K23 Aim 3 MBQR Study Protocol

Brown University School of Public Health

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1. SPECIFIC AIMS (5-year project; Aim 3 highlighted)

This K23 aims to develop an internet-delivered MBI to address minority stress and its negative HIV-related health consequences experienced by young men who have sex with men (YMSM). Specifically, we propose to adapt, refine, and pilot-test an evidence-based MBI, Mindfulness-based Stress Reduction (MBSR), to promote mental and sexual health and HIV testing engagement among distressed, high-risk YMSM. Aims 1-3 will support the subsequent production and evaluation of the adapted intervention. To maximize reach, scalability, and availability to a population that experience challenges seeking in-person counseling and health services, the intervention will also be adapted for internet-based delivery.

Aim 1. Adapt MBSR for distressed, high-risk YMSM using internet delivery, guided by the ADAPT-ITT model. We will conduct iterative phases of formative research including online-based focus groups with YMSM, solicitation of feedback from stakeholders, and revision of intervention protocols. This process will result in the first-draft of an internet-delivered, mindfulness-based intervention protocol for use with YMSM.

Aim 2. Refine intervention protocol by administering adapted materials to distressed, high-risk YMSM (*n*=18) through internet-based open pilot and gather feedback. Following integration of feedback, this process will result in a finalized protocol of an internet-delivered, mindfulness-based intervention protocol for YMSM.

Aim 3. Examine the feasibility and acceptability of the internet-delivered mindfulness-based intervention (iMBI), called “Mindfulness-based Queer Resilience (MBQR)”, for HIV prevention. We will enroll and randomize a sample of 60 distressed, high-risk YMSM into one of two groups: MBQR intervention (n=30) or active control condition (n=30). We will aim to over enroll YMSM of color (e.g., Black/Latinx YMSM) and anticipate the group to include **approximately 50-60% Black/Latinx YMSM (or YMSM of color)**. Primary outcomes are **HIV and STI testing** and self-reported sexual risk behaviors. Secondary outcomes are stress biomarker (fingernail cortisol levels), psychological health, minority stress and coping. The study will examine recruitment and retention, number of sessions attended, self-reported at-home practice of mindfulness, completion of assessment, and acceptability of the intervention.

2. Aim 3 Study Design Overview

The methodological approach includes a 2-arm trial of MBQR *vs. a health education* control group, with up to n=30 per arm (total Aim 3 sample size = up to 60 participants enrolled and randomized). The study is intended to evaluate the impacts of MBQR on the outcomes outlined in the Specific Aims above.

All research assessments will take place digitally using Qualtrics, LLC (Provo, UT, USA) survey management tool. Participants will be sent secure links via email and SMS that can be accessed with their participant identification number. The MBQR intervention classes will be offered online via Zoom by a trained and qualified mindfulness instructor.

Baseline assessment links will be sent to all enrolled participants and completed prior to the start of the interventions. Follow up assessments will be conducted at three time points (post-intervention, 6-months follow up, and at 1-year follow up (for intervention participants only)).

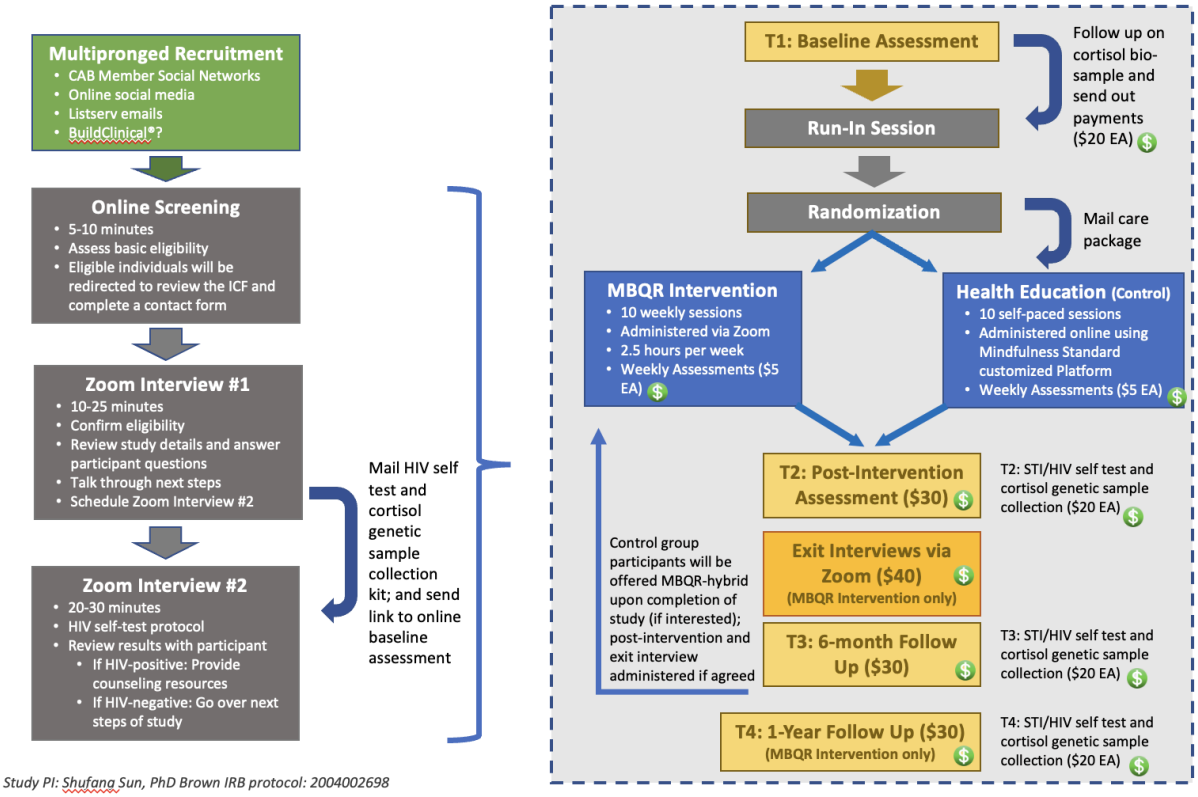
Participants who were randomized to the control group will be offered a MBQR-hybrid course after the 6-month follow-up assessment is complete. This additional course is optional. Control group members who opt to take MBQR-hybrid will be invited to complete a post-intervention assessment and exit interview. The total length of involvement for control group participants who opt not to take MBQR-hybrid will be around 6-months from the time of enrollment to the time of the final research assessment, while control group participants opting into the MBQR-hybrid will be done with participation in the study around 9-12 months after enrollment. Participants randomized to the MBQR intervention group will be invited to complete a 1-year follow up assessment in addition to the other assessments, thus their involvement in the study will last around 12 months from the time of enrollment. The study interventions last 10 weeks and take place in the first two months of study involvement.

The figure below provides a visual outline of the study flow, including the screening and assessment sequence.

BROWN School of Public Health
Mindfulness for Health Equity Lab

MINDFULNESS-BASED QUEER RESILIENCE

Study Flow Chart



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3. Selection Criteria for Aim 3:

The following is the most updated inclusion/exclusion criteria:

- Inclusion criteria:
  (1) assigned male at birth,
  (2) being 18 to 34 of age,
  (3) identify as a cisgender man or nonbinary,
  (4) reside in the United States,
  (5) can read and speak English,
  (6) engaged in condomless anal sex with another man in past 6 months,
  (7) endorse distress, measured by the PHQ-9 and GAD-7,
  (8) possess a devise (phone, tablet, computer) that allows for online conferencing.
  (9) HIV-negative at time of screening

- About HIV status: HIV status will be assessed in 2 steps: (1) by self-report in online survey and (2) by rapid HIV testing via Zoom with a trained study RA (optional; other options could include local testing or by self-report). We will provide rapid oral HIV testing in Aim 3. At screening, participants will participate in rapid oral HIV testing (optional), and at post-intervention and follow-up, participants will engage in both HIV and STI testing (see more in HIV/STI testing protocol).

- Exclusion criteria: YMSM will be excluded from the study if they are determined to have symptoms that would prevent them from giving meaningful consent or participate in study activities including any of the following criteria:
  (1) Significant cognitive impairment
  (2) Psychosis
  (3) Imminent suicidal risk

4. Steps in Recruitment, Screening, and Assessment:

Recruitment Timeline and Procedures

1) Timeline for recruitment:
   a. Recruitment efforts will commence 2-4 months prior to the start of each study intervention.
   b. Enrollment for each round will end on the date of the run-in session. Any individuals screened for the study after that date will be deferred to the next round (if applicable).
   c. All preparatory efforts to be ready at least 8 weeks prior to the RCT
   d. Participants will be recruited and enrolled into cohorts based on intervention scheduling. We anticipate enrolling around 8-10 participants

into each intervention and control group (e.g., we anticipate running two summer cohorts and one fall cohort).

2) Multi-Pronged Recruitment Strategy: Recruitment will be conducted primarily through four methods:
    a. Community Advisory Board (CAB) member social networks – IRB approved recruitment materials will be provided to CAB members to distribute to their social networks and for them to post on their social media accounts.
    b. Online social media (e.g., Facebook-based community groups for gay and bisexual men, Reddit threads, Twitter, etc.)
    c. Emails to University/College campus groups, Community-based Organizations, and partner health groups (e.g., the Fenway Institute in Boston)
    d. Targeted recruitment through BuildClinical® - see separate BuildClinical® recruitment proposal

Screening Procedures: Participants will be screened for eligibility in three steps.

1) Online Screening Form - First, individuals interested in the study, will be prompted to complete a brief (5-15 minute) internet-based screening form via Qualtrics to determine their initial eligibility. Individuals who screen eligible will then be redirected to a separate Qualtrics form where they can review the Informed Consent Form (ICF) and complete a contact form for follow-up.

2) Zoom Screening Interview #1: Trained research staff will then follow up with eligible participants to schedule a Zoom-based screening interview (the first of two). This interview will take 10-25 minutes to complete and will serve the following purposes: (a) Review the Informed Consent Form and study procedures; (b) Answer any questions the participant might have; (c) Confirm participant eligibility; and (d) Inform the participant (if eligible and interested) of the next steps, including scheduling the second Zoom screening interview. The study RA will then mail out a HIV self-testing kit to the participant along with testing instructions (see HIV/STI testing protocol).

3) Zoom Screening Interview #2: This second Zoom interview will take place 1-2 weeks after the initial Zoom call to allow for the HIV test to arrive in the mail. The participant will be encouraged to find a private location for the call where they will have access to a bathroom for HIV self-testing. The call will take 20-30 minutes and will involve having the participant complete a HIV self-test. The study RA will walk the participant through the testing procedures (or provide participant with a prerecorded instruction video).

    a. Staff performing Zoom calls will be trained in providing HIV-counseling in the event that the test result is HIV-positive.

b. If HIV-negative, the RA will go over the next study steps with the participant, including inviting the participant to complete baseline survey via Qualtrics.
c. If excluded, RA will record reason for exclusion.
d. Alternative HIV testing procedures include:
    i. Completing a self-test on one's own and sending a picture to our study Qualtrics link (or sharing results on Zoom)
    ii. Testing at a local HIV clinic
    iii. Opting out of HIV self-testing and instead self-report status

Informed Consent

Informed consent is an ongoing process. Participants will first be presented with the Informed Consent Form (ICF) at the time of initial online screening. They will have the option to download and save the ICF and will also be prompted to click through the ICF text in full (displayed on multiple screens in Qualtrics). The consent process will continue into the Zoom Interviews #1 and #2, where a trained research staff member will review the ICF with the participant and answer any questions they might have. A waiver of documentation of consent will be requested since data collection procedures all take place online.

Baseline Procedures, Enrollment, Run-In, and Randomization

1) Baseline Procedures:
    a. Eligible participants will be asked to complete a baseline survey via Qualtrics that is estimated to take 60-80 minutes to complete (see separate Assessment document for details).
    b. At baseline they will also be mailed a Cortisol genetic testing kit that will provide them with the necessary equipment to collect a baseline nail sample (see separate cortisol nail sampling protocol for details). Participants will then mail back the completed sample back to the study staff for further processing. Participants will be compensated $20 for each genetic sample provided.
    c. Following baseline survey completion, participants are considered as "enrolled and ready to be randomized".

2) Run-in Session: Prior to randomization participants will be asked to attend a mandatory 30-minute introduction session via Zoom that will serve as a 'run-in' session for individuals interested in the study. The purpose of this session will be to:
    a. Provide a brief overview of the randomization process and intervention arms. This includes an emphasis on the time commitment required for the interventions and for the study as a whole.
    b. Introduce the research team and the course interventionists.

c. Walk through the HIV/STI self testing and genetic cortisol sampling procedures; remind participants to mail in their samples / submit their results.
d. Answer any questions.
e. Allow participants an opportunity to opt out of the study (submitted privately by email, phone, text, etc.) prior to the randomization. Note that participants can withdraw at any time. The run-in session allows participants an additional opportunity to opt out prior to being included in the randomization. This helps with overall group balance and retention.
f. Participants who complete the baseline assessment and opt in to the study following the run-in session will be included in the randomization; they will be coded as "enrolled and randomized".

3) Randomization:
   a. Prior to intervention commencement, participants will be randomly assigned to one of two groups: (1) MBQR Intervention group; or (2) a health education control group.
   b. Control group participants who complete the study will be given the opportunity to participate in the intervention (MBQR-hybrid) after the 6-month follow up assessments are completed.
   c. A covariate adaptive randomization process will be used, balancing groups based on race (white vs. non-white); anxiety/depressive symptomology (high vs. moderate); and gender identity (cis-male vs. non-binary) if sample size allows for this.

4) Care Packages:
   a. Prior to the start of the interventions, all participants (intervention and control) will be sent a study care package, which will contain a yoga mat, condoms, lubricant, raisins, pen, journal, stickers, and a fidget spinner / stress ball, along with a brief description and purpose for each of the items.

<u>Weekly Assessments, Post-Intervention and Follow-up Procedures</u>

1) *Weekly Assessments:* During the 10-week intervention period, participants will be sent invites (via Qualtrics- individualized links) to complete weekly assessments designed to capture: (a) monitoring of sexual risk (condomless sex); (b) monitoring of depression (PHQ-9) and anxiety symptoms (GAD-7); and (c) self-report of weekly/daily practice time spent on intervention. Participants will be compensated $5 per each weekly assessment completed (up to $50 total).

2) *Post-Intervention Assessment:*
   a. Similar to the baseline survey, participants will be asked to complete a post-intervention assessment via Qualtrics. The assessment is estimated

to take 60 minutes to complete, and participants will be compensated $30 for their time.
   b. Cortisol genetic testing kits and STI/HIV self-tests will be mailed out to participants post-intervention. Participants will be compensated $20 for each completed test ($40 total).

3) *Exit Interviews (Intervention Group Only):*
   a. Semi-structured interviews with intervention group participants will be conducted one-on-one via Zoom post-intervention to gather qualitative feedback on the study intervention.
   b. Interviews are estimated to take 90-120 minutes.
   c. Participants will be compensated $40 for their time.

4) *6-month Follow Up Assessment:*
   a. Similar to the baseline and post-intervention surveys, participants will be asked to complete a 6-month follow up assessment via Qualtrics. The assessment is estimated to take 60 minutes to complete, and participants will be compensated $30 for their time.
   b. Cortisol genetic testing kits and STI/HIV self-tests will be mailed out to participants post-intervention. Participants will be compensated $20 for each completed test ($40 total).
   c. This will be the final assessment for control group participants. Following their study involvement, control group participants will be given the option to participate in a MBQR-hybrid program. This additional course is optional. Control group members who opt to take MBQR-hybrid will be invited to complete a post-intervention assessment and exit interview.

5) *1-year Follow Up Assessment (Intervention Group Only):*
   a. Intervention participants will be asked to complete a final 1-year follow up assessment via Qualtrics. The assessment is estimated to take 60 minutes to complete, and participants will be compensated $30 for their time.
   b. Cortisol genetic testing kits and STI/HIV self-tests will be mailed out to participants post-intervention. Participants will be compensated $20 for each completed test ($40 total).
   c. This will be the final assessment for intervention group participants.

5. MBQR Intervention and Health Education Control:

Mindfulness-Based Queer Resilience (MBQR):
MBQR is an online, Zoom-based mindfulness course that meets 2.5 hour per week for ten weeks, facilitated by queer mindfulness teachers, with weekly home practice and additional reflection and reading activities that can be completed by participants independently via study website portal.

MBQR is designed to alleviate the burden of minority stress and mental health and promote HIV testing and healthy sex behaviors among young adult gay men, bisexual men, queer men, and non-binary people assigned male at birth. Principles of MBQR include (a) reducing minority stress as a key theoretical guide, (b) affirming LGBTQ + identity and facilitating healthy identity development, (c) attending to intersectionality, (d) facilitating resilience and self-empowerment, (e) trauma sensitivity, and (f) promoting healthy relationships and a healthy community. Key techniques include through attention regulation to facilitate agency and self-awareness, enhancing emotion regulation, reducing reactivity to minority stress-informed thoughts, self-compassion to increase self-acceptance, and reducing behavioral avoidance. Formal and informal mindfulness practices will be offered, such as mindful walking, body scan, attention practice, self-compassion, etc. In addition to the 10 weekly sessions there is an all-day retreat (6hrs) that takes place around week 5. The participants also meet one-on-one with the instructor at the beginning and middle of class for a 30-minute welcome call and check in.

Health Education Active Control:

The online Health Education course, used as an active control in the RCT, is a self-paced program that can be largely completed independently (no group meeting, no all-day) by control group participants. The ten weekly modules are estimated to take 30 to 90 minutes each to complete and consist of readings, videos, infographics, and other related activities (e.g., reflections, quizzes).

The purpose of the health education course is to provide participants with general information on health, factors that affect health, and to promote health behaviors. Topics include sleep, exercise, healthy eating and body image, time management, alcohol and substance use, sexual health, school/work life balance, and healthy relationships. This information is provided without an emphasis on mindfulness.

Mindfulness-Based Queer Resilience (MBQR)-hybrid:

MBQR-hybrid is an online-based mindfulness course asynchronously facilitated by queer mindfulness teachers, with weekly home practice and additional reflection and reading activities that can be completed by participants independently via study website portal. Participants will also have the option of participating in weekly live 1-hour sessions. MBQR-hybrid is designed to be completed within a 3-months time frame (10 modules that can be paced to complete in a 10-14 weeks time frame).

6. Other Study Details:

Compensation

Participants will have the opportunity to earn up to $340 (intervention group) and up to $300 (control group) for their time and effort in this study. Participants will only be compensated for the study components that they choose to complete. Partial

compensation will not be provided. If a participant withdraws from the study early, they will not be compensated for the study components that are incomplete.

Below is an outline of the compensation structure by study element.

T1: Baseline ($40 Total)
$20 - HIV testing**
$20 - Cortisol nail sample

Intervention / Control ($50 Total)
$50 - $5 per assessment x 10

T2: Post-Intervention ($70 - 110 Total)
$20 - STI/HIV testing
$20 - Cortisol nail sample
$30 - Assessment
$40 - Exit Interview*

T3: 6-Month Follow Up ($70 Total)
$20 - STI/HIV testing
$20 - Cortisol nail sample
$30 - Assessment

T4: 1-year* Follow Up ($70 Total)
$20 - STI/HIV testing
$20 - Cortisol nail sample
$30 - Assessment

*MBQR Intervention Group Only; Control group will be invited to take part in a MBQR-hybrid course after their 6-month follow up is complete. This additional course is optional. Control group members who opt to take MBQR-hybrid will be invited to complete a post-intervention assessment and exit interview ($30 and $40 each).

**Compensation for HIV testing is not limited to the self-testing kit provided by the study.

Total Possible Compensation for Control Participants = $300
Total Possible Compensation for Intervention Participants = $340

Withdrawal during intervention
We anticipate some amount of dropout during the study. If a participant in MBQR decides to withdraw from the study during the course or if a control participant discontinues the health education training, they will still be invited to take part in the follow up assessments.

Confidentiality

Randomly generated participant identification (PID) numbers will be automatically generated and assigned through Qualtrics at screening. All questionnaires and tasks will be completed under the assigned participant identification numbers. Consent forms and personal identifiable information will be kept separate and securely away from participant identification numbers in a secure digital file on closed network servers (i.e., Brown Stronghold).

Safety Monitoring

Oversight of internal monitoring of the participants' safety will be conducted by the PI, Dr. Shufang Sun, who is a licensed psychologist.

Entities Conducting Monitoring: The Institutional Review Board (IRBs) at Brown University will review all research procedures and will provide oversight. Internal monitoring will be done by the Brown University principal investigator (Dr. Sun) and the Brown University IRB. Any serious adverse effects will be immediately reported to the principal investigator (Sun).

What is Monitored: Monitoring is done of all procedures to ensure that they conform to the approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in US Department of Health and Human Services regulations for the protection of human research subjects 45 CFR Part 46, and the FDA 312.32 (death, life-threatening experience, new or prolonged hospitalization, persistent or significant disability/incapacity); of other significant adverse events (adverse events that lead to drop out by participant or termination by the investigator); of unexpected adverse events resulting from the study; and of expected adverse events.

Monitoring is done of all study inclusion and exclusion criteria. During this clinical trial, we will notify officials, as mandated by law, if a participant reports intention to harm him/herself or others, or reports child abuse or abuse of an elder.

Frequency of Monitoring: All adverse events will be continuously monitored by the PI as they are documented by the study staff in accordance with the protocol. Participants will be given contact information so that they can inform us of events that occur in between study visits. The PI will meet with staff regularly as schedules allow to review participant progress and to check in about the experiences with the experimental procedures, including adverse events. Any adverse events that are observed and/or reported will be reported to Dr. Sun. The Investigator will be available to meet outside of the regularly scheduled meetings, if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol, or terminate the study. The Brown University IRB conducts the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of serious adverse events from the PI or anyone else.

Reporting Plan: Any serious adverse events that are observed and/or reported will be immediately reported to Dr. Sun. Unexpected serious adverse events related to the study are to be reported to the Brown University IRB. Brown University's IRB requires fatalities related to the study be reported within 24 hours. All serious adverse events related to this study will be reported to the Brown University IRB immediately by telephone and by written report within 48 hours of our receipt of information regarding the event.

Any actions taken by the IRB, other than acceptance of the adverse event report. Proposed changes or amendments to the protocol in general must be approved in writing by both the Brown University IRB.

Risks and Benefits

Possible Risks

Meditation-related risks: The National Center for Complimentary and Integrative Health (NCCIH) states that meditation is generally safe for healthy people, but that adverse effects have also been reported. [34] Undesirable side effects and risks of meditation have been documented in more than 40 scientific reports [for reviews see [35-37]] and are listed in the Mindfulness-Based Intervention Guidelines.[38,39] More common, less serious side effects that have been reported by individuals within the context of MBIs or of individuals who are meditating less than an hour per day include: increased depression, anxiety or panic, re-experiencing of traumatic memories, dissociation, executive dysfunction, headaches/body pain and insomnia.[35,40-45] A few case reports of more serious side effects including mania, psychosis, and suicidality have been reported, mostly in the contexts of intensive retreats (>5 hrs/day) or in conjunction with pre-existing psychopathology.[35,37,38,46] The frequency of serious adverse effects in the context of MBIs is estimated to be less than 1%, although adequate estimates are not available.[47]

A number of actions have been taken to minimize meditation-related risks at different stages of the study. During the pre-enrollment stage, individuals with severe mental illness that could preclude regular class attendance or impact group participation (i.e., symptomatic, untreated bipolar disorder or a history of psychosis and/or schizophrenia are excluded from the study and all risks are clearly communicated in the consent form. During treatment, meditations are relatively short and interspersed with dyads and reflections. Mindfulness homework assigned as part of the intervention is optional and is recommended to not exceed 1 hour per day. Teachers query participants about their experiences with meditation, and provide corrective feedback or modifications when needed. Developing strategies for working with physical and emotional discomfort is an explicit goal of the program. Because not all participants feel comfortable disclosing difficulties in class, an online "safety check-in" questionnaire will query meditation-related risks.

Psychological distress: Research subjects participating in this study may experience possible psychological distress caused by questions asked during the in-person and online questionnaires that bring up painful memories or feelings. However, the resulting potential for injury to research subjects is judged to be minimal. With regard to psychological distress from taking part in the MBQR intervention, given that screening questions will exclude participants with substantial mental illness, and given the NCCIH statement above that "Meditation is considered to be safe for healthy people."[48] we expect that risk of psychological distress will be

low. The risk of increased psychological distress from meditation will be clearly outlined in the consent form and participants will be encouraged to consult with both the course instructor and study staff in the case of any increased distress.

Loss of confidentiality: Likelihood: rare. Minimization: Confidentiality will be maintained by using deidentifying data sets. All electronic data files containing identifying information will be encrypted with a cloud-based software. Note that although these measures have been taken to protect participants' personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet. All information obtained from participants will be accessible only to research staff.

Possible Benefits

Possible direct benefits to participating students include, but are not limited to: development of a personal mindfulness meditation practice, increased awareness of their present experience, and practice identifying and attempting behavioral change. Possible benefits to the current body of science include, but are not limited to: the fine-tuning of a protocol for future mindfulness-based randomized controlled trials, influence on the next generation of researchers to have first-hand experience in mindfulness meditation, and increased knowledge about the potential impact of tailored mindfulness-based interventions, specifically those designed for YMSM.

Data Collection and Quality Assurance

Data Collection Forms

Questionnaire data will typically be collected using Qualtrics, LLC (Provo, UT, USA) survey instruments, so that participants can complete questionnaires on their own time within the defined assessment windows, using their computers or smart phones. Exceptions to this include the Zoom interviews and intervention course work.

Data Management

Data management will be performed by downloading data routinely during active data collection periods, and assessing data for missingness and errors. Data will be maintained in password-protected Microsoft Excel Spreadsheets, and then exported using .csv or SPSS functions for data analysis.

Quality Assurance

Provider Training: MBQR delivery will be performed by (a) qualified or certified MBSR instructor(s), or (b) PhD-level psychologists/licensed mental health professionals with more than 400+ clinical hours as well as extensive experience in working with LGBTQ+ populations and/or mindfulness[49]. MBQR instructor training involves a 20-30 hour intensive training that covers the principles of MBQR, specific teaching content, diversity-related issues, group dynamics, and inquiries. Training will take the format of presentations, group discussion, role-play, and feedback from PI and peers. Training will be delivered by PI Sun.

MBSR teacher certification is fairly extensive, and accreditation occurs through qualified schools / centers for mindfulness. Examples of criteria for becoming a certified MBSR teaching include (i) completion of an eight-week MBSR course as a participant, (ii) completion of several

multi-day residential training courses in mindfulness based stress reduction practice and teaching, (iii) substantial experience in teaching MBSR, (iv) strong references letters from colleagues and participants who have taken your MBSR courses, (v) completion of several multi-day mindfulness meditation retreats, (vi) have a graduate degree in a field connected to MBSR (e.g. education, psychology, medicine) or demonstration of equivalent understanding through work experience in a related field.

Delivery of treatment: We will assess participants' perceptions of provider warmth and credibility using brief measures based on the validated Working Alliance Inventory,[53] and Therapist Empathy Scale[54] at Weeks 4 and 8 of the intervention. Feedback will be provided to the interventionist.

Receipt of treatment and enactment of treatment skills: Adherence to the prescribed MBQR practices will be monitored through class attendance, practice logs and diaries. Adherence data will be collected weekly during the course of the intervention.

Fidelity Monitoring: Intervention fidelity will be ensured by (1) rigorous, program specific training for the instructor with feedback (2) recording of all sessions with a 10% quality audit reviewed with instructor after each cohort (3) monitoring participant attendance, home practice of treatment skills, and understanding of skills (see Feasibility) (4) a comprehensive mixed methods approach (e.g. practice logs) for understanding of treatment enactment. In assessing MBQR Instructor competency and treatment fidelity, a randomly selected 10% or more of the recorded sessions will be reviewed by trained research assistants and rated for proportion of adherence to the MBQR curriculum guide. Intervention integrity for MBQR will be assessed using the Mindfulness-Based Interventions-Teaching Assessment Criteria (MBC-TAC), which is the most respected quantitative approach world-wide for assessing mindfulness-based programs. In order for the MBQR intervention and its associated data to be included in the sample, the instructor needs to demonstrate 90% or greater curriculum adherence.

Protocol Deviations:
Protocol deviations will be reported to the Brown University IRB. A description of the deviations, and any effects on the protection of human subjects will be documented. Investigator(s) will review protocol deviations and determine on a case by case base which data (if any) will be excluded from the final data set.

Participant Rights and Confidentiality

Institutional Review Board

The protocol, the informed consent document, and any subsequent modifications, will be reviewed and approved by the Brown University IRB responsible for oversight of the study.

Informed Consent Documents

Prior to enrollment, all participants will be provided with an IRB-approved Informed Consent document. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. Informed consent is an ongoing process. Participants will first be presented with the Informed Consent Form (ICF) at the time of initial online screening. They will have the option to download and save the ICF and will also be prompted to click through the ICF text in full (displayed on multiple screens in Qualtrics). The consent process will continue into the Zoom Interviews #1 and #2, where a trained research staff member will review the ICF with the participant and answer any questions they might have.

A waiver of documentation of consent will be requested since data collection procedures all take place online.

Participant Confidentiality
The clinical data will be de-identified but linked. Private information such as name, contact information, and mailing address will be kept in a password protected, encrypted database on a different disk that the clinical data help by the Project Coordinator. All computer entry and networking programs will be done using PIDs only. The principal investigator will only be given access to identifiable personal information for the purposes of patient safety, data safety monitoring boards or HIPPA compliance officer approved agents. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB and the OHRP.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify participants in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless the participant has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if the participant has consented to the disclosure, including for their medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH. A Certificate of Confidentiality does not prevent participants from voluntarily releasing information about themselves or their involvement in the research. If they want their research information released to an insurer, medical care provider, or any other person not connected with the research, they must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of situations of child abuse and neglect, or harm to self or others.

Finally, Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, participant records may be examined. The reviewers will protect participant confidentiality.

Entities Conducting Monitoring:
The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the principal investigators (Dr. Sun) and the Brown University IRB.

References:

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