BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Project Title: Developing and Testing Internet-Based Mindfulness Intervention to Reduce Minority Stress and Promote HIV-Related Behavioral Health Among Young Adult Sexual Minority Men: A Randomized Controlled Trial for Aim 3

Version 1.0, April 4, 2023

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- *PURPOSE*: In this study, we are looking to see if a customized mindfulness course, Mindfulness-Based Queer Resilience (MBQR), helps address minority stress and promote mental and sexual health among young adult gay men, bisexual men, queer men, and non-binary people assigned male at birth.
- *PROCEDURES*: If enrolled, you will be asked to complete up to four online questionnaires each averaging 60-90 minutes taking place (a) at baseline (prior to the intervention), (b) post-intervention, and at (c) 6-months and (d) 1-year from enrollment. Participants randomly assigned to MBQR will be asked to take part in a 10-week mindfulness course, lasting up to 2.5 hours per week, while control group participants will be invited to complete a 10-week self-paced online health education course. All participants will be asked to complete routine HIV/STI self-testing at each of the four time points as well as submit cortisol bio-samples taken from nail clippings (read below for additional information). Participants assigned to MBQR will also be invited to complete semi-structured exit interviews and 1-year follow up assessments. Prior to the start of the interventions, all participants will be asked to attend a mandatory 30-minute introductory session via Zoom to find out more about the study.
- *TIME INVOLVED*: The total estimated time on the study is dependent upon which group you ae randomly assigned to and which research activities you choose to take part in. Participants assigned to the MBQR intervention will participate in research activities that can take up to 68.4 hours spread out over the course of 1 year, while participation in the health education group may take up to 67.4 hours spread out over 6-9 months (length of involvement is dependent on your desire to complete the optional mindfulness course offered after the six month follow up).
- *COMPENSATION*: Health Education group participants are able to earn up to $300 for their time on the study, while MBQR intervention participants can earn up to $340. Payment is dependent on research activities completed. Payments are made in the form of Amazon gift cards.
- *RISKS*: The risks to you in this study include possible psychological discomfort during research assessments and/or the 10-week intervention as well as possible increases in anxiety, depression, or insomnia during the mindfulness intervention. However, the likelihood of experiencing these are minimal. All participants will be provided a list of resources several times throughtout the study. All aspects of the study are voluntary. You can withdraw from the study at any time.
- *BENEFITS*: There are no guaranteed direct benefits to participating in this study. We are investigating whether or not the 10-week mindfulness intervention actually works to address minority stress and promote mental and sexual health among young adult gay men, bisexual men, queer men, and non-binary people assigned male at birth.
- *ALTERNATIVES TO PARTICIPATION*: Several different therapies, including counseling services, physical activity, and reducing excessive alcohol consumption may also be beneficial for improving one's well-being. Education about these therapies are integrated into this course as

well as into the health education course, but other forms of these alternative therapies are also available in the community.

1. Researcher(s):

Shufang Sun, PhD (Email: mHEAL@brown.edu; Address: 121 South Main St., Providence, RI 02912) is the Principal Investigator.

2. What is this study about?

The purpose of this study is to develop and test an internet-delivered mindfulness-based intervention known as Mindfulness-Based Queer Resilience (MBQR) to address minority stress and promote mental and sexual health among young adult gay men, bisexual men, queer men, and non-binary people assigned male at birth. You are being asked to be in this study because you expressed interest and may meet the entrance eligibility criteria.

3. What will I be asked to do?

There are several components to this research study (refer to Table 1 on p.3 for an overview of all study procedures and the estimated time involved).

1) *Screening.* There are three distinct steps to determining whether or not you are a good fit for this study.
   a) First, you will first fill out a brief online screening survey. If eligible, you will be redirected to a separate contact form where you will be presented with this consent form. If willing, you will be asked to provide your contact information.
   b) A trained study RA will then reach out to you (email or phone) to schedule a 10 to 25-minute Zoom-based video screening, during which RA will confirm your eligibility and willingness to the study, go through the study protocol, and answer any questions. Note: This Zoom call will not be recorded; however, we will require that you turn on your camera for the call as well as show a valid ID to confirm your identity.
   c) The study RA will then mail out a free HIV self-testing kit to the address you provide and will schedule a time to complete a second Zoom interview with you during which time you will be prompted to complete the HIV self-test with the RA present on the call. Staff performing Zoom calls will be trained in providing HIV-counseling in the event that the test result is HIV-positive. This is the final step of determining your eligibility for this study. Alternatives to completing the HIV self-test include: (i) completing a self-test on your own and sharing the results with the research team; (ii) testing at a local health clinic; and (iii) opting out of HIV testing and instead self-reporting your HIV-status. Seeking alternative HIV testing is optional and would be done so at your own expense.
2) *Assessments.* If you are determined to be eligible, you will be asked to complete an online baseline assessment using an individualized link, which is expected to take around 60-80 minutes and includes questions concerning your mental, physical, and sexual health; life experiences; sexual identity; and possible childhood trauma and abuse. You will be asked to complete this same online assessment (minus any information that does not change over time (e.g., your demographic information) up to three other times: (i) after the intervention has ended; (ii) at 6-months follow up, and (iii) at 1-year follow up.
3) *Intro Session.* Participation in a mandatory 30-minute group introductory session to be held

online via Zoom prior to the randomization. The purpose of the introductory session will be to allow prospective participants a chance to interact with the mindfulness instructors and research staff, ask questions, and to find out more about the program. You will then be given a chance to opt-out of the study prior to the randomization.

4) *Care Package / Intervention Materials.* Prior to the start of the program, we will mail you a study care package consisting of a yoga mat, lubricated latex-free condoms, journal and pen, raisins, stickers, a fidget spinner/stress ball, some study swag, and a brief description and purpose for each of the items. We will ask for your mailing address at the time of the online screener.

Timeline and Outline of Study Procedure	**Estimated Time Commitment**
Online Screener (already completed)	5-10 minutes
Zoom Interview #1 - video conference call	10-25 minutes
Zoom Interview #2 - video conference call and HIV-self test	20-30 minutes
Baseline online research assessment and at home cortisol nail bio-sample collection	60-90 minutes
Mandatory Group Introduction Session via Zoom	30 minutes
You will be randomized to either… (1) MBQR: 10-week online Mindfulness Class (via Zoom) (2) Health Education: self-paced online course	MBQR: (~2.5hrs per week x 10 weeks + 6hr all-day session, plus home practice) = 58 hours) Health Education = 10 sessions x 1 hour per session = 10 hours
Weekly online assessments	10 minutes (x 10 total)
Exit Interview conducted via Zoom (MBQR group only)	90-120 minutes
Post-intervention assessment – online survey, HIV/STI home self-testing, and home cortisol nail bio-sample collection	60-90 minutes
6-month follow up assessment – online survey, HIV/STI home self-testing, and home cortisol nail bio-sample collection	60-90 minutes
1-year follow up assessment (MBQR group only) – online survey, HIV/STI home self-testing, and home cortisol nail bio-sample collection	60-90 minutes

After the 6-month follow up, health education group members, who completed the study, will be offered an opportunity to take part in the following: - MBQR-hybrid: asynchronous online course 10 modules with optional 1hr live weekly drop-in sessions - Post-intervention assessment and activities - Exit Interview	MBQR-hybrid = 30-47 hrs Post-Intervention = 60-90 minutes Exit Interview = 90-120 minutes
Total Estimated Time	**MBQR Intervention Group: up to 68.4 hours** **Health Education Group: up to 67.4 hours**

5) *Study Interventions and RCT Description.* This is a Randomized Control Trial (RCT) with two study interventions. Participants enrolled into the study will be randomly assigned to one of two groups: (a) the MBQR study intervention or (b) a health education group.

   a) Group 1 – Mindfulness-Based Queer Resilience (MBQR): MBQR is an online, Zoom-based mindfulness course customized for the LGBTQ+ community 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. Formal and informal mindfulness practices will be taught, 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. Participants will also meet one-on-one with the instructor at the beginning and middle of the course for a 30-minute welcome call and mid-course check in.

      MBQR Class sessions may be video and/or audio recorded using the online video conferencing platform, Zoom, for training purposes and in order to analyze the quality of the treatment you receive. Class videotapes may be made available to MBQR supervisors, teacher trainers, teacher trainees and researchers through the Mindfulness Center at Brown University. It may be used by them for professional education and training purposes via various secured outlets, including a password-protected and private YouTube channel, a password-protected and private DropBox account, and electronic academic learning software tools. As a participant you have the option of turning off your video monitor and/or muting your audio at any time; however, active participation is encouraged.

   b) Group 2 – Health Education Course: Participants randomly assigned to complete the online Health Education course will do so at their own pace over the course of 10 weeks using an online platform. 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). Topics include sleep, exercise, healthy eating and body image, time management, alcohol and substance use, sexual health, school/work life balance, and healthy relationships.

      If you are randomly selected to the health education group, we will be asking you to refrain from initiating and engaging in mindfulness practices and formal meditation during the six-month period of your participation in this research study. As part of this research study we are evaluating the impact of the mindfulness course on the health of its participants. If the health education group members engage in mindfulness during the intervention period, it may misguide the study results.

Health education group participants who complete the study will be offered an opportunity to take a MBQR-hybrid course after the 6-month follow-up assessment is complete. This additional course is optional.

c) MBQR-hybrid is an asynchronous online-based mindfulness course offered to health education group members after their six month follow up assessment is complete. Similar to MBQR, MBQR-hybrid is facilitated by queer mindfulness teachers and consists of 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-month time frame (10 modules that can be paced to be completed in 10-14 weeks).

6) *Weekly Assessments.* During the ten weeks that you and others are completing the intervention, you will be asked to fill out a brief survey (5-10 minutes) each week on your mental health, sexual health, and weekly/daily engagement with your course material.

7) *Cortisol Bio-Sampling.* We will be providing you with a nail collection kit in which a cortisol bio-sample may be provided as part of the study (aka – nail trimmings can be used to assess your cortisol stress levels during the study). This will be done up to four times (baseline, post-intervention, 6-months follow up, and 1-year follow up).

8) *HIV/STI Self-Testing.* In addition to the cortisol bio-samples, we will also provide you with a free HIV/STI home self-testing kit that checks for six sexually transmitted infections through a urine sample and a finger prick blood sample (STI testing kit valued at $169). Testing can be done from the privacy of your home, samples are then mailed via USPS in discrete packaging and processed in a lab, and results are shared with you via an app. In addition to the treatment and counseling services offered to you by the testing manufacturer (e.g., Everlywell), our research staff are trained to connect you with healthcare and counseling resources in your area. HIV-testing will be done up to four times (baseline, post-intervention, 6-months follow up, and 1-year follow up), while STI testing is not carried out at baseline.

9) *Exit Interviews.* After completion of the MBQR program, participants in this group will be invited to participate in one-on-one exit interviews over Zoom lasting 90-to-120-minutes. Interviews will focus on your experience in the study, feasibility and acceptability of the intervention, areas for further adaptation, etc. and will be conducted by a study team member or study PI (Dr. Sun). Exit interviews will be recorded and transcribed for research purposes and the recording will be stored on a secure server (i.e., Brown University Stronghold). The recordings will be destroyed once the transcriptions are complete. The transcriptions and coded data will not contain any personally identifiable data (ID only).

10) *Intervention / Course Platform.* Both interventions (MBQR and the Health Education course) will utilize a secure web platform customized for our study courses where we will store course materials, health education, homework, journaling prompts, group discussions, and practice logs. To access the participant learning portal, you will be provided study login information based on your participant ID (not identifiable) to register an account to enroll. Your engagement and activities through this online portal will be recorded as study engagement data for research purposes.

4. How much time will the study take?

The total estimated time you will devote to this study is dependent on many factors, including which of the two groups you are randomly assigned to complete.

Participants assigned to the MBQR intervention will participate in research activities that can take up to 68.4 hours spread out over the course of 1 year, while participation in the health education group may take up to 67.4 hours spread out over 6-9 months (length of involvement is dependent on your desire to complete the optional mindfulness course offered after the six month follow up). The MBQR course may take up to 58 hours spread out over 10 weeks and consists of 31 hours of class time (2.5 hr weekly sessions x 10 weeks + 6 hr all-day retreat) plus an estimated 27 hours of home practice (~3hrs per week x 9 wks). The Health Education course is expected to take around 10 hours to complete (~1hr per session x 10 sessions), while the MBQR-hybrid course may take up to 47 hours.

Table 1 on page 3 of this document, provides an outline of all the study procedures including the estimated time for each study component.

5. Will I be paid?

Yes, all research participants will be compensated for their time on this study. Health education group participants are able to earn up to $300 for their time on the study, while intervention participants can earn up to $340. Payments are dependent on which research activities you complete and are provided in the form of Amazon gift cards.Partial compensation will not be provided. If you choose to withdraw from the study prior to completion, you will only be compensated for the study components you completed. Compensation will be sent out in batches throughout the project (i.e., after baseline assessment are complete, after the intervention is complete, etc.).

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

MBQR / Health Education ($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; Health Education 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. Participants 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 Health Education Participants = $300
Total Possible Compensation for MBQR Participants = $340

Note that to receive the initial study compensation, you must meet all eligibility criteria, complete the online screening Zoom calls (where ID and eligibility are checked), and successfully complete the

questionnaires (i.e., valid data detected). Partial compensation will not be provided. Individuals determined to be ineligible after the study has started will not be compensated unless the error is determined to be on our end.

Participant IP addresses will be collected in Qualtrics for data quality purposes. IP addresses will be discarded at the conclusion of the study. If responses to the survey are found to be fraudulent (e.g., bots, en mass responses, etc.), multiple responses are made by the same user, or an individual is found to be purposely manipulating the survey, (e.g., participating in a survey for which they are not eligible, giving dishonest or inconsistent responses), payment will be withheld.

6. What are the risks?

The risks to you for taking part in this study are minimal and may include: 1) Loss of privacy protection: It is possible the data we collect could be lost or revealed. We will do everything we can to protect your privacy and have described the steps we are taking to protect the information you give us in the "Confidentiality" section of this form. 2) You may experience some discomfort in answering sensitive questions. You will not be identified in any of the data analysis but rather the data will be reported in aggregate. You have the right to not answer any question you are uncomfortable with and you can end your participation at any time. (3) Possible side effects of mindfulness practices: There have been some reports of side effects from other mindfulness meditation training interventions. These rare side effects include trouble thinking clearly or making decisions, increased anxiety symptoms, repeated thoughts of a stressful experience from the past, irritability, trouble enjoying things that were previously enjoyable, feeling distant or cut off from people, difficulty sleeping, headaches and/or body pain, hearing sensitivity, feeling disconnected from everything, feeling negative emotions more strongly, feelings of distress. We will ask you about side effects from the program after completion.

As part of the mindfulness intervention you will be invited to engage in gentle mindful movements (i.e., yoga). It is possible that injuries or discomfort (e.g. muscle soreness) could be sustained from these activities. To help limit this, you will receive a handout showing the yoga poses that will be offered during the course that you can show your health care provider so that they can advise on which poses to do, and which to avoid. Modifications of poses will be available as needed. None of the poses (or the yoga as a whole) are mandatory to be done. You will be encouraged to not go beyond any physical limits of your body, and will be encouraged to ask your healthcare provider about advised physical activities and mindful movements if you have any physical limitations.

While physical and mental injury is always a possibility the potential for harm is limited. Note that a research injury is any physical or mental injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you are covered by insurance and suffer a research injury, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered by your health insurance company, it is possible you would have to pay for these costs out of pocket. Brown University's policies do not cover payment for such things as lost wages, medical care expenses, or pain and suffering.

Precautions should be taken to avoid injuries. If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured.

The mindfulness classes may be video and/or audio recorded for training and educational purposes. The video monitor will focus on the face of the course instructor, and not on the faces of study participants. However, there is a possibility that your voice and face may be recorded.

If you experience distress at any time throughout the study, please let one of the research staff or interventionist instructors know so that resources can be provided. The study clinician is also available if you wish to talk to a licensed therapist. Refer to section 11 of this document for study contact information.

7. What are the benefits?

There are no direct benefits to you for participating in this study. You may learn more about yourself during participation in this study and may gain knowledge about important health topics, such as sleep, diet, physical activity, etc.. It is possible that you may notice decreased stress over the course of the study, and you may become more aware of your mental and sexual health.

8. How will my information be protected?

All questionnaires will be recorded in a secure research database application (Qualtrics) and only the PI and members of research team will have access to this data. Every participant will be given a number called a Participant ID and all data will be matched to the ID rather than identifiers such as your name. The study key matching the ID to identifiers will be saved in a secure, password-protected server (Stronghold) and only the PI and research team will have access to it. It will be destroyed upon study completion. Deidentified data may be used and/or shared for future research. The survey data collected from you as part of this research study will not be linked to your contact information. Furthermore, we will not identify you by name. All results will be presented in aggregate and not individually. The researcher will not share your responses with anyone other than approved researchers.

When completing the online assessments and Zoom calls, you will be encouraged to find a time and place that maximizes privacy and minimizes distractions. We encourage you to close your browser windows after use, especially if using a shared computer in a public setting. The research staff conducting the zoom interviews have been trained to respect your privacy and will not discuss your responses outside of the research team.

Limitations. While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then follow up with a health care provider may be taken (i.e., 911 called or a collaborator who is a licensed psychiatrist may contact you to discuss your responses and possible referral to a treatment provider.) Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

Publications. The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

Keeping study records: The Principal Investigator(s) for this study will keep your deidentified research records indefinitely for research purposes.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you 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 you have 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 you have consented to the disclosure, including for your 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 the National Center for Complementary and Integrative Health, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you 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, your records may be examined. The reviewers will protect your confidentiality.

9. Are there any alternatives to this study?

Several different therapies, including counseling services, physical activity, and reducing excessive alcohol consumption may also be beneficial for improving one's well-being. Education about these therapies are integrated into this course as well as into the health education course, but other forms of these alternative therapies are also available in the community.

10. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. If you refuse to participate in or leave the study, your current or future relationship with Brown University as well as with your physician will; not be affected. If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

There may also be circumstances when the study investigator or interventionist decide to withdraw a participant from the study for safety reasons or for the overall well-being of the MBQR group. If circumstances lead to your withdrawal from the study, you will be contacted by a research staff member and resources will be provided.

11. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the Senior Project Coordinator, Frances Saadeh, at 401-863-6361 or email at mheal@brown.edu. You may also contact the Principal Investigators at any time, Dr. Shufang Sun at 401-863-5735 or Email: Shufang_Sun@brown.edu.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

12. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu. The IRB protocol number in the consent document is #2004002698.

13. Consent to Participate

Clicking the link below confirms that you have read and understood the information in this document, are at least 18 years old, and that you agree to volunteer as a research participant for this study.

You can download or print a copy of this form.