Intervention

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 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

- 21-39 years AND gay, cis bisexual, or trans/gender diverse 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; or
- enrollment in intensive mental health treatment within the past year

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 randomized 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 $50 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).

- **HIV Risk.** HIRI is an HIV-risk screening tool to identify optimal candidates for PrEP use among men who have sex with men and trans/gender diverse youth. HIV risk measured by HIRI score. HIRI score of ≥ 10 indicates a higher chance of acquiring HIV. [19]

Ref: Wilton J, Kain T, Fowler S, Hart TA, Grennan T, Maxwell J, Tan DH. Use of an HIV-risk screening tool to identify optimal candidates for PrEP scale-up among men who have sex with men in Toronto, Canada: disconnect between objective and subjective HIV risk. Journal of the International AIDS Society. 2016 Jan;19(1):20777. https://pmc.ncbi.nlm.nih.gov/articles/PMC4911732/

- **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 scales (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 to capture 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-reportedhealth 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, will assess **HIV risk measured by HIRI index or score. HIV Risk.** HIRI is an HIV-risk screening tool to identify optimal candidates for PrEP use among men who have sex with men and trans/gender diverse youth. HIV risk measured by HIRI score. HIRI score of ≥ 10 indicates a higher chance of acquiring HIV. [19]

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) ***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

2) ***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. For scoring, see Scoring Sheet.
   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.
For scoring, see ARM-R User Manual https://resilienceresearch.org/wp-content/uploads/2022/03/CYRM-ARM-user-manual-V2.5.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 and analyses by age group (21-25; 26-29; 30-39)

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.