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

Version 1.0, June 24, 2022

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

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

- PURPOSE: This study aims to pilot an internet-delivered mindfulness-based intervention to address minority stress and promote mental and sexual health among young adult gay, bisexual, and queer men. You are being asked to be in this study because you expressed interest and may meet the entrance eligibility criteria.

- PROCEDURES: There are several components to this research study (refer to Table 1 on p.2 for an overview of all study procedures and the time involved).

  1) You will first fill an online screening survey. If eligible, you will be asked to be directed to put in your contact information. As the intervention is group-based, you will be asked to provide your availability for several options of group times.
  2) A study RA will reach out to you (email or phone) to schedule a 15 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. We will select a group time where most eligible participants can make. 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.
  3) If you are determined as eligible, you will be asked to complete a baseline assessment using an individualized link, which is expected to take around 40 minutes.
  4) Following this assessment, you will be officially enrolled in the intervention program, "Mindfulness-based Queer Resilience (MBQR)". The Program is a 10-week group-based intervention, including 1 week of orientation and 9 weeks of LGBTQ-tailored mindfulness classes (including a week where there is an All-Day mindfulness retreat). During the program, you will attend Zoom-based weekly groups with other participants and 1-2 mindfulness teachers who have been thoroughly trained to deliver this program. The program is specifically tailored to LGBTQ experience. As part of the study, you will be asked to complete a brief survey (5-10 minutes) weekly on your mental health, sexual health, and weekly/daily practice.
  5) After the end of the program, you will be asked to complete an online post-program survey, which will take about 40 minutes to complete.

6) After completion of the program, to participate in a 90-minute to two-hour exit interview over Zoom. This call will be recorded and transcribed for research purpose. and the recording will be stored on a secure server. The recording will be destroyed once the transcription is complete. The transcription and coded data will not contain any personally identifiable data (ID only). This exit-interview will focus on your experience in the study, feasibility and acceptability of the intervention, areas for further adaptation, etc. The one-on-one, Zoom-based interview will be conducted by a study team member or PI.

If you are eligible and decided to enroll, the program that you will participate mainly take place via Zoom, a free video conferencing software. Besides the Zoom-based group program, you will also be provided access to a program participant learning portal [insert name/link], a platform where we will store course materials, health education, homework, and practice log. To access the participant learning portal, you will be provided study login in 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.

Timeline and Outline of Study Procedure	**Estimated Time Commitment**
Online Screener (already completed)	5-10 minutes
Zoom Interview - video conference call	15-25 minutes
Baseline online research assessment	40 minutes
Study orientation	30 minutes
Online Mindfulness Classes	10 weeks, (2.5 X 9 weeks + 6 = 28.5 hours)
Weekly assessments	10 minutes (x 9 total)
TA check-ins	30 minutes (x 2 total)
Post-intervention survey	40 minutes
Exit Interview conducted via Zoom	90 minutes – 2 hours
Total Estimated Time	**35.0 hours**

- TIME INVOLVED: We estimate the total study involvement to be up to 35.0 hours over the course of 10-12 weeks. This consists (a) the confidential online screening assessment that takes 5-10 minutes to complete; (b) the Zoom screening interview that will take 15 to 25 minutes; (c) the baseline online research assessment (40 minutes); (d) the online mindfulness class orientation; (e) the mindfulness classes (2.5 hours per week for 9 weeks + a 6 hour all-day retreat – all take place online); (f) the weekly assessments (10 minutes x 9 weeks); (g) the post-intervention survey (40 minutes); and (j) the 90-minute to two-hour exit interview conducted over zoom after the intervention is complete.

- COMPENSATION: You will be compensated up to $140 for your time on this study. The compensation is based on each study component completed, specifically, you will receive $15 for completing the baseline survey, $5 for each weekly assessment (9 x $5 each = $45 total), $40 for completing the post-intervention survey, and $40 for participating in the Zoom exit-interview.

  Note that in order to receive the baseline compensation, you must meet all eligibility criteria, complete the online screening Zoom call (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.

  Note that 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.

- RISKS: There is minimal risk associated with being in the study. 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.

- BENEFITS: There are no direct benefits to you for participating in this study. You may learn more about yourself during participation in this study. 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.

- CONFIDENTIALITY: 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.

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.

- VOLUNTARY: 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.

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.
  - There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.
  - Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

- CONTACT INFORMATION: If you have any questions about your participation in this study, you can call Dr. Shufang Sun at 401-863-5735 or Email: shufang_sun@brown.edu.

- YOUR RIGHTS: 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.

- 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. <include URL>