Shift-and-Persist and cardiometabolic markers among women in Puerto Rico: a pilot of mindfulness-based trial

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PROTOCOL TITLE: Shift-and-persist and cardiometabolic markers among women in Puerto Rico: a pilot of a mindfulness-based trial.

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1. Study Summary

Study Title	Shift-and-persist and cardiometabolic markers among women in Puerto Rico: a pilot of a mindfulness-based trial.
Study Design	One arm behavioral intervention
Primary Objective	To evaluate the feasibility and acceptability of a 4-week mindfulness program among young women in Puerto Rico with elevated stress
Secondary Objective(s)	To explore changes in psychological resilience, health behaviors, stress, and cardiometabolic markers
Research Intervention(s)/Interactions	3 study assessments (baseline, post-intervention, 1mo post-intervention) 4-week intervention (1 weekly virtual session)
Study Population	Young women residing in Puerto Rico (18-29y) with elevated stress
Sample Size	30
Study Duration for individual participants	2-4 months
Study Specific Abbreviations/ Definitions	MBSR: mindfulness-based stress reduction
Funding Source (if any)	Emory BIRCWH program

2. Objectives

1. To evaluate the feasibility and acceptability of a 4-week mindfulness program among young women in Puerto Rico with elevated stress
2. To explore changes in psychological resilience, psychological distress, health behaviors, and cardiometabolic markers (blood pressure, pulse, weight, and waist circumference).

3. Background

Cardiometabolic diseases among women in Puerto Rico. The 1.7 million women residing in Puerto Rico (99% identifying as Latinx)[29] experience a great load of cardiometabolic diseases (i.e., adiposity, type 2 diabetes, hypertension, and hyperlipidemia).[1-3] It is estimated that, among women in PR, the prevalence of overweight and obesity is 67.1%, hypertension 39.2%, hyperlipidemia 36.8%, and type 2 diabetes 16.3%, with estimates of obesity and type 2 diabetes being higher than in men.[1] With cardiometabolic diseases driving the majority of deaths and disability in Puerto Rico -including women,[30] the steep

societal and individual cost of these diseases-particularly in the context of Puerto Rico's financial crisis,[31] it is imperative to understand modifiable factors influencing women's cardiometabolic health and guide early prevention efforts.

Psychological well-being and cardiometabolic health. Psychological well-being has gained attention as a protective factor against cardiovascular disease.[4-7] This is of particular importance to women in Puerto Rico as they report greater psychological distress than Puerto Rico men.[1] The protective effect of psychological well-being on cardiometabolic health is believed to partially occur by buffering the effects of stress on health.[8] This is of particular importance to women in Puerto Rico given that stress has been shown to be detrimental to Latinx cardiometabolic health.[33,34] Puerto Ricans in the mainland US have lower psychological well-being, as measured by optimism, than other Latinx heritage groups.[32] Although studies of psychological well-being in Puerto Rico women are scarce, our preliminary work suggests that women on the island also have lower optimism scores than Latinx women on the mainland US (unpublished data). Prioritizing studies on well-being among women in Puerto Rico is of utmost importance given their disproportionate exposure to stressors: a 15 year-long economic crisis, the ravaging 2017 hurricane season (Hurricanes Irma and María) and its subsequent humanitarian crisis, the 2020 sequence of tremors, ongoing political turmoil, and the highest poverty rate in the US, among others.[14-17]

Mindfulness-based Stress reduction programs (MBSR). The high burden of cardiometabolic diseases among women in Puerto Rico,[1] their disproportionate exposure to stressors,[14-17] and potentially low psychological well-being, highlight the need for effective behavioral interventions. The American Heart Association has issued a call to action for studies testing mindfulness-based interventions for cardiometabolic health.[18] At its core, this program empowers participants to develop a profound awareness of the present moment, fostering a deeper understanding of their thoughts, emotions, and bodily sensations. Through mindfulness meditation and a series of carefully crafted exercises, MBSR equips individuals with powerful tools to manage stress, reduce anxiety, and enhance their overall well-being. MBSR consists of an 8 week program with weekly sessions (usually lasting 2.5hrs), daily practice exercises (of 45min duration each) and an end-of-program day-long retreat. MBSR has been shown to improve psychological well-being, with studies documenting greater intervention effectiveness and acceptability for women than men. Additionally, studies have shown that mindfulness-based interventions reduce adiposity and hypertension.[21,23] However, there is limited data on MBSR in Latinx women-less in Puerto Rico. The Puerto Rico population has unique socio-cultural values and norms that merit MBSR to be tested in this group.

MBSR interventions have critical pitfalls, such as time and transportation barriers, that need to be addressed to improve implementation.[29] The only study in Puerto Rico evaluating a MBSR reported time commitment and lack of transportation as barriers to participation.[30] Dr. Rosal and Camrody at UMass Medical School did some preliminary work to address these limitations. They, have adapted the original MBSR to use shortened weekly sessions (1.5- 1hr) and home practice exercises (5-15min).[31] They also selected 4 sessions out of the original 8-week MBSR sessions to shorten the program. This responds to preliminary data from our focus group discussions among young women in Puerto Rico documenting that an 8-week long program with weekly sessions was a burden and would hinder participation.

We took these modifications by Rosal and Camrody and further made adaptations to make the 4-week MBSR program to be delivered virtually. The original 4-week protocol by Rosal and Camrody was already

available in English and Spanish. In the present study, we will test the feasibility and acceptability of the Spanish version 4-week MBSR program among young women (18-29yr) with elevated stress residing in Puerto Rico, and will explore changes in resilience, stress, health behavior, and cardiometabolic outcomes. Testing the Spanish 4-week MBSR protocol in young women in Puerto Rico is needed to evaluate novel strategies that may be feasible and acceptable for this group.

4. Study Endpoints

Primary endpoints:

-Rates of recruitment and retention, adherence, and satisfaction. Adherence will be measured by the number of phone sessions attended and the frequency of self-reported completed home practice, both assessed at post-intervention assessments.
-Ratings of satisfaction, also assessed by survey in post-intervention assessments, will be measured with several questions, including one that reads "Overall, how satisfied were you with the stress reduction program", "How satisfied are you NOW (after the stress reduction program) with your ability to manage the stress in your life?", and "¿How much did the program helped you manage your stress?"
-We will also ask questions on satisfaction of the instructor and group setting: "Did you feel that the other participants cared about the group?", "You felt that the instructor was very knowledgeable about the program", "It was easy for you to communicate with the instructor", and "Did you feel that the instructor cared about you?"

Secondary endpoints:

-Baseline and post-intervention secondary outcome data on cardiometabolic markers (adiposity, pulse, and blood pressure) will be assessed online via self-report and include: changes in weight, pulse, and blood pressure (systolic and diastolic).
-Baseline, post-intervention, and 1-month post-intervention changes on psychological resilience and psychological distress will be assessed through an online survey:

-Psychological resilience: shift-and-persist (Chen et al scale), mindfulness (FFMQ-15), psychological flexibility (Acceptance and Action Questionnaire - version 2 (AAQ-2)).
-Psychological distress: depression symptoms (CESD-10), PTSD symptoms (PCL-2), anxiety symptoms (GAD-7), and perceived stress (PSS-4)
-Health behaviors: emotional eating (TFEQ) and reward-based eating (RBD scale).
-self-reported height, weight, and blood pressure

5. Study Intervention/Design

This is a one-arm intervention study that will explore if a 4-week MBSR program is feasible and acceptable among young women in Puerto Rico with elevated stress. The intervention consists of 4 weekly virtual sessions and daily mindfulness exercises at home (between 5-16mmin of duration each, according to participant's availability). The participants will also complete three study assessments: baseline, post-intervention, and 1-month post-intervention. All study measures at all time points will be done online through questionnaires to be filled out by participants.

6. Procedures Involved

Interested individuals who contact the study (via email or phone/text) for more information and/or provide their contact information through the Google Forms survey (see Google Forms survey document), will be contacted via phone, text or email by our research staff to set up a screening call

(described in detail in the Recruitment and Inclusion and Exclusion Criteria sections). All interested individuals will provide verbal consent prior to screening. A maximum of 10 attempts will be done to contact interested participants for scheduling a screening call.

Eligible individuals will receive the REDCap link (via email or text, according to the participant's preference) leading to the electronic informed consent after confirming eligibility by a research staff. The study personnel will describe the study protocol, discuss the informed consent, and answer any questions. Individuals will then fill out the electronic consent form and will be given access to the online baseline questionnaire (email or text). Study staff will also fill out the contact information form upon completion of consent (see Contact information form), where data on the participant's email, phone number, address and at least 2 emergency contacts will be collected. The survey is meant to be completed by participants on their own, but study staff will be available via phone or email if any question arises. This approach is currently being used in the PR-OUTLOOK study, a study of young adults in Puerto Rico. The PI of the study has also conducted online surveys filled by participants in Puerto Rico during the pandemic (as part of other studies) and got good response rates.

Individuals will receive the 4-week tailored intervention in groups (3 waves of approximately 10 participants each; these may be stacked, overlapping, or following completion of each group, according to the instructor's availability). All weekly sessions will be delivered via Zoom. My team and I have the expertise and are equipped to recruit and implement the telephone-delivered program given our prior virtual studies in Puerto Rico and US Latinxs during the COVID-19 pandemic. Once in the intervention, participants will join one session weekly (on Zoom) and will receive access to online audio files, which are the daily practice exercises to be done at home.

Each session has a duration of 1hr (except the first session which is longer due to introductions and describing the program's logistics and expectations). The sessions follow a brief check-in, lecture on the week's topic, and guided practice. For the audio files, for each exercise, participants will have the opportunity to select a short version of the practice (5-8min) or a longer version (12-16min) according to their daily availability. The following table outlines the 4-week MBSR session topics and daily home-practice exercises.

Session	Topic	Home exercise
Week 1	Orientation; Introduction to stress and its consequences	Awareness of breathing
Week 2	Awareness of sensations	Body Scan
Week 3	Thoughts are not facts	Awareness of thoughts
Week 4	Recap; Mindful eating, mindful walking	Awareness of eating

After completion of the intervention, participants are encouraged to continue doing the mindful daily exercises at home by accessing the audio files. Following the last session, participants will be given access to the online questionnaire for the post-intervention measures, which will include the Contact information form. Research staff will have 10 attempts (via email, text or call) to contact participants and remind them to fill out the questionnaire.

1mo post-intervention, participants will be contacted to complete the third and final assessment, an online questionnaire, which will also include the Contact Information Form. The link to the survey will be

provided and up to 10 reminders (via email, text or call) will be sent out to complete the assessment. The link to this last assessment will be sent out 1-month after completion of the intervention, but at least 3 weeks after the post-intervention assessment.

A weekly reminder will be sent out (the day prior to the session, via text and email) to remind participants to join the weekly Zoom call. Up to 10 reminders (on each occasion, via text, email or call) will be sent out to participants to complete the baseline, post-intervention, and 1mo post-intervention online questionnaire.

All gift cards will be electronic gift cards and the information will be sent out to participants via email or text.

Participants will be notified that all experiences shared during intervention sessions are considered confidential and should not be discussed outside of the group.

The following table shows the different measures being collected at the different time points (also see questionnaire/instruments provided for data collection at baseline, post-intervention, and 1mo post-intervention).

Timepoint	**Baseline**	**Post intervention**	**1mo post intervention**
Socio-demographics			
Age	X		
Gender	X		
Health insurance	X		
Education	X		
Income	X		
Municipality	X		
Food security	X		
SNAP	X		
Marital Status	X		
Perceived income	X		
Employment	X		
Mental health			
Depression (CESD-10)	X	X	X
PTSD (PCL-2)	X	X	X
Anxiety (GAD)	X	X	X
Perceived stress (PSS-4)	NA-included in screening	X	X
Resilience			
SP (Chen et al)	X	X	X
Mindfulness (FFMG-15)	X	X	X
Psychological flexibility (AAQ2)	X	X	X
Health behaviors			

PA (WHI)	X	X	
Perceived sleep qual	X	X	
Diet screener (Mattei et al)	X	X	
Emotional eating (TFEQ R18 V2)	X	X	X
Reward based eating (Reward based eating scale (RED))	X	X	X
Smoking	X	X	
e-cigarettes	X	X	
Clinical characteristics			
Self-reported diagnosis	X		
Medical care for mental health	X		
Medications for mental health	X		
Anthropometrics			
Self-reported blood pressure	X	X	X
Self-reported weight	X	X	X
Self-reported height	x	x	x
Self-reported pulse	x	x	x
Intervention			
Satisfaction		X	
Stress management		X	
Group and instructor environment		x	
Exercise that helped the most		X	X
Exercise most often practiced		X	X
# sessions attended		x	
Frequency of daily practice and duration		X	X
Overall feedback		X	

We have delineated a suicide prevention protocol as explained in section #19 of this document.

7. Data Specimen Banking

No specimens will be collected as a part of this study. Trained study staff will assess the eligibility of participants using a database (Excel or REDCap). Data from study assessments will be directly collected in REDCap. Essential study staff will only have access to the REDCap project and their study roles will dictate what type of access they will have.

8. Sharing of Results with Participants

- Publication of study findings is expected, where data will be published in aggregate and without identifying study participants.
-A summary of the main study results will be emailed to participants upon completion of the study. These results will all be in aggregate and without identifying study participants.

9. Study Timelines

Each participant will participate in three study assessments and in the 4-week intervention. It is expected that each participant will be in the study for about 2-4 months, depending on the timing of the baseline assessment and the intervention initiation, and the timing of the 1-month post-intervention assessment.

Study timeline

Research Activity	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Study Recruitment wave 1 and baseline assessment	X								
Wave 1: 4-week intervention		X							
Study Recruitment wave 2 and baseline assessment		X							
Post-intervention assessment wave 1			X						
1-month post-intervention assessment wave 1				X					
Wave 2: 4-week intervention			X						
Study Recruitment wave 3 and baseline assessment			X						
Post-intervention assessment wave 2				X					
1mo post-intervention assessment wave 2					X				
Wave 3: 4-week intervention				X					
Post-intervention assessment wave 3					X				
1mo post-intervention assessment wave 3						X			
Data analysis					X	X	X		
Manuscript preparation and submission					X	X	X	X	X

10. Inclusion and Exclusion Criteria

Inclusion criteria

- Reporting female sex at birth
- Not identifying as a man, trans man, or trans woman.
- Between the ages of 18-29 years
- Individuals residing in Puerto Rico
- Spanish speaking
- Currently not pregnant
- Elevated stress (defined as a score ≥6 in the Perceived Stress Scale (PSS-4)[34])
- Willing to undergo research activities (focus group discussions).

Exclusion criteria

- Male sex at birth
- Identifying as a man, trans man, or trans woman.
- Currently pregnant
- Previous participation in an 8-week MBSR program
- Younger than 18y or 30y or older
- Experiencing moderately severe or severe depressive symptoms (PHQ-9>15)[35])
- Have active suicidal ideation (PHQ-9 item #9)[35]
- Self-report history of cognitive and psychiatric conditions
- Lack of have access to internet/phone (mode of focus group discussions—via Zoom)

11. Population

We will exclude the following special populations:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Prisoners
- Cognitively impaired or Individuals with Impaired Decision-Making Capacity
- Pregnant persons

We will not include vulnerable populations.

12. Local Number of Participants

We will enroll 30 women.

Given that 99.8% of individuals in Puerto Rico self-report as Hispanic, we expect to enroll Hispanic individuals.

13. Recruitment Methods

Spanish-speaking women between 18-29 y will be recruited through flyers posted/disseminated through social media (e.g., Instagram, Facebook, Twitter) and social pages/accounts. These pages are those from mentors and collaborators outside of Emory University given that Emory pages do not currently have the reach to the population in Puerto Rico. These pages include collaborators that have already worked with the PR in other studies and include: CienciaPR, PR-CEAL, Puerto Rico Public Health Trust, Ciencia en Tus Manos, Estudio PROSPECT, among others. Recruitment flyers will also be disseminated through newsletters and email blasts at academic organizations (not including Emory) including the University of Puerto Rico, Ponce Health Sciences University, and San Juan Bautista School of Medicine, among others.

Additionally, the printed flyer will be distributed (in-person) at community events, health fairs and billboards.

The study flyer includes a study email where interested individuals can contact the study staff for more information and to assess eligibility. The flyer also includes a QR code and its respective link to a Google Forms survey where interested individuals can enter their contact information. Specifically, the Google Forms survey only asks for 1) First and Last Name, 2) phone number and 3) email.

Interested individuals will provide verbal consent (see Verbal Consent document). Afterwards, individuals will be screened for eligibility via phone (see Screening Questionnaire)). Data will be directly entered in the database (REDCap or excel). Screening questions include age, sex, gender, PSS-4, PHQ-9, history of cognitive and psychiatric conditions, prior participation in an 8-week MBR program, currently pregnant, and access to internet/phone:

1- Female sex at birth
2- Not identifying as man, trans man, or trans woman
3- Self-reported age = needs to be between 18-29y
4- Currently residing in Puerto Rico
5- PSS-4 score $\geq$6
6- PHQ-9 scores $\leq$15
7- A negative response to item #9 (“Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?)
8- No self-reported history of cognitive and psychiatric conditions
9- Affirmative response on access to internet/phone
10- No prior participation in an 8-week MBSR program
11- Currently not pregnant

Eligibility will be assessed via stages, first through socio-demographic characteristics (age, sex, gender, pregnancy, place of residence). If the individual does not meet the socio-demographic criteria, then they will be notified that they are not eligible. It they do meet these criteria, they will go through the PSS scale and notified if they are eligible upon scoring their responses. Afterwards, they will complete the PHQ-9 and eligibility will be assessed and notified if they are not eligible. Lastly, questions on criteria #8-#10 will be asked and the participant will be notified of their eligibility status. The staged eligibility screening is done to reduce the number of people exposed to the PSS and PHQ-9 questions if they are not eligible according to the prior criteria. If eligible and interested in participating, the staff will send the REDCap link (via email or text, according to the participant’s preference) leading to the electronic informed consent. The study personnel will describe the study protocol, discuss the informed consent, and answer any questions. Individuals will then fill out the electronic consent form and will be given access to the online baseline questionnaire (REDCap).

14. Withdrawal of Participants

Participants can leave a study at any time without penalty.

The person in charge of the research study, Dr. Andrea López-Cepero, or any of the study representatives designated by her can remove a study participant due to lack of commitment to the

study, hostility or aggressive behavior towards study staff, study discontinuation, or changes in study protocols.

15. Risk to Participants

There may be side effects from the mindfulness program that are not known at this time. The most common risks and discomforts expected in this study are the time commitment for the weekly sessions and the completion of the study assessments. The mindfulness intervention that is being tested may not work for study participants and they may not perceive any benefits from the intervention. Researchers may ask questions about stress and stress management that may upset some participants. Interviewers are trained on cultural sensitivity and how to minimize any discomfort, including handling sensitive questions and emotional reactions. We will provide a toll-free phone number that individuals may call for any emotional or psychological advice or referrals at any time (from línea PAS). Línea PAS is a 24hr 365days/year phone line responding to individuals with suicidal behavior and mental health disorders. It offers crisis counseling and emotional support, screening, psychiatric and psychological evaluation, and referrals (all free of charge). In addition, information on resources to coordinate mental health services will be provided to all prior to completing the screening questionnaire (see Mental Health Services document). Lastly, as with any study collecting identifiable information, there is a risk of loss of confidentiality but every effort will be made to keep all personal information confidential by use of id codes, password protected data files and analysis of de-identified data. Data on criminal or civil records, or any sensitive or personal information that may lead to such, will not be collected.

16. Potential Benefits to Participants

We do not know if all participants will receive personal benefits from taking part in this study.
They may not benefit directly from joining the study. However, the potential benefits could include learning about mindfulness, reductions in stress, and improved emotional well-being. We also hope that the knowledge gained from this study may help others in the future.

17. Compensation to Participants

If all study components are completed, participants will get $100 worth in gift cards to compensate for their time and effort.

-After completion of the first study assessment, they will receive a $25 gift card.

-After completion of the 4-week program and the second study assessment they will receive a $50 gift card

-After completing the third and final study visit (1 month after completion of the program), they will receive a $25 gift card.

If they do not finish the study, we will compensate them for the visits they have completed.

18. Data Analysis, Management and Confidentiality

Baseline descriptive statistics will include frequencies for categorical variables and means and standard deviations for continuous ones. Recruitment, adherence, retention, and satisfaction will be calculated for the total sample and will be explored by sociodemographic characteristics (i.e., age, income, employment, and education level). Changes in each secondary outcome will be evaluated using mixed

linear regression models controlling baseline covariates. We will conduct exploratory analyses among those with high levels of adherence (vs. low). STATA version 17 and SAS version 9.4 will be used.

Sample size considerations are driven by publications regarding pilot study planning. A minimum of 12 individuals per group is recommended for feasibility and precision around the estimates. Other MBCT pilot studies have included a similar sample size. This sample size suits the goals of this study to assess feasibility.

All study staff will be up to date with the Collaborative Institutional Training Initiative (CITI) Human Subjects trainings and will be trained for all protocols, including informed consent and data collection. The research team will maintain all responses and documents confidential. Individuals participating in the intervention will be informed that information disclosed within the intervention sessions is considered confidential and should not be repeated outside of the group. The data collected will only be used for research purposes. Only the research team will have access to the files. The electronic consent form and eligibility criteria will remain stored electronically. Identifiable information will not be shared to anyone and will be kept in a password-protected computer at Emory University and in the PI's OneDrive/SharePoint files.

19. Provisions to Monitor the Data to Ensure the Safety of Participants

The screening and online survey will collect data on psychological distress, resilience, health behaviors, sociodemographic characteristics, and physical measurements (height, weight, waist circumference, and blood pressure), which will be entered real-time in REDCap (HIPPA compliant). The electronic consents and study files will be stored in the PI's (Emory University's) OneDrive and SharePoint platforms (HIPAA compliant). All data and project files will only be accessible by research study members. Access to any study documents are password protected and secure laptops.

Research staff will be trained on identification and report of adverse events. All participants receive an information sheet on mental health resources in Puerto Rico during their screening. The PI of the study will be present in all 4 weekly sessions to assess intervention fidelity. Any reports by participants of minor discomfort or any observations of a potential adverse event, whether directly related to the protocol or not, will be recorded and reported to the IRB in order to determine whether a formal report should be submitted. Serious adverse event will be reported immediately. Participants are those with elevated stress, however, they would be screened out (excluded) if they have major depression symptoms. Regardless, we have designed a suicide safety protocol:

If a participant reports suicidal ideation at any point during the study (e.g., intervention session or study visit), research staff will contact the participant and follow the following steps.

On the Call

Make notes while the participant is speaking.

1. Say, **"I care about your safety – would you mind sharing a little bit more about the thoughts that you mentioned about _____ (tailor according to what the participant expressed, i.e., hurting themselves or thoughts that they would be better off dead, etc.)**
2. If not already clear from what they have said, ask, **"Have you been thinking about how you would hurt yourself or end your life?"**
    a. If no: say, **"Thank you for clarifying – I know these thoughts can be difficult to talk about."** Skip to step 3.

b. If yes: **"Do you have any specific plans to harm yourself at this time?"**
   i. If no: say, "**Thank you for clarifying – I know these thoughts can be difficult to talk about."** Skip to step 3.
   ii. If yes: say, **"It sounds like you've been thinking about this a lot, and I'm sorry to hear that you're struggling with these thoughts. Have you thought about when you would carry out this plan?**
      1. If no, or yes but not within 24 hours: say, **"Thank you for clarifying – I know these thoughts can be difficult to talk about."** Skip to step 3.
      2. If yes within 24 hours: say, **"I appreciate your honesty and for sharing this with me – I want to help keep you safe. Would you be willing to admit yourself to a hospital?"** If the subject is unwilling, call 911.

3. Say, **"Have you ever attempted suicide in the past?"**
   a. If yes: "How long ago was that?"
   b. If no: Skip to step 4.
4. Say, **"Are you currently seeing a therapist or under the care of a psychiatrist?"**
   a. If yes: **"Please contact your provider to let them know how you are feeling so they can follow up with you."**
   b. If no: **"I will send you a list of resources on mental health resources available at no cost to you."** Ask the participant how he/she would like to receive the list (e.g., email, text, mail).
5. Say, **"We do make a record of everyone's answers to these questions, and a study investigator may be in touch to follow up with you."**

After the Call

1. Regardless of the participant's answers, research staff will notify the PI. Research staff will share the participant's name, phone number, and answers to the above questions.
2. The PI will decide on next steps upon consultation with a local (PR based) licensed therapist, such as reaching out to the participant.
3. Research staff will draft a note-to-file summarizing the situation. The PI will review and sign this document.

Lastly, we also collect information on emergency contacts if there ever is a need to contact someone.

20. Provisions to Protect the Privacy Interest of Participants

As previously mentioned, screening and all study data will be stored in the PI's (Emory University's) OneDrive/SharePoint files. Only trained study personnel needing to work directly with the study data will have access to the files and to the REDCap database for research purposes only.

Participants will be instructed to only share things that they are comfortable sharing during the sessions and that everything discussed during the sessions should remain confidential and should not be repeated outside of the group.

The data collected will only be used for research purposes. Study data will be linked using a unique study ID number and identifiers will be removed so there will only be a de-identified

dataset. Identifiable information will not be shared to anyone and will be kept in a password-protected computer at Emory University. Only the research team will have access to the files.

21. Economic Burden to Participants

The is no economic burden to participants as all study components are done online.

22. Informed Consent

Verbal consent, via phone, will be obtained for all interested individuals prior to conducting the study screening questionnaire and after the staff describes the screening process (see Verbal Consent document). Informed consent will be obtained immediately after assessing eligibility of a study participant. Individuals will receive the REDCap link that leads to the electronic consent form. Consent will occur via phone call after the staff discusses the study and consent process. If the individual agrees to participate, they will provide an electronic signature. If technical difficulties arise with participants providing an electronic signature, a check on the "Yes" box following the statement "I consent to participate in the study" will suffice.

Non-English-Speaking Participants

All study materials, including the informed consent will be in Spanish given that is the official language of Puerto Rico.

We will include a Spanish consent form with this protocol submission. This is the Spanish version of the English submitted form. The Spanish consent was translated by the PI, who is a bilingual- native Puerto Rican- with Spanish as her first language. Thus, the PI knows the Spanish dialect needed in the consent form for the population in PR.

Participants who are not yet adults

N/A

Cognitively impaired adults

N/A

Adults unable to consent

N/A

23. HIPAA

Medical records will not be reviewed.

24. Setting

Individuals will be recruited via social media, email blasts (e.g., academic organizations) and in-person dissemination of the flyer. All data will be collected remotely (online questionnaire) with data saved on HIPAA compliant, Emory University-supported servers.

25. Resources Available

The PI has led two studies in PR during the COVID-19 pandemic (December 2020-February 2021; and December 2021-January 2022) with similar recruitment methods. The first study had success in recruiting a sample of 1,945 adults (25% 18-29 y) and the second one recruited 788 adults (36% 18-29 y). The PI also conducted a total of 13 qualitative interviews among adults in PR during the pandemic using Zoom and obtaining electronic consent via REDCap (study based when the PI was at Harvard School of Public Health). Most importantly, the PI conducted focus groups as part of her KL2 BIRCWH Program at Emory (Aim 2 of the proposal; the submitted study is Aim 3 of the KL2 project). We used the same recruitment methods and eligibility criteria formulated for the present study. Of the 41 women screened, 18 (44%) were eligible. The recruitment rate was 83% (n=15). Only one participant was unable to join a focus group discussion, thus a total of 14 women joined one of four distinct focus group calls.

The intervention will be delivered by a MBSR instructor at the Instituto de Mindfulness. The instructor (Delia Roman) is a mindfulness facilitator at schools, non-profit organizations and private companies in Puerto Rico. She is a certified trained teacher of the Mindfulness in Schools Project curriculum, she uses Mindful Schools' curriculum to teach at schools. Through Insight In Action she facilitates mindfulness in the PR Multiple Sclerosis Foundation, PR Youth at Risk, and "Caras con Causa". Below are her certifications:

-Certification as a Mindfulness facilitator from the Awareness Training Institute, UC Berkeley, 2018-2020.

-Certification as a Mindfulness instructor from the Mindfulness in Schools Project, .B curriculum, July 2015, New York.

-Mindful Schools, Curriculum Training/ Bring Mindfulness To Youth Program, 2015. Training in mindfulness curriculum for students from kindergarten to teenagers.

-Mindfulness-Based Stress Reduction (MBSR), Online Training, 2015. Certified MBSR practitioner.

26. Multi-Site or Collaborative Research

NA.

27. References

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28. Protocol Checklist

Please note that protocol sections with an asterisk (*) should always be included in the protocol; if the section does not have an asterisk, and you have not included the section in the protocol, the IRB will consider it your attestation that the section does not apply to your study.

Protocol Section	**Added to the protocol?**
External Collaborators- if applicable, add each external collaborator information and indicate whether that institution's IRB will review (or has already reviewed) that individual's engagement in human participants research activities)	☒ **Yes**

Funding Source*: Include the information for the funding entity for this study. Please explain if this study is covered by a sub-award or other pertinent information. Say "department" if you do not have any other funding.	☒ **Yes**
Objectives*: Describe the purpose, specific aims, or objectives and state the hypotheses to be tested	☒ **Yes**
Background*: Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Describe any relevant preliminary data or knowledge to be built upon in this study. Examples of issues to address are cultural expectations, political conditions, economic conditions, disease prevalence/incidence, environmental factors. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Include any other non-research rationale for the work, if this study is a mix of non-research and research	☒ **Yes**
Study Endpoints: Sample: provide some information about the data set that the research team will be analyzing.	☒ **Yes**
Study Intervention/Design*: Describe the study intervention that is being evaluated, and/or the nature of interactions proposed.	☒ **Yes**
Procedures involved*: Describe and explain the study design in more detail. Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks. Procedures performed to lessen the probability or magnitude of risks.	☒ **Yes**
Procedures-Source Records*: The source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms in the smartform on the "Study-Related Documents" page under "Other Attachments." If unable to attach data collection instruments due to copyright requirements, include a description of the instrument in the protocol document	☒ **Yes**
Procedures-Data collection*: What data, specifically, will be collected during the study, and how that data will be obtained. If audio/video-recordings will be generated, describe processes for transcribing audio/video recordings. Will audio-recordings be destroyed after transcription? If so, how long after transcription? If not, how will they be kept secure? If video-recordings will be used beyond the current research procedures for educational/presentation purposes.	☒ **Yes**

Procedures- Long Term Follow Up*: If there are plans for long-term follow-up (once all research-related procedures are complete), what data will be collected during this period.	☒ **Yes**
Procedures-Deception: Does the research design require subjects to be deceived? Describe and justify the need for deception. Describe the plan to debrief participants after study participation is completed. Will the subjects be exposed to any stress? Describe and justify the need for stress.	☐ **Yes**
Data and Specimen Banking: If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens. List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.	☒ **Yes**
Sharing of Results with Participants*: Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.	☒ **Yes**
Study timelines*: Describe the duration of an individual subject's participation in the study, the duration anticipated to enroll all study participants, and the approximate total duration of the overall study	☒ **Yes**
Population and Inclusion/Exclusion Criteria*: Describe how individuals will be screened for eligibility; the criteria that define who will be included or excluded in your final study sample; and indicate specifically whether you will include or exclude each of the following special populations: • Adults unable to consent • Individuals who are not yet adults (infants, children, teenagers) • Pregnant women • Prisoners Note: you cannot exclude people with limited English proficiency unless you can demonstrate the scientific need for such exclusion. Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?	☒ **Yes**

Research with pregnant women, fetuses, or neonates: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☒ **Yes**
Research with neonates of uncertain viability: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☒ **Yes**
Research involving prisoners: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☒ **Yes**
Research involving children: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☒ **Yes**
Research involving cognitively impaired adults: review this checklist to verify you have provided enough information to ensure the safety and well-being of this population.	☒ **Yes**
Research involving economically or educationally disadvantaged persons: describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects	☒ **Yes**
Local Number of Participants*: Indicate the total number of participants to be accrued locally. If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.) Provide your projected enrolling goals, including the percentage of participants according to sex and race.	☒ **Yes**
Recruitment Methods*: Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants. Describe the source of participants. Describe the methods that will be used to identify potential participants. Describe materials that will be used to recruit participants. (Attach copies of these documents in Smartform on the "Study-Related Documents" page under "Recruitment material templates." with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.) How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier). If recruiting online, describe how potential participants would be directed to your recruitment information and study description.	☒ **Yes**

If using contests or raffles as an incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law. If recruiting online, describe how potential participants would be directed to your recruitment information and study description. All research recruitment through social media needs to follow this guidance, which does not allow the use of personal social media accounts for some recruitment activities	
Withdrawal of Participants*: Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.	☒ **Yes**
Risk to Participants*: List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Include risks of loss of privacy or breach of confidentiality. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not participants. Do not state that there are no risks.	☒ **Yes**
Potential Benefits to Participants*: Describe the potential benefits that individual participants may experience Indicate if there is no direct benefit. Do not include benefits to society or others. Describe areas of knowledge that would be strengthened. Compensation should NOT be stated as a benefit.	☒ **Yes**
Compensation to Participants*: Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early?	☒ **Yes**
Data Analysis, Management and Confidentiality*: Describe the data analysis plan, including any statistical procedures or power analysis. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical	☒ **Yes**

controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.	
Describe how data or specimens will be handled study-wide*: What information will be included in that data or associated with the specimens? • Where and how data or specimens will be stored? • How long the data or specimens will be stored? • Who will have access to the data or specimens? • Who is responsible for receipt or transmission of the data or specimens? • How data or specimens will be transported?	☒ **Yes**

Data Monitoring and Participants Safety
(if this study is no more than minimal risk, this section is not required)
• Ensure that you review our Data and Safety Monitoring plan guidance for specific details about this section, and examples of what the IRB will be requiring according to the level of risk.
• If a DSMB is needed, please describe the composition of the board (if not already detailed in the protocol). Review this guidance for more information. If the sponsor protocol does not contain all required information, please in this section.
• Describe the plan to periodically monitor the data at the site level, and if you have international sites.
• Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.
• Please address the specific details below. If deemed not applicable, please provide rationale:
• Subject safety:
  ○ Specific subject safety parameters
  ○ Frequency of subject safety observations
  ○ Individual responsible for safety monitoring
  ○ Subject stopping rules – under what conditions will a subject be removed from study participation and who will make the decision?
  ○ Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision?
  ○ Reporting mechanisms (i.e. Deviations, adverse events, UPs)
• Data Integrity:
	☒ **Yes**

○ Specific data elements to be reviewed ○ Frequency of monitoring data, points in time, or after a specific number of participants ○ Individual responsible for data monitoring	
Provisions to Protect the Privacy Interests of Participants*: • Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or whom they provide personal information. • Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures. • Indicate how the research team is permitted to access any sources of information about the participants.	☒ **Yes**
Economic Burden to Participants*: Describe any costs that participants may be responsible for because of participation in the research.	☒ **Yes**
Informed Consent*: Describe where the consent process will take place, any waiting period available between informing the prospective subject and obtaining the consent; and the process to ensure ongoing consent. Describe the role of the individuals listed in the application as being involved in the consent process; the time that will be devoted to the consent discussion; steps that will be taken to minimize the possibility of coercion or undue influence; and steps that will be taken to ensure the participants' understanding. Note: If you are planning to obtain consent via electronic signature, please review this document. Additional guidance on consent documentation and process can be found on our website, under the consent toolkit.	☒ **Yes**
Consent Process-Non-English-Speaking Participants*: Indicate what language(s) other than English are understood by prospective participants or representatives. If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. If you checked N/A, please provide reasoning of why subjects with limited English proficiency are excluded.	☒ **Yes**

Note: if you stated that subjects with LEP will be enrolled, you are approved for the use of the Emory IRB short forms. Please read the guidance about the use of short forms here.	
Consent Process-Children: After determining if the subject is a child per GA law (or if enrolled outside GA, per state/country law), please describe whether parental permission will be obtained from: • Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. • One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care. When assent of children is obtained describe whether and how it will be documented per Emory Policies and Procedures	☐ **Yes**
Consent Process-Cognitively Impaired Adults: describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.	☐ **Yes**
Consent Process-Adults Unable to Consent: List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.) For research conducted in the state, review "46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. Describe the process for the assent of the participants. Indicate whether: • Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not. • If assent will not be obtained from some or all participants, an explanation of why not.	☐ **Yes**

Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents	
Waiver or Alteration of Consent and HIPAA authorization (consent will not be obtained, required information will not be disclosed, or the research involves deception) Review the Emory IRB waiver document to ensure you have provided sufficient information for the IRB to make these determinations. If the research involves a waiver of the consent process for planned emergency research, please review the Emory P&Ps, Chapter 48, WAIVERS OF, AND EXCEPTIONS FROM, INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH to ensure you have provided sufficient information for the IRB to make these determinations.	☒ **Yes**
Setting*: Describe the sites or locations where your research team will conduct the research including where the subject will be identified and recruited, where the research procedures will be performed, and if you will involve a community advisory board. For research conducted outside the organization and its affiliates describe the site-specific regulations or customs affecting the research outside the organization and the local scientific and ethical review structure outside the organization.	☒ **Yes**
Resources Available*: Describe the resources available to conduct the research such us the feasibility of recruiting the required number of suitable participants within the agreed recruitment period; describe the time that you will devote to conducting and completing the research; describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequences of the human research; describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.	☒ **Yes**
Multi-Site Research when Emory is the Lead Site Study -Wide Number of Participants: indicate the total number of participants to be accrued across all sites. Study-Wide Recruitment Methods: If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Describe when, where, and how potential participants will be recruited. Describe the methods that will be used to identify potential participants. Describe materials that will be used to recruit participants. Describe the processes to ensure communication among sites. See "WORKSHEET: Communication and Responsibilities (HRP-830)." All sites have the most current version of the protocol, consent document, and HIPAA authorization.	☒ **Yes**

All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record). All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented. All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies. All local site investigators conduct the study in accordance with applicable federal regulations and local laws. All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):	
• Problems (inclusive of reportable events). • Interim results. • The closure of a study	
If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")	
• Where and how data or specimens will be stored locally? • How long the data or specimens will be stored locally? • Who will have access to the data or specimens locally? • Who is responsible for receipt or transmission of the data or specimens locally? • How data and specimens will be transported locally?	