PROTOCOL TITLE:

Growth, Empowerment, and Mindfulness (GEM): Pilot Trial of a Mindfulness-based Intervention to Address Mental Health in Young Adults with Early Life Adversities

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	1/13/2026	- New documents “MINI – Major Depressive Episode Referral Plan_GEM.docx”; “ICF Checklist_GEM.docx”; “Outline_GEM.docx”; and “Intervention_GEM.docx” have been added - Several changes were made to existing documents based on request made in “STUDY-1023_DR Clarification Request.docx”	Yes
2	2/5/2026	Changes were made to the following documents based on request made on Huron: - HRP - “Intervention_GEM.docx” - “Outline_GEM.dcox” - “Recruitment_GEM.docx” - “Recruitment Email Drafts_GEM.docx” - “Compiled measures_GEM.docx”	No
3	3/3/2026	Changes were made to Section 13.1 of the HRP to include Today@Brown as a recruitment method. A document containing all information that will be entered on Today@Brown has also been added (“Today@Brown_GEM.docx”). The inclusion/exclusion criteria (Section 10.2) has been modified as well. Changes in inclusion/exclusion criteria has been	

		reflected across the following documents, consistent with the modification in the HRP-503: - “Recruitment Email Drafts_GEM.docx” - “Compiled measures_GEM.docx” - “ICF Checklist_GEM_R3.docx”	

Table of Contents

1.0 Study Summary

Protocol Information	Description
Study Title	Growth, Empowerment, and Mindfulness (GEM): Pilot Trial of a Mindfulness-based Intervention to Address Mental Health in Young Adults with Early Life Adversities
Study Design	Single-arm feasibility study
Primary Objective	Examine the feasibility, acceptability, and preliminary efficacy of a mindfulness-based, app-delivered intervention to address mental health and emotion regulation challenges experienced by young adults with early life adversities (ELAs)
Secondary Objective(s)	Understand mechanisms of change underlying the intervention, including the role of mindfulness (i.e., interoceptive awareness and de-centering), rumination, and sleep using real-time data collection via ecological momentary assessments (EMAs) and wearable devices
Research Intervention(s)/ Investigational Agent(s)	Growth, Empowerment, and Mindfulness intervention
IND/IDE #	N/A
Study Population	Young adults aged 18-24 residing in the U.S.
Sample Size	*n* = 44 expected
Study Duration for individual participants	Total study duration for each participant is 3-4 months, comprising a baseline assessment,4-6 weeks of active intervention, a post-intervention assessment, and a 3-month follow-up assessment.
Study Specific Abbreviations/ Definitions	EMA = Ecological Momentary Assessment EMI = Ecological Momentary Intervention ELA = early life adversity

2.0 Objectives

2.1 The objectives of this study are to: (a) examine the feasibility, acceptability, and preliminary efficacy of a mindfulness-based, app-delivered intervention to address mental health and emotion regulation challenges experienced by young adults with early life adversities (ELAs); and (b) understand mechanisms of change underlying the intervention, including the role of mindfulness (i.e., interoceptive awareness and de-centering), rumination, and sleep using real-time data collection via ecological momentary assessments (EMAs) and wearable devices.

2.2 We hypothesize that young adults will find the Growth, Empowerment, and Mindfulness (GEM) intervention to be both feasible and acceptable, as demonstrated by participants' engagement and quantitative/qualitative feedback; we also hypothesize that the engagement with the intervention will demonstrate preliminary efficacy for improving outcome measures including depression, anxiety, self-compassion, emotion regulation, loneliness, and healthier phone use. We further hypothesize that the mechanisms underlying the benefits of the intervention will be improvements in mindfulness and sleep, as well as reductions in rumination.

3.0 Background

3.1 mHEAL research team has extensive experience in developing and evaluating mindfulness-based, transdiagnostic interventions for young adults. Examples include Mindfulness-based Queer-Resilience (with over 200 pages of materials, 30+ created videos, and 50+ recorded audios in our lab library) for young adults with depression/anxiety and affected by trauma, stigma, and childhood adversity as well as Mindfulness for Pandemic Resilience, a mobile app for youth in China with psychiatric symptoms and affected by strict pandemic lockdowns. Both programs have been evaluated by RCTs and shown acceptability, feasibility, and preliminary efficacy. Finidings showed that the intervention was efficacious especially for participants with experiences of early life adversities. However, there has not been a mindfulness intervention tailored specifically towards young adults who have lived experiences of early life adversities, representing an important opportunity for action. Further, studies that examine mechanisms underlying specific mindfulness practices and their effectiveness at addressing specific stressors are lacking.

3.2 N/A

3.3 Facing early life adversity is common among the United States population, with one epidemiological study finding that 53.4% of surveyed participants had experienced at least one adverse childhood event (Green et al., 2010). Early life adversity has been associated with poorer mental health, which can also contribute to a greater likelihood of engaging in risky health behaviors (Duffy et al., 2018). Additionally, early life adversity has been associated with alterations in neural functioning and compromised emotional regulation skills (Krugers et al., 2017). Mindfulness interventions have been found to reduce symptoms of anxiety and depression (Hofmann & Gómez, 2018) and improve emotional regulation abilities (Goldin &

Gross, 2014) across a wide range of populations. Overall, this study aims to fill this gap and improve health outcomes for the identified vulnerable population. By assessing the feasibility of an app-delivered MBI, we hope to contribute to the continued development of effective, accessible methods of addressing emotional health challenges attributable to the presence of ELAs, thus promoting overall psychological well-being. Further, given the landscape of existing research and literature, we aim to further understand the role of mindfulness in reducing mental health and emotion regulation challenges among young adults, done so through the lens of an app-delivered intervention.

Duffy, K. A., McLaughlin, K. A., & Green, P. A. (2018). Early life adversity and health-risk behaviors: proposed psychological and neural mechanisms. *Annals of the New York Academy of Sciences, 1428*(1), 151–169. https://doi.org/10.1111/nyas.13928

Goldin, P. R., & Gross, J. J. (2010). Effects of mindfulness-based stress reduction (MBSR) on emotion regulation in social anxiety disorder. *Emotion (Washington, D.C.), 10*(1), 83–91. https://doi.org/10.1037/a0018441

Green, J. G., McLaughlin, K. A., Berglund, P. A., Gruber, M. J., Sampson, N. A., Zaslavsky, A. M., & Kessler, R. C. (2010). Childhood adversities and adult psychiatric disorders in the national comorbidity survey replication I: associations with first onset of DSM-IV disorders. *Archives of general psychiatry, 67*(2), 113–123. https://doi.org/10.1001/archgenpsychiatry.2009.186

Hofmann, S. G., & Gómez, A. F. (2017). Mindfulness-Based Interventions for Anxiety and Depression. *The Psychiatric clinics of North America, 40*(4), 739–749. https://doi.org/10.1016/j.psc.2017.08.008

Krugers, H. J., Arp, J. M., Xiong, H., Kanatsou, S., Lesuis, S. L., Korosi, A., Joels, M., & Lucassen, P. J. (2016). Early life adversity: Lasting consequences for emotional learning. *Neurobiology of stress, 6*, 14–21. https://doi.org/10.1016/j.ynstr.2016.11.005

4.0 Study Endpoints

4.1 We will collect quantitative and qualitative data from young adults, aged 18-24 (n=44). We will end data collection when the target sample size is reached or when sufficient data is collected to assess feasibility, acceptability, and preliminary efficacy outcomes (whichever comes first).

4.2 For safety endpoints, we will monitor for adverse events or any negative effects of the intervention; participants are free to withdraw from the study at any time, in which case their participation will end immediately with no penalty.

5.0 Study Intervention/Investigational Agent

5.1 The Growth, Empowerment, and Mindfulness (GEM) intervention is a structured, mindfulness-based intervention designed to offer support for young adults with early life adversities and their negative behavioral health consequences through

the development of awareness, emotion regulation, and adaptive coping skills. Through psychoeducation content, group practice sessions, and formal and informal mindfulness practices, GEM is aimed at helping participants build foundational mindfulness and self-compassion skills, increase interoceptive awareness, reduce experiential avoidance and de-centering, improve emotion regulation and decrease rumination, and integrate mindfulness skills into daily life. The specific content of the GEM intervention is currently under development with community feedback from relevant Community Advisory Board members (refer to "Intervention_GEM.docx" for drafted scripts of Weeks 1-4 and the Bonus Modules, which will guide the recorded materials; also refer to "Outline_GEM.docx" for intervention outline for each week).

5.2 Contents of the GEM intervention is delivered through an existing third-party mobile application (i.e., Expiwell) and consists of 4 weeks of "Recommended Modules" and 2 weeks of "Bonus Modules". Each week, participants will gain access to a set of 5-11 modules, with each module combining formats of text and audio recordings of psychoeducational content and mindfulness practices. Each week's modules are further divided into 'core' and 'optional tailored' modules.

	Recommended Modules (i.e., Weeks 1-4)	**Bonus Modules (i.e., Weeks 5-6)**
Core modules	Core modules in weeks 1-4 cover topics of early life stress and resilience, environmental stress and disembodied living, experiential avoidance, emotion regulation, mindful self-care, and self-compassion	Core modules in weeks 5-6 cover topics related to media consumption and purpose
Optional tailored modules	Throughout Weeks 1-6, Optional tailored modules will focus on topics of (a) minority stress for participants who identify as a minority member and (b) trauma for participants wanting to receive more information about trauma	

On the application, participants will also have access to a list of all mindfulness exercises that have been taught each week.

In addition to the weekly modules, participants will complete EMAs and EMIs 3 times per day during the Recommended Modules (i.e., first four weeks of intervention period). The EMI will be delivered concurrently with the EMA, which will collect participant's response on their current mood, recent stressful experience, and type of stressor. Participants will then receive a list of mindfulness exercises, which will be tailored to the type of stressor/emotion they will have indicated. The intervention as well as EMAs and EMIs will be delivered on a mobile application named "Expiwell" (https://www.expiwell.com/).

At the end of each week, participants will also take part in a weekly "Group practice and connect" session on Zoom during the Recommended Modules (i.e., first four weeks of intervention period). The weekly sessions will be conducted in cohorts of 5-10 participants (depending on the recruitment speed), led by a research assistant who has previous experiences with mindfulness programs as well as lived experiences of early life adversity. Each session will last approximately one hour and will be structured roughly to reflect: group check-in, group discussion on past

week's weekly intervention content, one group meditation practice using audio, and reflections on the meditation practice.

5.3 This study will utilize Fitbit, a commercially available wearable device, for the purpose of passive data collection on sleep and physical activity. The Fitbit devices will be stored securely by the research team when not in use, distributed directly to participants during enrollment by mail, and collected at the end of the study. Names and addresses of participants will be shared with departmental operations staff through password-protected files to create shipping labels and facilitate mailing the Fitbits to participants via FedEx. When operations staff submit reconciliation for the transaction, it is on an aggregate level (i.e., without specific participant information or individual package tracking numbers). This ensures the confidentiality of each participant. Participants will be instructed on proper use and care of the device, and a pre-paid, pre-addressed return envelope will be provided so participants can directly mail the device back to the research team at the end of the study. Only authorized study team members will manage device distribution, collection, and data linkage.

5.4 N/A

6.0 Procedures Involved

6.1 We will conduct a single-arm, mixed methods feasibility trial design to evaluate the feasibility, acceptability, and preliminary effects of a mindfulness-based intervention ("Growth, Empowerment, and Mindfulness"; GEM) among young adults with early life adversities (n=44), with exploratory analyses of the preliminary outcomes to potentially inform future studies. The GEM intervention is an app-delivered program consisting of weekly learning modules, ecological momentary assessments and interventions (EMA/EMI), and weekly group practice sessions (described in greater detail in Section 5.0 Study Intervention/Investigational Agent). The intervention will offer support for young adults with experiences of early life adversities and its negative behavioral health consequences by helping participants build foundational mindfulness and self-compassion skills, increase interoceptive awareness, reduce experiential avoidance and de-centering, improve emotion regulation and decrease rumination, and integrate mindfulness skills into daily life. GEM is not intended to diagnose, treat, mitigate, or cure any mental health disorder.

6.2 Over the study duration of 3-4 months for each participant, we will use a mixed methods, longitudinal design incorporating (1) baseline, (2) post-intervention, and (3) follow-up assessments as well as (4) weekly assessments during the first four weeks of the intervention delivery period ("Recommended Modules") and (5) daily EMAs to evaluate the feasibility, acceptability, and preliminary effects of the GEM program integrating app-based intervention content, weekly group sessions, and EMI delivery. The research team will register and maintain the study information on ClinicalTrials.gov. Specifically, the study PI, with support from the research team members, will be responsible for registering the clinical trial before the enrollment of the first subject, regularly updating study record, posting the IRB-approved informed consent form after the study is closed to recruitment, but no later than 60 days after the last study visit by any

participant, and the timely update of the study materials and results when they become available.

Participant contact: The research team will utilize both email and Avochato (a messaging platform that facilitates text message communication between research staff and study participants without staff member using their personal phone numbers for the study; already vetted by the OIT) when communicating with participants in the study. Access to Avochato inbox used for this study will be limited to necessary study staff. Participants will be asked to indicate their preferred method of contact on the contact form (after consent) and will be contacted only via their selected method.

Baseline (T1), post-intervention (T2), and 3-month follow-up assessments (T3): At each timepoint, participants will complete a Qualtrics survey, which will be accessed through a unique link created based on each participant's deidentified participant identification number (PID).

The Baseline assessment (T1) will include a set of sociodemographic questions as well as a total of 27 scales, measuring depression, anxiety, PTSD, functional impairment due to depression, functional impairment due to anxiety, interoceptive awareness, de-centering, rumination/perseverative thinking, theories of psychological distress, theories of emotion, internalized stigma, emotion regulation, loneliness, mindfulness, self-compassion, perceived stress, political stress, sleep, phone use, early life adversity, childhood trauma, experiences of stress and adversity, everyday experiences of discrimination, rejection sensitivity, Major Depressive Episode, Generalized Anxiety Disorder, and overall well-being (see "Compiled Measures_GEM.docx").

Additionally during the Zoom call for baseline assessment (T1), the RA will "onboard" the participant and (a) review how to use a FitBit, (b) install the study application, and (c) problem solve any logistic issues. The baseline assessment and onboarding will take a total of 90-120 minutes.

The post-intervention assessment (T2) will take place 1-2 weeks after the recommended modules are completed and include a total of 26 scales, measuring depression, anxiety, PTSD, functional impairment due to depression, functional impairment due to anxiety, interoceptive awareness, Major Depressive Episode, Generalized Anxiety Disorder, de-centering, rumination/perseverative thinking, theories of psychological distress, theories of emotion, internalized stigma, emotion regulation, loneliness, mindfulness, self-compassion, perceived stress, political stress, sleep, phone use, applied mindfulness process, overall well-being, client satisfaction, session evaluation, and adverse effects. The post-intervention assessment will take a total of 60-90 minutes.

Additionally at T2, participants will be invited to complete an exit interview via Zoom, the University approved web conferencing platform. Interview will take 90-120 minutes. In line with previous studies from our team, the interview will be recorded using the native recording feature on the Zoom platform (i.e., capturing both video and audio recording) and saved to the interviewer's Brown Zoom cloud. The RA recording the interview will ensure that the setting "Allow cloud recording sharing" is disabled on

Zoom. By disabling this setting, nobody other than the person who made the recording will be able to access that recording on the cloud. Therefore the recording saved to the interviewer's Brown Zoom cloud will be only accessible to the interviewer creating the recording. An audio-only recording file will be downloaded from the Zoom cloud to Stronghold, and the original recording will be deleted from the Brown Zoom cloud.

At follow-up assessment (T3), which will take place 3 months after the baseline assessment, we will include a total of 21 scales, measuring depression, anxiety, PTSD, functional impairment due to depression, functional impairment due to anxiety, Major Depressive Episode, Generalized Anxiety Disorder, interoceptive awareness, de-centering, rumination/perseverative thinking, theories of psychological distress, theories of emotion, internalized stigma, emotion regulation, loneliness, mindfulness, self-compassion, perceived stress, political stress, sleep, phone use, applied mindfulness process, and overall well-being. The follow-up assessment will take a total of 60-90 minutes.

At each of these assessments, participants will join a Zoom meeting with an RA. To mitigate confidentiality risks and risk of third-party participants, The RA will begin the call by instructing participants to complete the procedure in a private location. Participants will be reminded to pause the assessment if another person enters the space. Then, the RA will verbally administer MINI-Major Depressive Episode and MINI-Generalized Anxiety Disorder. Before beginning the MINI modules, RA will remind participants that if they disclose information indicating imminent risk of serious harm to themselves or others, this information must be reported to relevant law enforcement or other authorities. During the assessment, the RAs will have access to a Qualtrics survey with both measures, which will serve as their guide to administer the measures (refer to "Compiled Measures_GEM.docx" for the scale and questions asked). The Qualtrics survey will be accessed only by the RA (i.e., the survey won't be sent directly to the participant) and filled out by the RA as the assessment progresses. The Qualtrics data will only be linked to the participant ID number (deidentified only) and will be kept in a secure location with other de-identified data. After both MINI modules are administered, the participant will be given access the aforementioned unique Qualtrics link to complete the rest of the measures, during which time the participants can ask any questions as they come up during the assessment.

For participants who report suicidality in the MINI-Standard: Major Depressive Episode module, the suicide safety assessment and plan will be followed accordingly (refer to document named "Suicide Safety Plan_GEM.docx and to Section 18.0). Because all eligible participants at this point will have only mild to moderately severe symptoms of depression (individuals with severe symptoms are screened ineligible at the Qualtrics screener survey), there is low likelihood that a participant will be at imminent risk of suicide; however, the suicide safety assessment and plan has been developed out of an abundance of caution. The Suicide Safety Assessment and Plan will be conducted by Dr. Shufang Sun, a licensed psychologist and the principal investigator of the study, or by a study team member who has been formally trained by Dr. Sun and

operates under her direct supervision and oversight, consistent with existing clinical trial protocols for NIH-funded studies in the lab. All study personnel will receive training from Dr. Sun on identifying and responding to suicide risk. In addition, Dr. Sun will be on-call and will be notified immediately of any safety concerns.

Growth, Empowerment, and Mindfulness (GEM) intervention: Participants will complete the intervention through Expiwell, a mobile application native to iOS and Android. The intervention will include 4 weeks of Recommended Modules followed by 2 weeks of Bonus Modules that participants can opt to complete. Each week, participants will gain access to (a) a set of 5-7 'core' modules focused on the topics of early life stress and resilience, environmental stress and disembodied living, experiential avoidance, emotion regulation, mindful self-care, and self-compassion; and (b) 0-4 'optional tailored' modules, specifically on the topics of minority stress and trauma for participants with interest in these topics. On Expiwell, participants will also have access to a list of all mindfulness exercises that have been taught each week. As a meditation-based intervention, the risk of increased psychological distress from meditation (refer to Section 15.1 for more details on foreseeable risks) will also be clearly outlined and communicated in the consent form, and participants will be encouraged to consult with study staff in the case of any increased distress.

In addition to the weekly modules, participants will take part in a weekly, 1-hour "Group practice and connect" session on Zoom. The online sessions will comprise a cohort of 5-10 participants (depending on recruitment) and will be led by a research assistant, who has previous experiences with mindfulness programs as well as lived experiences of early life adversity. During each session, participants will be invited to participate in a group practice and reflection and to join group discussions on experiences regarding past week's practice. In the contact form (which is completed after the consent form), participants will be presented with the day and time of weekly sessions for the next two cohorts and asked to choose the times they are available for. If the participant is not available for either of the offered times, they will be marked as "deferred enrollment" in our participant tracking spreadsheet. A study RA will follow up with information about future cohort scheduling as that information becomes available.

Ecological momentary assessments and interventions: Over the first 4 weeks of the intervention period (i.e., Recommended Modules), participants will also complete 3 EMAs + EMIs per day through Expiwell. EMA and EMI will be delivered concurrently; the EMA will collect participant's response on their current mood, recent stressful experience, and type of stressor; participants will then receive a list of mindfulness exercises, which will be tailored to the type of stressor/emotion they will have indicated. The last EMA of the day will also include an option for the participants to submit a voice recording, serving as a "daily journal" at the end of the day to understand participant's daily experiences, including daily stressors and mindfulness practice application. To mitigate the risk of recording third-party participant voices, participants in the study will be

instructed to complete the voice recording in a private location and to ensure no other individuals are present or speaking during the recording. Participants will be reminded to pause, stop, or restart the recording if another person enters the space. Participants will also be reminded that the voice recording is optional--they may skip voice recording submission without penalty and still receive compensation. Audio will be downloaded from Expiwell, uploaded to Stronghold, then deleted from Expiwell's storage. The audio housed in Stronghold will be deleted after the they are transcribed and vetted for accuracy by study staff. A research assistant will monitor responses to the EMA on a daily basis (including the voice recording, where a transcript will automatically become available through Expiwell's AWS service). Any reportable events that are observed will be reported to the PI, and the PI will be available to meet, if necessary, to review concerns regarding a particular participant or any problems that may arise for participants.

Weekly assessments: During first 4 weeks of intervention period (i.e., Recommended Modules), participants will be asked to complete a survey every week. The survey consists of 2 scales (PHQ-9 and GAD-7) as well as 3 items from interoceptive awareness scale, 3 items from de-centering scale, 3 items from perseverative thinking scale, and 1 item from theory of distress scale. Each survey will take 4-5 minutes, with a total of 16-20 minutes over the 4 week period.

Wearable device: Also during the first 4 weeks of intervention period (i.e., Recommended Modules), data will be collected from a Fitbit from each participant. Data collected include total sleep time, sleep onset latency, REM and non-REM sleep duration, sleep/wake variability, and resting heart rate. Each participant will be mailed a Fitbit from the study team along with a pre-paid return envelope at the enrollment in the study. These devices will be assigned to participants and linked to de-identified study accounts only. Participants will be instructed to wear the Fitbit device daily, before going to bed, for the entire 4-week period. At the end of the intervention, participants will be asked to return the Fitbit using the pre-paid return envelope.

Data analysis: Feasibility, acceptability, and preliminary effects will be assessed using data from the T1, T2, and T3 surveys as well as EMA responses. Qualitative data analysis will also be performed for the exit-interviews and voice recordings to further qualify our findings after transcription and deidentification. Exit interviews will be transcribed using Dedoose (already vetted through OIT), while EMA voice recordings will be transcribed automatically through Expiwell's AWS service. Additionally, recruitment and retention rates, completion of weekly modules, adherence to daily EMA and EMI prompts, weekly session attendance, and other engagement metrics from the application (e.g., frequency of EMI-triggered vs. self-initiated practice use, time spent in modules) will be used to inform study and intervention feasibility.

6.3 We will take all reasonable precautions to prevent adverse events to participants. As a meditation-based intervention, 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. During treatment, meditations are created to be relatively short and interspersed with dyads and reflections to minimize probability of risk. Developing strategies for working with physical and emotional discomfort is also an explicit goal of the program.

No drugs will be administered as part of this study. The only devices used are a) the participant's personal cell phone with the intervention content loaded through the Expiwell app and b) a wearable device Fitbit, which is commercially available and FDA-cleared for general wellness monitoring; it will be used solely to collect sleep and physiological data.

For all assessments and guides used for data collection, please refer to the document named "Compiled measures_GEM.docx".

6.4 A list of all data that and how they will be collected during the study is listed below:

Self-report data on feasibility, acceptability, and preliminary efficacy: Data on feasibility and acceptability as well as preliminary efficacy of the intervention on study outcomes (including mental health, functional impairment, emotion regulation, loneliness, mindfulness, self-compassion, stress, sleep, phone use, overall well-being, etc. – refer to Section 6.2 for full list of scales measured at each time point) will be collected via Qualtrics at baseline, post-intervention, 3-month follow-up, and weekly assessments during the first 4 weeks of intervention period (i.e., Recommended Modules).

EMAs: Daily self-reports on stress, mood, and emotional states will be collected on the Expiwell application. Furthermore, voice recordings for a "daily journal" will be collected during the last EMA of the day. Participants will be reminded that the voice recording is optional--they may skip voice recording submission without penalty and still receive compensation.

App engagement metrics: Frequency and duration of EMI-triggered and self-initiated mindfulness practice sessions will be collected on Expiwell.

Sleep metrics: Continuous objective data on sleep metrics (e.g., sleep latency, REM/non-REM sleep, sleep fragmentation, total sleep time, sleep efficiency) will be collected using wearable devices (i.e., Fitbits).

Semi-structured interviews: Qualitative feedback on intervention experience, feasibility, acceptability, and suggestions for improvement will be collected through a semi-structured Zoom interview with an RA.

6.5 Participants will complete a 3-month post-baseline follow-up survey after the 4-6-week intervention (4 weeks recommended, 2 weeks optional/bonus). Similarly to post-intervention survey, this assessment will collect self-report data on mental health, functional impairment, emotion regulation, loneliness, mindfulness, self-compassion, stress, sleep, phone use, overall well-being, etc. (refer to Section 6.2 for full list of scales measured 3-month follow-up).

6.6 N/A

7.0 Data and Specimen Banking

7.1 De-identified data (i.e., data linked to PID) will be kept indefinitely after the completion of the study. These de-identified data include (1) data collected from T1, T2, T3, and weekly Qualtrics survey; (2) data from wearable devices (e.g., sleep duration, sleep activity); (3) de-identified data downloaded from Expiwell (e.g., timestamps of EMA completions and other adherence information); (4) de-identified interview and voice recording transcripts, with all potentially identifying information removed; and (5) de-identified data collected during Zoom screening interview (collected after consent). Access to the data will be restricted to authorized study personnel, including the principal investigator and designated research staff responsible for receipt, storage, and analysis of data. Screening data from the screening Qualtrics survey will not be stored or used for any other purposes. Qualtrics software will be accessible only to authorized study personnel. Identifiable consent information will be downloaded from Qualtrics and securely stored on Stronghold and will be deleted from Qualtrics once successful transfer and storage have been confirmed.

As described in section 6.2, video recordings of the exit interview will be deleted as soon as the audio can be downloaded from the Brown Zoom cloud and successfully uploaded to Stronghold. Audio of the interview will be deleted after the interviews are transcribed and vetted for accuracy by study staff. Audio recordings obtained through Expiwell will be downloaded and transferred to Stronghold. Audio will be deleted from Expiwell's cloud after it is successfully uploaded to Stronghold. These audios will be deleted from Stronghold after they are transcribed and vetted for accuracy by study staff. Therefore, we will only use deidentified transcripts of all audio data in analysis.

The crosswalk files linking PII to PID will be retained until either a manuscript utilizing the data is submitted for publication or for a period of 5 years after study completion (whichever comes first), consistent with institutional policy. This allows for the deletion of a participant's data upon request, at any time prior to dissemination.

Further, participants will be asked in the future contact form whether they would be interested in being contacted about future research studies in the lab. For participants who consent to being contacted in the future, we will retain their contact information in a separate file not linked to their PID for up to 5 years, after which point we will destroy the information.

7.2 Data that will be stored for future use will be de-identified and linked to each participant's unique PID. These include (a) Qualtrics survey responses from T1, T2, T3, and weekly assessments; (b) data from wearable devices (e.g., sleep duration, sleep activity); (c) study participation records (e.g., timestamps of survey or EMA completions and other adherence information); (d) de-identified transcripts of exit interviews and EMA voice recordings; and (e) de-identified data collected during Zoom screening interview (collected after consent). The password-protected file linking PID to participant name (described in Section 17.2) will also be destroyed 5 years after study completion.

7.3 Representatives of the institutional IRB or regulatory agencies may request to inspect all documents and records related to the study by contacting the study PI.

8.0 Sharing of Results with Subjects

8.1 Results will not be shared with the subjects of this study.

9.0 Study Timelines

9.1 Each participant will be involved in the study for approximately 3-4 months, including eligibility screening, baseline assessment, 4-6 weeks of intervention with daily EMA/EMI, post-intervention assessments, and a 3-month follow-up. We anticipate enrolling participants over a 2–3-month period. Primary analyses and study completion will be completed 6 months post data collection.

10.0 Inclusion and Exclusion Criteria

10.1 Screening survey: Individuals interested in the study will access a Qualtrics survey via recruitment links. The survey will be developed based on the study's inclusion and exclusion criteria (except for imminent risk of suicide and current Major Depressive Episode, which will be assessed during the Zoom screening interview). Scores on screening measures within the survey will be calculated in real time using Qualtrics' scoring feature—if a potential participant's score meets the study's inclusion threshold (see section 10.2), the survey flow will set an embedded variable ("eligible") to true; otherwise, it will be set to false. Statement addressing the legal concerns of underage consumption of alcohol and illegal substance use has been added to the screener.

Individuals who meet the eligibility criteria will be redirected to a separate Qualtrics form where they can review the Informed Consent Form (ICF) and complete a contact form, which will collect their full name and email address. These individuals will also be asked if they would like to be notified for future research. Please refer to the document named "Compiled measures_GEM.docx" for the screening survey, contact form, and future contact form. A trained research staff will then follow up with the eligible participants to schedule a Zoom-based screening interview.

Zoom screening interview: The interview will take 15-30 minutes to complete and will serve the following purposes: (a) confirm participant eligibility and identity by participant showing any form of ID including photo, name, and age; (b) review informed consent form; (c) review study procedures and answer any questions the participant may have; (d), screen for current Major Depressive Episode and imminent risk of suicide; and (e) inform the participant (if eligible and interested to enroll) of the next steps, which includes the next Zoom call meeting for baseline assessment and onboarding (refer to section 6.2). At the beginning of the screening call, RA will remind participants that if they disclose information indicating imminent risk of serious harm to themselves or others, this information must be reported to relevant law enforcement or other authorities. The RA conducting this interview will use a Qualtrics survey with the questions/measures that need to be administered (e.g., the MINI-Major

Depressive Episode module or the suicide screener), which will serve as their guide during the interview. The qualtrics survey will be accessed only by the RA (i.e., the survey won't be sent directly to the participant) and filled out by the RA as the interview progresses. The Qualtrics data will only be linked to the participant ID number (deidentified only) and will be kept in a secure location with other de-identified data. Please refer to "ICF Checklist_GEM.docx" for a full list of screening questions that will be asked, including screening for current Major Depressive Episode and suicidal ideation. To mitigate confidentiality risks and risk of third-party participants, participants will be instructed to complete the procedure in a private location. Participants will be reminded to pause the assessment if another person enters the space. Please refer to the document named "Compiled measures_GEM.docx" for the general structure of the interview and "ICF Checklist_GEM.docx" for more detailed interview guide to be used by the RA conducting the interview.

For participants who report suicidality in the MINI-Standard: Major Depressive Episode module or during the suicide screener, the suicide safety assessment and plan will be followed accordingly (refer to document named "Suicide Safety Plan_GEM.docx). Because all eligible participants at this point will have only mild to moderately severe symptoms of depression (individuals with severe symptoms are screened ineligible at the Qualtrics screener survey), there is low likelihood that a participant will be at imminent risk of suicide; however, the suicide safety assessment and plan has been developed out of an abundance of caution.

The Suicide Safety Assessment and Plan will be conducted by Dr. Shufang Sun, a licensed psychologist and the principal investigator of the study, or by a study team member who has been formally trained by Dr. Sun and operates under her direct supervision and oversight, consistent with existing clinical trial protocols for NIH-funded studies in the lab. All study personnel will receive training from Dr. Sun on identifying and responding to suicide risk. In addition, Dr. Sun will be on-call and will be notified immediately of any safety concerns.

10.2 Inclusion criteria:

(1) Age 18-24
(2) Reside in the US
(3) Experiences of psychosocial forms of early life adversity, defined as saying yes to at least one of these following questions:
    - Did you ever miss school due to fear of being bullied?
    - Were you ever injured or threatened with a weapon or otherwise assaulted by a peer at school?
    - Were you ever physically attacked, hit, hurt, or injured by a parent, primary caregiver, or guardian?
    - Were you ever touched sexually against your wishes or forced to touch someone else sexually?
    - Were you ever forced to engage in sexual intercourse?
    - Were you ever forced to have sex or were you ever sexually abused (e.g., being touched or fondled by an adult?)

(4) Experience more than minimal symptoms of anxiety (GAD-7 score of 5 or higher) and/or mild to moderately severe depression symptoms (PHQ-9 score between 5–19)
(5) Not currently in mental health treatment
(6) Being willing to answer 3-4 short surveys daily, each 2-5 mins
(7) Being willing to engage in recommended daily mindfulness practices for 4-6 weeks
(8) Have not been extensively exposed to mindfulness, defined as meditation retreat experience, consistent mindfulness practice (> once/week) within the past 6 months, or prior participation in a mindfulness course/program

Exclusion criteria:

(1) At imminent risk of suicide
(2) Have a history of psychotic disorder (e.g., schizophrenia) or psychotic episode
(3) Have a current diagnosis of Major Depressive Disorder
(4) Meet the criteria for Major Depressive Episode based on the MINI-Major Depressive Episode module at screening
(5) Score 20 or higher on Alcohol Use Disorders Identification Test (AUDIT) at screening
(6) Score 25 or higher on Drug Use Disorders Identification Test (DUDIT) at screening
(7) Have ever been diagnosed with bipolar disorder

10.3 We will not include any of the listed special populations in this research.

11.0 Vulnerable Populations

11.1 N/A

12.0 Local Number of Subjects

12.1 We anticipate enrolling 44 *participants in the single-arm trial.*

12.2 A larger number of young adults will be screened for eligibility, and 44 participants will be recruited to enroll in the single-arm trial. From these 44 participants, we aim to have at least 35 participants (i.e., approximately 80%) who complete all intervention procedures and follow-up assessments. Screening more participants ensures that we can meet the target enrollment despite ineligible candidates, and enrolling more ensures that we collect enough data points even with potential withdrawals.

13.0 Recruitment Methods

13.1 We will implement a nationwide, remote recruitment strategy using a multi-pronged approach. Potential participants will be recruited over a 2-3 month period from various recruitment sources: (1) providing IRB approved recruitment materials (see section 13.4) to CAB members for them to distribute to their social networks and post on their social media accounts; (2) posting recruitment materials on online social media, such as Facebook-based community groups, Reddit threads, X, etc.; (3) targeted recruitment through OpenClinica (also formerly known as BuildClinical and vetted and approved by Brown OIT; OpenClinica is a specialized service that uses targeted digital outreach and pre-screening to connect

researchers with qualified participants by running data-driven digital advertising campaign across their digital network;); (4) sending emails to university/college campus groups, community-based organizations, and partner health groups (e.g., Project Weber/RENEW)—the email will include the recruitment material and a script, which the organizations can use to share information directly with potentially eligible participants (e.g., via email) or post the materials on their community channels (e.g., newsletters, listservs, websites); and (5) sharing study information on Today@Brown, a daily email delivered to all students, faculty and staff at Brown (also refer to Today@Brown_GEM.docx for language). Specifically, OpenClinica's involvement in recruiting is in digital outreach (e.g., using targeted digital ads through their pre-existing channels). It connects researchers with potential participants by engaging and generating leads from individuals interested in the study, and these individuals will be provided with link to the study team's Qualtrics survey screener. Therefore, OpenClinica itself will not have any access to identifiable information or the screening survey, independently perform consent, make screening decisions, or enroll participants into the study; instead, those will remain as functions of the research team, per the screening protocol described in this document. Please refer to the document titled "Recruitment Email Drafts_GEM.docx" for the email draft as well as the written script, which will be used to explain the study purpose and procedures.

13.2 The source of participants will be local and online communities where individuals with lived experiences of early life adversities and mental health challenges may be present. These communities include, but are not limited to social networks, LGBTQ+ groups, foster care and youth residential programs, and networks that provide support for survivors of abuse and violence.

13.3 Potential participants will be identified by having them self-report their age, experiences of early life adversities, and depression or anxiety symptoms through the screening Qualtrics survey. The research team will contact individuals for further screening (i.e., schedule Zoom screening interview) if they are deemed potentially eligible from the screening survey (see Sections 10.1 and 10.2).

13.4 Other than the email draft and written script described in Section 13.1, recruitment materials will include flyers and graphics for social media posts. Each material will provide a brief study description, eligibility criteria, and contact information. Please refer to the files titled "Recruitment_GEM.docx" for flyers and social media graphics. Furthermore, recruitment materials created by OpenClinica will be submitted to the IRB for review when they are created, after a contract is finalized.

13.5 Participants will only be compensated for the study components that they choose to complete. If a participant withdraws from the study early, they will not be compensated for the study components that are incomplete. Compensation will be provided through Amazon gift cards. Total possible compensation for participants is $168:

Study Procedure	Compensation	Compensation period

Baseline assessment (T1)	$25	Paid after survey completion
Ecological momentary assessment (during the first 4 weeks of intervention period; i.e., recommended modules)	Maximum of $56: *$2/day for completing at least 2 of 3 daily EMA prompts over a maximum of 28 days (i.e., 4-weeks)*	Paid in a single installment at the end of Week 4
Weekly assessments (during the first 4 weeks of intervention period; i.e., recommended modules)	Maximum of $12: $3 for completing each assessment, once a week over 4 weeks	
Post-intervention assessment (T2)	$25	Paid after (1) survey/interview completion AND (2) Fitbit device is returned to the study team
Exit interview (T2)	$25	
Follow-up assessment (T3)	$25	Paid after survey completion

14.0 Withdrawal of Subjects

14.1 Circumstances under which participants will be withdrawn from the research without their consent include significant cognitive impairment, psychosis, and/or imminent suicidal risk.

14.2 In the event of withdrawal, the study staff will debrief the participant, provide mental health resources if needed, and provide guidance for safely discontinuing participation (e.g., closing out their application account) and instructions for returning any study-provided materials (e.g., Fitbit devices).

14.3 When a participant withdraws from research, they may request their data to be deleted. Compensation will be provided based on completed study assessments; they will not be compensated for the study components that are incomplete. For participants who partially withdraw with continued data collection, only agreed-upon assessments (e.g., only EMAs) will continue to be used to gather data on study experience, acceptability, and feasibility. If they partially withdraw before the exit interviews are conducted, they will still be contacted and be invited to participate in the exit interview.

15.0 Risks to Subjects

15.1 Meditation-related risks: The National Center for Complementary and Integrative Health (NCCIH) states that meditation is generally safe for healthy people, but that adverse effects have also been reported. 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. 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. The frequency of serious adverse effects in the context of MBIs is estimated to be less than 1%, although adequate estimates are not available.

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 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,” we expect that the risk will be low.

Loss of confidentiality: Confidentiality will be maintained by using deidentified data sets. All electronic data files containing identifying information will be encrypted with cloud-based software. Although these measures have been taken to protect participants’ personal information and the likelihood of loss of confidentiality is minimal, complete confidentiality cannot be guaranteed when transmitting information over the internet. All information obtained from participants will be accessible only to research staff.

Risks Related to Wearable Devices: Wearing the Fitbit device may cause minor physical discomfort (e.g., skin irritation) or inconvenience in daily routines.

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

15.2 N/A

15.3 N/A

15.4 N/A

16.0 Potential Benefits to Subjects

16.1 Potential benefits from participating in the research include (a) increased awareness of daily mood, stressors, and present experience through EMAs; (b) development of a personal mindfulness meditation practice, which may help participants develop healthy coping strategies, improve emotion regulation, and reduce stress; and (c) practice of identifying and attempting behavioral change, which may lead to improvements in mental health indicators such as anxiety, depression, and loneliness. While the magnitude and duration of these benefits may vary by individual, participation offers the opportunity for personalized insight into their own behavioral and emotional patterns as well as skill-building.

16.2 N/A

17.0 Data Management and Confidentiality

17.1 Quantitative data will be analyzed using a combination of descriptive and inferential statistics. Feasibility and acceptability data (e.g., CSQ-8 and SEF scores, proportion of completed EMA prompts, engagement metrics such as weekly practice rates and frequency of practice use) will be summarized using means and standard deviations. Preliminary effects on other primary, secondary, and exploratory outcomes (e.g., depression, anxiety, sleep quality, emotion regulation, mindfulness) will be evaluated using repeated measures analyses, such as mixed-effects models, to characterize effect sizes (e.g., Cohen's d). We will use mixed-effects modeling with time as fixed effect and participant as random effect to model trajectories, incorporating baseline covariates, to account for within-subject correlations across time points. EMA data will be analyzed using mixed-effects models to assess within-person day-to-day associations between stress and intervention engagement.

Qualitative exit interview data will be transcribed using Dedoose, deidentified, and analyzed using thematic analysis. Framework analysis, a structured qualitative analysis method, will be used. We will follow a standard procedure, including (1) data familiarization, (2) deductive coding based on relevant research questions and inductive coding emerging from the data, (3) development of a framework of codes specific to intervention messages and content, (4) organization of relevant codes into themes, and (5) integration and interpretation of the themes to provide meaning and explanation for the results. Multiple coders will be involved in the data analysis process to ensure analyst triangulation and rigor. We will follow best practices on enhancing rigor of qualitative research, adhere to reporting standards outlined by the American Psychological Association, and demonstrate trustworthiness (credibility, transferability, dependability, and confirmability). Voice recording data will similarly be transcribed automatically through Expiwell's AWS and be verified/deidentified before analysis. Natural language processing will be used for the deidentified transcripts of the voice recordings, for example, to run sentiment analysis to examine changes in participant's emotions over time. To mitigate the risk of recording third-party participant voices, participants in the study will be instructed to complete the voice recording in a private location and to ensure no other individuals are present or speaking during the recording. Participants will be reminded to pause, stop, or restart the recording if another person enters the space.

17.2 Access to documents and records produced with study data will be limited to the PIs, project managers, research coordinators, and other related research personnel. All personnel involved will be required to sign confidentiality agreements and strict confidentiality will be maintained. Files with personal identifiable information (e.g., password-protected file linking PID to participant name, signed informed consent forms, interview recordings, and voice recordings) will be kept in closed network servers (i.e., Brown Stronghold) that only research staff have access to. Specifically for exit interview recordings, the interview will be recorded using the native recording feature on the Zoom platform (i.e., capturing both video and audio recording) and saved to the interviewer's Brown Zoom cloud. The RA

recording the interview will ensure that the setting “Allow cloud recording sharing” is disabled on Zoom. By disabling this setting, nobody other than the person who made the recording will be able to access that recording on the cloud. Therefore, the recording saved to the interviewer’s Brown Zoom cloud will be only accessible to the interviewer creating the recording. An audio-only recording file will then be downloaded from the Zoom cloud to Stronghold, and the original recording will be deleted from the Brown Zoom cloud.

17.3 Data will be monitored regularly for accuracy and cleaned according to set protocols. Standardized protocols will be followed by research staff for all data collection procedures, and regular audits will be conducted. All research staff will be trained in consistent data handling and confidentiality procedures.

17.4 The crosswalk files linking personally identifiable information (e.g., name, contact information) to PID will be stored separately from study data in encrypted, password-protected files and will remain there until either a manuscript utilizing the data is submitted for publication or for a period of 5 years after study completion (whichever comes first), consistent with institutional policy. This allows for the deletion of a participant’s data upon request, at any time prior to dissemination. The same will be applied to the contact information of participants who consent to being contacted about future research studies in the lab--their contact information (not linked to PID) will be retained for up to 5 years, after which point we will destroy the information. All de-identified study data, including survey responses, EMA data (including transcripts of the voice recordings), passive data from wearable devices, and exit interview transcripts, will be linked to a unique PID. De-identified data will be stored on secure, HIPAA-compliant servers at the Brown University School of Public Health indefinitely after the completion of the study. Access to data with personally identifiable information will be restricted to authorized study personnel, including the principal investigator and designated research staff, who are responsible for receipt and storage of data. The de-identified data can be shared with other researchers upon request after signing data confidentiality agreement; this process will be handled by the PI.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 Data collected in this study regarding potential suicidality will be evaluated at each timepoint (i.e., Zoom Screening Interview, T1, T2, and T3) to ensure the safety of participants. Specifically, we will review results of the MINI-Major Depressive Episode module, including participant response for question A3.g in the MINI-Major Depressive Episode module: “Did you repeatedly think about death (fear of dying does not count here), or have any thoughts of killing yourself, or have any intent or plan to kill yourself? Did you attempt suicide?”

The MINI-Major Depressive Episode module will be administered verbally by a research staff conducting the assessment on Zoom call (Refer to Section 6.2 for more details). At any time point, Dr. Sun will be notified of participants who have current Major Depressive Episode according to the module. At screening, if they screen positive they will be provided with

resources and excluded. while those who have current Major Depressive Episode at T1, T2, or T3 assessments will be provided with local mental health resources after the assessment is completed without being excluded from the study (refer to “MINI – Major Depressive Episode Referral Plan.docx”).

Further, as described in “Compiled Measures_GEM.docx”, for any participant saying Yes to question A3.g in the MINI-Major Depressive Episode module, the suicide safety and assessment plan will be automatically triggered through Qualtrics by redirecting the RA to a message telling them to stop assessment and administer the safety and assessment plan (refer to document named “Suicide Safety Plan_GEM.docx). Because all eligible participants at this point will have only mild to moderately severe symptoms of depression (individuals with severe symptoms are screened ineligible at the Qualtrics screener survey), there is low likelihood that a participant will be at imminent risk of suicide; however, the suicide safety assessment and plan has been developed out of an abundance of caution. The Suicide Safety Assessment and Plan will be conducted by Dr. Shufang Sun, a licensed psychologist and the principal investigator of the study, or by a study team member who has been formally trained by Dr. Sun and operates under her direct supervision and oversight, consistent with existing clinical trial protocols for NIH-funded studies in the lab. All study personnel will receive training from Dr. Sun on identifying and responding to suicide risk. In addition, Dr. Sun will be on-call and will be notified immediately of any safety concerns. Participants who have active suicide ideation according to the suicide safety assessment will be excluded from the study, and study staff will take actions according to the suicide assessment and safety plan (please refer to “Suicide Safety Plan_GEM.docx”)

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 All participant data will be de-identified and linked to unique study PIDs. Personally identifiable information (names, emails, phone numbers) will be stored separately in a password protected file in Stronghold. Only authorized study personnel will have access to these files. Links for the Qualtrics survey will be tailored to each participant's PID, eliminating the need for participants to provide any identifying information. Furthermore, all study data collected through Expiwell will only be linked to each participant’s PID.

19.2 Participants will be informed that the study data collected will remain confidential and that they may skip any questions or withdraw from the study at any time without penalty. Study staff will use neutral, supportive language during participant interactions and provide clear explanations of procedures. Sensitive topics will be discussed with nonjudgement, and participants will have access to resources and support if needed (e.g., mental health resources).

19.3 The research team’s access will be restricted to team members who have signed confidentiality agreements, including PIs, project managers, research coordinators, and interviewers. Only these authorized personnel will access deidentified datasets and qualitative transcripts. Access to

identifiable information will be managed through Stronghold, which will be used for scheduling interviews or follow-up, will be strictly controlled and limited to necessary staff.

20.0 Compensation for Research-Related Injury

20.1 N/A

20.2 N/A

21.0 Economic Burden to Subjects

21.1 Participation in this study is not expected to impose economic costs on the participants. There can be instances where participants will want to download data-heavy materials from the application. We will encourage them to download these materials in a wifi-supported environment.

22.0 Consent Process

22.1 Informed consent will be an ongoing process. Participants will first be presented with the IRB-approved ICF at the time of initial online screening, which will describe the purpose of the study, procedures to be followed, and the risks and benefits of participation. 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. Consent will be documented electronically within the Qualtrics survey; participants must confirm electronically that they have read and understood the ICF before beginning study activities. The consent process will continue into the Screening Zoom Interview, where a trained research staff member will review the ICF with the participant and answer any questions they might have (also see section 10.1).

23.0 Process to Document Consent in Writing

23.1 Consent will be documented electronically within the Qualtrics survey; participants must confirm electronically that they have read and understood the ICF before beginning study activities.

23.2 The research presents no more than minimal risk of harm to participants and involves no procedures for which written documentation of consent is normally required outside of the research context. Waiver to obtain written documentation of consent is requested.

23.3 A copy of the Informed Consent Form is attached, under file name “Informed consent form_GEM.docx”.

24.0 Setting

24.1 To fully leverage the potential of mobile health interventions, we will use a national, remote recruitment and participation strategy using social media, online communities, contact with community-based organizations and universities. All procedures, including study onboarding, data collection, intervention delivery, and exit interviews, will be conducted virtually. This remote model enables accessibility across geographic backgrounds.

A community advisory board (CAB) will be formed and be asked to provide input in all stages of research, including informing study protocol, facilitating

results interpretation, and disseminating study findings. The CAB will meet regularly (monthly/biweekly depending on study phase). Two CAB members will be selected and recommended as co-chairs through CAB group discussion, and they will be responsible for preparing meeting agendas and providing a discussion summary to the research team. The investigative team will be present at the start of the CAB, and a team member (e.g., study coordinator) will attend CAB meetings as needed (e.g., to present the measurement package and solicit feedback). Consistent with our team's practice, members will be compensated for their time, and we will involve CAB in dissemination (e.g., co-writing certain products, authorship and/or acknowledging their contributions in papers, summary reports, etc.) as a capacity building activity.

25.0 Resources Available

25.1 The research team will have full access to the Brown School of Public Health's facilities and core resources, including dedicated office space at 155 South Main Street, Providence, RI 02903, data management support, and access to any additional necessary tools and infrastructure. The feasibility of recruiting 44 participants within 2 months is made possible through the team's past experiences and subsequent development of rigorous protocols regarding outreach (via social media, online communities, universities, and 300+ community-based organizations from previous research). The study is expected to be completed within a one-year period from the start date. Brown University IRB will be notified after study completion. This notification will include a final report summarizing the study findings, protocol adherence and other related documents. Any protocol deviations will be recorded and reported promptly. Oversight of internal monitoring of the participants' safety will be conducted by the PI, Dr. Shufang Sun, who is a licensed psychologist. Researchers involved in this study will receive appropriate training regarding study procedures from team members with experiences conducting clinical trials and have their CITI training completed before beginning the study.

26.0 Multi-Site Research

26.1 N/A

26.2 N/A