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CONSENT FOR RESEARCH PARTICIPATION

Growth, Empowerment, and Mindfulness (GEM): Pilot Trial of a Mindfulness-based Intervention to Address Mental Health in Young Adults with Early Life Adversities
Version 2, January 13, 2026

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary. We provide the key information regarding our study below; more detailed information can be found in the rest of the document.

- PURPOSE: In this study, we are examining an app-delivered mindfulness intervention, 'Growth, Empowerment, and Mindfulness' (GEM), tailored for young adults with early life adversities (ELA; e.g., bullying, or sexual or physical abuse during childhood). We are particularly interested in the feasibility, acceptability, and preliminary efficacy of the intervention, as well as how GEM can offer support for young adults with experiences of ELAs and its negative mental health consequences.
- PROCEDURES: If enrolled in the study, you will be asked to complete various study components over the course of 3-4 months. These study components include three online surveys each averaging 60-90 minutes and taking place (1) at baseline (prior to the intervention), (2) post-intervention (after the first 4 weeks of the intervention are completed), and at (3) 3-months post-baseline. You will also be asked to take part in a 4-6-week mindfulness course, which will include modules of audio recordings and text as well as weekly 1-hour Zoom sessions. During the first four weeks of the said mindfulness course, you will also be asked to complete three ecological momentary assessments per day spread throughout the day (i.e., one in the morning, afternoon and at night), followed immediately by a 5-10 minute mindfulness exercise; weekly online survey, each averaging 4-5 minutes; and collection of sleep data through Fitbit. Lastly, you will also be invited to complete semi-structured exit interviews at post-intervention timepoints. You will also attend an onboarding meeting with an RA over Zoom to install the study application, review how to use a FitBit, and solve any logistical issues.
- TIME INVOLVED: The study will take up to 32.1 hours of your time, spread across 3 months
- COMPENSATION: You will receive up to $168 for your time, contingent on the completion of the study procedures.
- RISKS: While participating in the intervention, you may experience meditation-related risks such as re-experiencing traumatic memories, dissociation, and/or headaches. Additional risks include experiencing psychological distress, loss of confidentiality, and risk related to wearing a wearable device (i.e., Fitbit)

- BENEFITS: Benefits of participating in this study will vary depending on the individual, but some common benefits include: increased awareness of daily mood, development of a personal mindfulness practice, and identification and attempt to modify behavior.
- 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.

1. Researcher(s):

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2. What is this study about?

The purpose of the study is to investigate the effectiveness of an app-delivered mindfulness intervention for young adults with early life adversities. We are seeking to determine how feasible, acceptable, and successful this intervention is for addressing the mental health and emotional regulation challenges often experienced by young adults in this demographic. Additionally, this study aims to better understand the mechanisms of change underlying the mindfulness intervention, especially focusing on the role of mindfulness (i.e., interoceptive awareness and de-centering), rumination, and sleep.

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You are being asked to be in this study because you are between the ages of 18-24, live in the United States, and have experienced early life adversity.

3. What will I be asked to do?

There are several components to this research study (refer to the Table on p.5 for an overview of all study procedures and the estimated time involved).

1. *Screening.* There are two distinct steps to determining whether or not you are a good fit for this study.
    a. First, you will 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 15 to 30-minute Zoom-based video screening, during which RA will confirm your eligibility and willingness to participate in 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 eligibility (e.g., by verifying your age and that you live in the US).
2. *Survey 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 60-90 minutes and includes questions concerning your mental health and physical health, and possible childhood trauma and abuse. You will be asked to complete this online assessment on a Zoom meeting with an RA, for you to ask any questions as they come up during the assessment. You will be asked to complete a similar online assessment (minus any information that does not change over time; e.g., your demographic information) up to two other times: after the first four weeks of the intervention and at 3-months follow up.
3. *Onboarding Session.* Additionally during the Zoom call for baseline assessment, the RA will support you in (a) reviewing how to use a FitBit, (b) installing the study application, and (c) solving any logistic issues.
4. *Study Materials.* Prior to the start of the program, we will mail you a wearable device (i.e., Fitbit) and a brief description and purpose of the device. We will ask for your mailing address at the time of the online screener. Your name and address will be shared with departmental operations staff at the Brown School of Public Health through password-protected files to facilitate mailing the Fitbits to you.
5. *Study Intervention and Description.* This is a single-arm, feasibility trial. If enrolled into the study, you will all receive the Growth, Empowerment, and Mindfulness (GEM) intervention:

    Mobile application. You will complete the intervention through Expiwell, a

mobile application native to iOS and Android. The intervention will include 4 weeks of recommended learning modules followed by 2 weeks of bonus modules that you can opt to complete. Each week, you 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 additional 'tailored' modules, specifically on the topics of minority stress and trauma if you have an interest for these topics. On Expiwell, you will also have access to a list of all mindfulness exercises that have been taught each week.

Weekly practice session. In addition to the weekly modules, you will take part in a weekly, 1-hour "Group practice and connect" session on Zoom for the first 4 weeks of the intervention. The online sessions will comprise a cohort of 5-10 participants (depending on recruitment) and will be led by a peer facilitator, who has previous experiences with mindfulness programs as well as lived experiences of early life adversity. During each session, you will be invited to participate in a group practice and reflection and to join group discussions on experiences regarding past week's practice.

6. *Ecological momentary assessments and interventions (EMAs and EMIs).* Over the course of the Recommended Modules (i.e., first 4 weeks of intervention period), you will also complete three EMAs, immediately followed by EMIs everyday through Expiwell. EMA and EMI will be delivered concurrently; the EMA will collect your response on your current mood, recent stressful experience, and type of stressor; you will then receive a list of mindfulness exercises, which will be tailored to the type of stressor/emotion you will have indicated (i.e., EMI). The last EMA of the day will also include an option for you to submit a voice recording, serving as a "daily journal" at the end of the day to understand your daily experiences, including daily stressors and mindfulness practice application.
7. *Weekly assessments.* Over the course of the Recommended Modules (i.e., first 4 weeks of intervention period), you will also be asked to complete an online survey once a week. Each survey is expected to take around 4-5 minutes and includes questions concerning your mental health, coping strategies, and awareness.
8. *Exit Interviews.* After completion of the GEM program, you 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. In line with previous studies, the exit interviews will be recorded using the native recording feature on the Zoom platform to the interviewer's Brown Zoom cloud (i.e., capturing both video and audio recording). 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 a secure, closed network server that only research staff have access to, and the original

recording will be deleted from the Brown Zoom cloud. Exit interviews will then be transcribed for research purposes, and the recordings will be destroyed once the transcriptions are complete. The transcriptions and coded data will not contain any personally identifiable data (just your deidentified participant ID number that's generated for the purposes of this study).

Timeline and Outline of Study Procedure	Estimated Time Commitment
Online Screener (already completed)	5-10 minutes
Zoom Screening Interview - video conference call	15-30 minutes
Baseline online assessment and onboarding call	90-120 minutes
Growth, Empowerment, and Mindfulness Intervention	**Intervention:** 5-11 modules each week, which are about 4-5 minutes each; 20-55 minutes a week, for 6 weeks: 2 to 5.5 hours total **Ecological Momentary Assessments and Intervention:** 3 EMA/EMIs per day, with each taking 5-10 minutes for 28 days: 7 to 14 hours total Weekly Assessments: 4-5 minutes every week for 4 weeks: 16-20 minutes total **Weekly Sessions:** 1 hour session each week: 4 hours total
Exit Interview conducted via Zoom	90-120 minutes
Post-intervention assessment – online survey while on video conference call	60-90 minutes
Follow-up assessment – online survey while on video conference call	60-90 minutes

Total Estimated Time	**Up to 32.1 hours spread across 3 months**

4. Will I be paid?

You will be paid up to $168 for participating in this study, in the form of Amazon gift cards. You will only be compensated for the study components that you choose to complete. If you withdraw from the study early, you will not be compensated for the study components that are incomplete.

Below is the list of study procedures, along with their corresponding compensation.

- Completion of the assessments through Qualtrics, at baseline, post-intervention, 3-month follow-up - $25/assessment - amounting to a total of up to $75
- Completion of exit interview - $25
- EMA participation during the first four weeks of intervention period - $2/day for completing at least 2 of 3 daily EMA prompts - amounting to a total of up to $56
- Weekly assessments during the first four weeks of intervention period - $3 for each survey – amounting to a total of up to $12

Compensation will be provided after each relevant component is completed. For the EMA and weekly assessments that occur during the intervention period, compensation will be provided in a single installment at the end of Week 4. For post-intervention assessment and exit interview (both happening at T2), compensation will be provided once the research team has received the returned Fitbit device.

Below is a table overview of compensation and compensation period.

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

5. What are the risks?

The risks to you for taking part in this study may include:

1) Meditation-related risks: The National Center for Complementary and Integrative Health (NCCIH) states that meditation is generally safe for those who are healthy, but there may still be some risks. Some more common and less serious side effects individuals who are participating in an MBI or mediating for less than an hour have reported are: an increase in depression, anxiety, or panic; re-experiencing of traumatic memories, dissociation, executive dysfunction, headaches, body pain, and insomnia. A few less common but more severe side effects that have been reported include mania, psychosis, and suicidality. The majority of these cases occurred within the context of an intensive retreat longer than 5 hours a day or along with pre-existing psychopathology. The frequency of a serious adverse effect is estimated to be less than 1%, but adequate estimates are not available.

Several actions have been taken to minimize the risks related to meditation at the different states of the study. During the pre-enrollment stage, individuals with severe mental health conditions that could prevent regular class attendance or impact group participation such as symptomatic or untreated bipolar disorder or a history of psychosis are excluded. During the intervention, meditations are relatively short and mixed with dyads and reflections. The development of strategies to work with physical and emotional discomfort is a clear goal of the program.

2) Psychological Distress: During the study, you may potentially experience psychological distress caused by questions during the in-persona and online questionnaires that bring up painful memories or feelings. However, the potential for injury is judged to be minimal. While we expect this risk to be low, you are encouraged to consult with study staff in the case of any increased distress.

3) Loss of Confidentiality: It is possible that the data we collect from you could be lost or revealed. We will do everything we can to protect your privacy. During the study, your data files will be de-identified and encrypted with a cloud based software. Complete confidentiality cannot be guaranteed when transmitting information over the internet, but we estimate the

likelihood of loss of confidentiality is minimal. Oversight of internal monitoring of your safety will be conducted by the PI, Dr. Shufang Sun, who is a licensed psychologist.

If you experience distress at any time throughout the study, please let one of the research staff or interventionist instructors know so that appropriate resources can be provided. The study clinician is also available if you wish to talk to a licensed therapist. Refer to section 10 of this document for study contact information. The procedures can be stopped or paused at any time of the study, and you will not be penalized for doing so. However, if you withdraw from the study early, you will not be compensated for the study components that are incomplete.

Additionally, the screening interview will include some questions about underage alcohol consumption and drug use, including substances that may be illegal, similar to the screening survey you have completed. We will also ask questions regarding your past and current suicidal attempt and ideation in the screening interview as well as at each timepoint (i.e., baseline, post-intervention, and 3-month follow-up). While your responses to these questions are confidential, please note that **if you disclose information indicating imminent risk of serious harm to your self or others, relevant law enforcement or other authorities must be informed.**

6. What are the benefits?

The benefits of participating in this study may vary by individuals. Through participating in this study, you may develop an increased awareness of daily mood, stressors, and present experience through ecological momentary assessments. Establishing a personal mindfulness meditation practice could help you develop healthy coping strategies, improve emotional regulation, and reduce stress. Finally, participating in the practice of identifying and attempting behavioral change may lead to improvement in mental health symptoms such as anxiety, depression, and loneliness. Participating in this study offers an opportunity for personalizing insight into your behavior and emotional patterns and for skill building.

7. How will my information be protected?

We will collect directly identifiable data which will be coded/linked by a participant ID (PID). 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 the baseline, post-intervention, follow-up, and weekly Qualtrics survey; (2) de-identified data downloaded from Expiwell; (3) de-identified interview and voice recording transcripts, with all potentially identifying information removed; (4) data from wearable devices (e.g., sleep duration, sleep activity); and (5) de-identified data collected during Zoom screening interview, which is 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.

The crosswalk files linking your personally identifiable information (e.g., name, contact information) to your unique 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 your data upon request, at any time prior to the publication of study results. The same will be applied to the contact information you have provided, if you agreed to be contacted about future research studies in the lab--your contact information will be retained for up to 5 years, after which point we will destroy the information.

Specifically, for handling of video and audio recordings, 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 a closed network server, and audio will be deleted from Expiwell's cloud after it is successfully uploaded. These audios will be deleted from the closed network server after they are transcribed and vetted for accuracy by study staff. Therefore, only deidentified transcripts of all audio data will be used in analysis.

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 the data will be restricted to authorized study personnel, including the principal investigator and designated research staff, who are responsible for receipt and storage of data. 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.

The survey data collected from you as part of this research study may be used and/or shared for future research. The study team will not share your responses with anyone other than approved researchers who sign the confidentiality agreement. Results from this study will be published, but your information will be anonymized.

A description of this clinical trial will be available on ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

8. 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. Other forms of these alternative therapies are also available in the community.

9. 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 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. We will also provide guidance for safely discontinuing participation (e.g., closing out your application account) and instructions for returning any study-provided materials (e.g., Fitbit devices). Under certain circumstances, you may also be withdrawn from this study without your consent. Specific examples include being at imminent suicidal risk or developing significant cognitive impairment. If you are withdrawn without your consent, you will be compensated for the study components that you have completed.

10. 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 email Taekmin Kenneth Kang (Staff Research Assistant at taekmin_kang@brown.edu) or email the research team at mheal@brown.edu. You may also contact the Principal Investigator at any time, Dr. Shufang Sun at 401-863-5735 or email at 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 website at any time.

11. 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.

12. Consent to Participate

Consenting to participate in this study confirms that you have read and understood the information in this document, are 18-24 years old and that you agree to volunteer as a research participant for this study.