Supplementary Text S1 – SPIRIT Checklist



Standard Protocol Items: Recommendations for Interventional Trials

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number on which
		Beseription	

Item is reported

Administrative info	rmation		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization	Items 1-10: 1-2
		Trial Registration Data Set	ltem 11: 9,
			Item 12: 2-7
			Item 13: 8-14
			Item 14: 8
Trial registration			Item 15: 7
indiregistration			Item 16: NA
			Item 17: 13
			Item 18: 8
			Item 19-20: 11-12
			Item 21: 9
			Item 22: NA
			Item 23: NA
			Item 24: 14
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	1
	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
Roles and	5c	Role of study sponsor and funders, if any, in	NA
responsibilities		study design; collection, management, analysis,	
		and interpretation of data; writing of the report;	
		and the decision to submit the report for	
		publication, including whether they will have	
		ultimate authority over any of these activities	

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	10
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-8
	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	9
Methods: Participa	ants, inte	rventions, and outcomes	
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10, 12-13
Interventions	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9

Outcomes	10	Primary cocondary and other outcomes	12 1/
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-14
Participant	13	Time schedule of enrolment, interventions	10
timeline	13	(including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignme Allocation:	ent of int	erventions (for controlled trials):	<u> </u>
Sequence	16a	Method of generating the allocation sequence	9
generation		(eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	9
Blinding	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
(masking)	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA

Methods: Data colle	ection, r	nanagement, and analysis	
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10, 13-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11-12
	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15
Statistical methods	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-15
Methods: Monitori	ng		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	11-12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA

Harms	22	Plans for collecting, assessing, reporting, and	11-12
		managing solicited and spontaneously reported	
		adverse events and other unintended effects of	
		trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial	12
		conduct, if any, and whether the process will be	
		independent from investigators and the sponsor	
Ethics and dissemine	nation		
Research ethics	24	Plans for seeking research ethics	11
approval		committee/institutional review board (REC/IRB)	
		approval	
Protocol	25	Plans for communicating important protocol	11
amendments		modifications (eg, changes to eligibility criteria,	
		outcomes, analyses) to relevant parties (eg,	
		investigators, REC/IRBs, trial participants, trial	
		registries, journals, regulators)	
	26a	Who will obtain informed consent or assent from	10
		potential trial participants or authorised	
Consent or assent		surrogates, and how (see Item 32)	
consent of assent	26b	Additional consent provisions for collection and	NA
		use of participant data and biological specimens	
		in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and	12
		enrolled participants will be collected, shared,	
		and maintained in order to protect	
		confidentiality before, during, and after the trial	
Declaration of	28	Financial and other competing interests for	17
interests		principal investigators for the overall trial and	
		each study site	
Access to data	29	Statement of who will have access to the final	15
		trial dataset, and disclosure of contractual	
		agreements that limit such access for	
	ļ	investigators	
Ancillary and post-	30	Provisions, if any, for ancillary and post-trial care,	NA
trial care		and for compensation to those who suffer harm	
	_	from trial participation	
	31a	Plans for investigators and sponsor to	15
		communicate trial results to participants,	
		healthcare professionals, the public, and other	
Dissemination		relevant groups (eg, via publication, reporting in	
policy		results databases, or other data sharing	
. ,		arrangements), including any publication	
	24	restrictions	
	31b	Authorship eligibility guidelines and any	NA
		intended use of professional writers	

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary text – S2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

Main Study Consent



BROWN UNIVERSITY CONSENT FOR RESEARCH PARTICIPATION

Targeting Worry to Improve Sleep Version 3 – 7/5/19

KEY INFORMATION:

You are invited to take part in a Brown University research study, which is being conducted at Brown in collaboration with Georgetown University. Your participation is voluntary.

- □ PURPOSE: The study is about seeing if an app-based mindfulness training program can help you decrease your worry and improve your sleep.
- PROCEDURES: You will be asked to complete four assessments; three will be in-person at Brown University and one will be completed online. You will also be asked to download and use the Unwinding Anxiety app on your phone on a daily basis. In addition, you will be asked to track your sleep for three, one week periods with a Fitbit Inspire & sleep diaries. You will also receive check-in phone calls.
- □ TIME INVOLVED: The first assessment will take ~1 hour to complete and the subsequent assessments will take ~45 minutes. In total the assessments will take approximately 3 hours and 30 minutes of your time. The daily app use will take approximately 10 15 minutes each day and you will be asked to complete the daily lesson once per day for 30 days.
- □ COMPENSATION: You will receive a \$25 Amazon gift card per assessment for a possible total of \$100 in Amazon gift cards. You will also receive lifetime access to the Unwinding Anxiety app and if you complete the entire study, you will get to keep the Fitbit Inspire.
- RISKS: 1) Loss of privacy protection: It is possible the data we collect could be lost or revealed. We will do everything we can to protect your privacy. 2) Possible side effects of using Unwinding Anxiety program: While we have not had reported side effects from this program, there have been some reports of side effects from other mindfulness meditation training interventions which will be described in more detail below. 3) Emotional distress from completing questionnaires: It is possible that you may experience temporary emotional distress as some of the questions are sensitive in nature.
- BENEFITS: There are no direct benefits to you for participating in this research study.
- □ ALTERNATIVES TO PARTICIPATION: Standard treatments for anxiety disorders include medication and talk therapy. Please contact your doctor for more information about anxiety treatments.
- 1. <u>Researcher(s):</u>

Principal Investigators: Judson Brewer, MD PhD, 401-863-2826 or judson_brewer@brown.edu and Elizabeth Hoge, MD, 202-687-0635 or eah103@georgetown.edu Project Coordinator: Alana Deluty, 401-297-0097, or Alana deluty@brown.edu (contact person).

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2. What is this study about?

The purpose of this study is to see if an app, Unwinding Anxiety, (UA) can help decrease worry and improve sleep.

You are being asked to be in this study because you are over the age of 18, have a smartphone, and worry interferes with your ability to sleep.

3. What will I be asked to do?

The study will consist of four assessments which are explained in more detail below.

Baseline, third, and fourth assessments (in-person)

Questionnaires

During your first visit, you will be asked to complete several questionnaires which will cover a range of topics from demographic information, worry, body awareness, and sleep quality. This will take approximately 30 minutes.

Shape-matching task

You will be presented with two shapes and you have to decide if they are the same shape. Sometimes a third "distractor" shape will be presented which you should ignore. This will take approximately 25 minutes.

Second assessment (online)

Questionnaires

You will complete several questionnaires pertaining to worry, body awareness, and sleep quality. This will take approximately 20 minutes.

In addition, you will be asked to keep a sleep diary of what time you go to bed and wake up and wear a sleep tracker for a one-week period after the baseline and before the third and fourth assessment.

This study has two different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. The groups are explained in more detail below:

If you are randomized into Group A – You will be asked to complete the baseline, second (online), and third (in-person) assessments and then you will be asked to download the app. You will complete the introductory module (~10-15 minutes) and an initial survey (~10 minutes). You will then complete the 30-day Core Training program of Unwinding Anxiety (~10-15 minutes/day). Sixty days after receiving the app you will be asked to return for a final in-person assessment.

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You will be contacted for check-in calls regarding your experience with the app which will occur on day 7, 14, and 45. App usage will be monitored and you may receive an additional phone call to troubleshoot any problems.

If you are randomized into Group B – You will be asked to complete the baseline assessment and upon completion, you will be asked to download the app. You will complete the introductory module (~10-15 minutes) and an initial survey (~10 minutes). You will then complete the 30-day Core Training program of Unwinding Anxiety (~10–15 minutes/day). You will be asked to complete the second assessment (online) when you reach module 14 (or one month after receiving the app) and the third assessment (inperson) when you reach module 30 (or 2 months after receiving the app). 120 days after receiving the app you will be asked to return for a final in-person assessment.

You will be contacted for check-ins regarding your experience with the app which will occur on day 7, 14, and 45. App usage will be monitored and you may receive an additional phone call to troubleshoot any problems.

Your participation in this study may last up to 120 days.

4. Will I be paid?

You will receive a \$25 Amazon gift card for each assessment you complete. If you complete all four assessments, you have the potential to receive a total of \$100 in Amazon gift cards. You will also receive lifetime access to the Unwinding Anxiety application and if you complete the entire study, you will get to keep the Fitbit Inspire. If you lose or damage the Fitbit Inspire, or if it is stolen, prior to completion of the study, you will not receive a new one and your participation in this study will end.

5. What are the risks?

There is a small risk that your personal information could be lost or exposed. This is very unlikely to happen and we will do everything in our power to make sure that your information is protected. Please note that any information you share on the online community is available to the public so use at your own discretion. Details below (part 7).

While we have not had report of side effects from this program "Unwinding Anxiety," there have been some reports of side effects from other mindfulness meditation training interventions. These rare side effects include trouble thinking clearly or making decisions, increased anxiety symptoms, repeated thoughts of a stressful experience from the past, irritability, trouble enjoying things that were previously enjoyable, feeling distant or cut off from people, difficulty sleeping, headaches and/or body pain, hearing sensitivity, feeling disconnected from everything, feeling negative emotions more strongly, feelings of distress. We will ask you about side effects from the program after completion

There is a small possibility that the questionnaires completed during the assessments may cause temporary emotional distress. You can skip any questions you do not feel comfortable answering and can stop study activities at any time.

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6. What are the benefits?

You may not directly benefit from being in this research study.

7. How will my information be protected?

All questionnaires will be recorded in a secure research database application and only the PI and members of research team will have access to it. Every participant will be given a number called a Participant ID and all data will be matched to the ID rather than identifiers. The study key matching the ID to identifiers will be saved in a secure, password-protected server (Stronghold) and only the PI and research team will have access to it. It will be kept for at least three years after the end of the study and then it will be destroyed. The research team will track the number of modules you complete through a password-protected server.

Signed and dated consent forms will be kept in a locked filing cabinet in a locked office on Brown University's campus which only study personnel will have access to. They will be maintained for at least three years after study completion.

The Unwinding Anxiety and Fitbit applications do collect data that will not be accessed by the researchers or used for research purposes. Please see the attached addenda (Fitbit Privacy Policy & Unwinding Anxiety Privacy Policy) for more details.

Brown University IRB and Georgetown University IRB staff and the National Institute of Health sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

Anonymized data may be used and/or shared for future research.

Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

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

8. Are there any alternatives to this study?

Standard therapy for anxiety includes medications (such as selection serotonin-reuptake inhibitors) and behavioral treatments (such as cognitive behavioral therapy). You can contact your doctor for more information. In addition, a resource/referral list will be provided after reviewing the consent form.

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 relationships with Brown University and Georgetown University will not be affected. You will be asked to return the Fitbit Inspire at a time convenient to you.

10. What are the financial interests in this study?

You are being given this information so that you can decide if this relationship affects whether you want to participate in this study. If you have any questions, please contact Project Coordinator: Alana Deluty, 401-297-0097, or Alana deluty@brown.edu (contact person). They will answer any questions you may have.

Dr. Brewer is the lead researcher in this study and is one of the founders of, and has equity in, MindSciences, the company that created the Unwinding Anxiety app being studied. He may benefit financially if the Unwinding Anxiety program is successful.

Dr. Brewer will not be enrolling or consenting participants. Any publication of this study will require a statistician independent of the study and Mindsciences. Dr. Brewer will disclose his relationship to the company in any publications or presentations about this study.

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

If you have any questions about your participation in this study, you can call Project Coordinator: Alana Deluty, 401-297-0097, or Alana_deluty@brown.edu (contact person). You can also call the Principal Investigator, Judson Brewer, MD PhD at 401-863-2826 or email him at Judson_brewer@brown.edu.

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

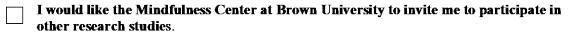
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If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

13. Future Studies

There are other studies that I may be eligible for in the future. The Mindfulness Center at Brown University may contact me to invite me to participate in other research studies if I check the box below.



14. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date	/	PRINTED NAME	
Research Staff Signature and Date	/	PRINTED NAME	

Baseline Survey

All responses are strictly confidential.

- 1. Participant ID
- 2. What year were you born?
- 3. What would you describe your gender as?
 - Male
 - Female
 - □ Non-binary
 - □ Prefer not to answer
- 4. What is your race?
 - White
 - □ Black or African American
 - □ Hispanic, Latinx or Spanish
 - Asian
 - □ American Indian or Alaskan Native
 - □ Native Hawaiian or Pacific Islander
 - Other _____
- 5. What is your relationship status?
 - □ Never married
 - □ Married/cohabiting
 - □ Separated/divorced
 - □ Widowed
- 6. What is the highest level of education you've completed?
 - □ Less than high school
 - □ High school graduate or equivalent (e.g. GED)
 - □ Some college but no degree
 - □ Associate's degree
 - □ Bachelor's degree
 - □ Graduate degree
- 7. Which of the below describes your work situation?
 - □ Employed full-time
 - □ Employed part-time
 - □ Homemaker (not looking for a job)
 - □ Disabled (unable to work)
 - Retired
 - □ Unemployed

- 8. What is your total household income?
 - □ Less than \$15,000
 - □ \$15,000 \$29,999
 - □ \$30,000 \$44,999
 - □ \$45,000 \$59,999
 - □ \$60,000 \$74,999
 - □ \$75,000 \$99,999
 - □ \$100,000 \$114,999
 - □ \$115,000 \$129,999
 - □ \$130,000 \$144,999
 - □ \$145,000 or more
 - \Box Prefer not to answer
 - Do not know
- 9. Please rate each of the following statements using the scale provided. Select the number that best describes <u>your own opinion</u> of what is <u>generally true for you</u>.

	Never or very rarely true	Rarely true	Sometimes true	Often true	Very often or always true
I perceive my feelings and emotions without having to react to them.	1	2	3	4	5
I watch my feelings without getting lost in them.	1	2	3	4	5
When I have distressing thoughts or images, I "step back" an am aware of the thought or image without getting taken over by it.	1	2	3	4	5
In difficult situations, I can pause without immediately reacting.	1	2	3	4	5
When I have distressing thoughts or images, I feel calm soon after.	1	2	3	4	5
When I have distressing thoughts or images, I am able to just notice them without reacting.	1	2	3	4	5
When I have distressing thoughts or images, I just notice them and let them go.	1	2	3	4	5

10. Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
My worries overwhelm me.	1	2	3	4	5
I do not tend to worry about things.	1	2	3	4	5
Many situations make me worry.	1	2	3	4	5
I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
When I am under pressure, I worry a lot.	1	2	3	4	5
I am always worrying about something.	1	2	3	4	5
I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
As soon as I finish one task, I start to worry about everything else I have to do.	1	2	3	4	5
I never worry about anything.	1	2	3	4	5
When there is nothing more I can do about a concern, I do not worry about it anymore.	1	2	3	4	5
I have never been a worrier all my life.	1	2	3	4	5
I notice that I have been worrying about things.	1	2	3	4	5
Once I start worrying, I cannot stop.	1	2	3	4	5
I worry all the time.	1	2	3	4	5
I worry about projects until they are done.	1	2	3	4	5

11. In the past week, how much of the time did worry interfere with your ability to get or stay asleep?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	0	0	0	0	0	0	0	0	0	0

12. Please respond to each question or statement by marking on box per row.

During the past 7 days...

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I felt physically tense at bedtime	1	2	3	4	5
I worried about not being able to fall asleep	1	2	3	4	5
I felt worried at bedtime	1	2	3	4	5
I had trouble stopping my thoughts at bedtime	1	2	3	4	5
Stress disturbed my sleep	1	2	3	4	5
I felt physically tense at bedtime	1	2	3	4	5
I worried about not being able to fall asleep	1	2	3	4	5

13. Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

	Never					Always
When I am tense, I notice where the tension is located in my body.	0	1	2	3	4	5
I notice when I am uncomfortable in my body.	0	1	2	3	4	5
I notice where in my body I am comfortable.	0	1	2	3	4	5
I notice changes in my breathing, such as whether it slows down or speeds up.	0	1	2	3	4	5
I do not notice (I ignore) physical tension or discomfort until they become more severe.	0	1	2	3	4	5
I distract myself from sensations of discomfort.	0	1	2	3	4	5
When I feel pain or discomfort, I try to power through it.	0	1	2	3	4	5

When I feel physical pain, I become upset.	0	1	2	3	4	5
	Never					Always
I start to worry that something is wrong if I feel any discomfort.	0	1	2	3	4	5
I can notice an unpleasant body sensation without worrying about it.	0	1	2	3	4	5
I pay attention to my breath without being distracted by things happening around me.	0	1	2	3	4	5
I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	0	1	2	3	4	5
When I am in a conversation with someone, I can pay attention to my posture.	0	1	2	3	4	5
I can return awareness to my body if I am distracted.	0	1	2	3	4	5
I can refocus my attention from thinking to sensing my body.	0	1	2	3	4	5
I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	0	1	2	3	4	5
I am able to consciously focus on my body as a whole.	0	1	2	3	4	5
I notice how my body changes when I am angry.	0	1	2	3	4	5
When something is wrong in my life, I can feel it in my body.	0	1	2	3	4	5
I notice that my body feels different after a peaceful experience.	0	1	2	3	4	5
I notice that my breathing becomes free and easy when I feel comfortable.	0	1	2	3	4	5

I notice how my body changes when I feel happy/joyful.	0	1	2	3	4	5
	Never					Always
When I feel overwhelmed, I can find a calm place inside.	0	1	2	3	4	5
When I bring awareness to my body, I feel a sense of calm.	0	1	2	3	4	5
I can use my breath to reduce tension.	0	1	2	3	4	5
When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	0	1	2	3	4	5
I listen for information from my body about my emotional state.	0	1	2	3	4	5
When I am upset, I take time to explore how my body feels.	0	1	2	3	4	5
I listen to my body to inform me about what to do.	0	1	2	3	4	5
I am at home in my body.	0	1	2	3	4	5
I feel my body is a safe place.	0	1	2	3	4	5
I trust my body sensations.	0	1	2	3	4	5

14. Over the last week, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge.	1	2	3	4
Not being able to stop or control worrying.	1	2	3	4
Worrying too much about different things.	1	2	3	4
Trouble relaxing.	1	2	3	4
Being so restless it is hard to sit still.	1	2	3	4

Becoming easily annoyed or irritable.	1	2	3	4
Feeling afraid, as if something awful might	1	2	3	4
happen.	1	2	0	т

15. At this point, how useful do you think the app will be in helping to reduce your worry to improve sleep?

- □ 9 Very useful
- □ 8
- □ 7
- □ 6
- □ 5 Somewhat useful
- □ 4
- □ 3
- □ 2
- □ 1 Not at all useful
- 16. How confident would you be in recommending this app to a friend who wanted to reduce their worry to improve sleep?
 - □ 9 Very confident
 - □ 8
 - □ 7
 - □ 6
 - \Box 5 Somewhat confident
 - □ 4
 - □ 3
 - □ 2
 - \Box 1 Not at all confident

17. By the end of this study, how much improvement in worrying do you think will occur?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	0	0	0	0	0	0	0	0	0	0

Assessment 2 – 4 Survey

All responses are strictly confidential.

- 1. Participant ID
- 2. Please rate each of the following statements using the scale provided. Select the number that best describes <u>your own opinion</u> of what is <u>generally true for you</u>.

	Never or very rarely true	Rarely true	Sometimes true	Often true	Very often or always true
I perceive my feelings and emotions without having to react to them.	1	2	3	4	5
I watch my feelings without getting lost in them.	1	2	3	4	5
When I have distressing thoughts or images, I "step back" an am aware of the thought or image without getting taken over by it.	1	2	3	4	5
In difficult situations, I can pause without immediately reacting.	1	2	3	4	5
When I have distressing thoughts or images, I feel calm soon after.	1	2	3	4	5
When I have distressing thoughts or images, I am able to just notice them without reacting.	1	2	3	4	5
When I have distressing thoughts or images, I just notice them and let them go.	1	2	3	4	5

3. Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
My worries overwhelm me.	1	2	3	4	5
I do not tend to worry about things.	1	2	3	4	5
Many situations make me worry.	1	2	3	4	5
I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
When I am under pressure, I worry a lot.	1	2	3	4	5
I am always worrying about something.	1	2	3	4	5
I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
As soon as I finish one task, I start to worry about everything else I have to do.	1	2	3	4	5
I never worry about anything.	1	2	3	4	5
When there is nothing more I can do about a concern, I do not worry about it anymore.	1	2	3	4	5
I have never been a worrier all my life.	1	2	3	4	5
I notice that I have been worrying about things.	1	2	3	4	5
Once I start worrying, I cannot stop.	1	2	3	4	5
I worry all the time.	1	2	3	4	5
I worry about projects until they are done.	1	2	3	4	5

4. In the past week, how much of the time did worry interfere with your ability to get or stay asleep?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	0	0	0	0	0	0	0	0	0	0

5. Please respond to each question or statement by marking on box per row.

During the past 7 days...

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I felt physically tense at bedtime	1	2	3	4	5
I worried about not being able to fall asleep	1	2	3	4	5
I felt worried at bedtime	1	2	3	4	5
I had trouble stopping my thoughts at bedtime	1	2	3	4	5
Stress disturbed my sleep	1	2	3	4	5
I felt physically tense at bedtime	1	2	3	4	5
I worried about not being able to fall asleep	1	2	3	4	5

6. Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

	Never					Always
When I am tense, I notice where the tension is located in my body.	0	1	2	3	4	5
I notice when I am uncomfortable in my body.	0	1	2	3	4	5
I notice where in my body I am comfortable.	0	1	2	3	4	5
I notice changes in my breathing, such as whether it slows down or speeds up.	0	1	2	3	4	5
I do not notice (I ignore) physical tension or discomfort until they become more severe.	0	1	2	3	4	5
I distract myself from sensations of discomfort.	0	1	2	3	4	5
When I feel pain or discomfort, I try to power through it.	0	1	2	3	4	5
When I feel physical pain, I become upset.	0	1	2	3	4	5

	Never					Always
I start to worry that something is wrong if I feel any discomfort.	0	1	2	3	4	5
I can notice an unpleasant body sensation without worrying about it.	0	1	2	3	4	5
I pay attention to my breath without being distracted by things happening around me.	0	1	2	3	4	5
I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	0	1	2	3	4	5
When I am in a conversation with someone, I can pay attention to my posture.	0	1	2	3	4	5
I can return awareness to my body if I am distracted.	0	1	2	3	4	5
I can refocus my attention from thinking to sensing my body.	0	1	2	3	4	5
I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	0	1	2	3	4	5
I am able to consciously focus on my body as a whole.	0	1	2	3	4	5
I notice how my body changes when I am angry.	0	1	2	3	4	5
When something is wrong in my life, I can feel it in my body.	0	1	2	3	4	5
I notice that my body feels different after a peaceful experience.	0	1	2	3	4	5
I notice that my breathing becomes free and easy when I feel comfortable.	0	1	2	3	4	5
I notice how my body changes when I feel happy/joyful.	0	1	2	3	4	5

	Never					Always
When I feel overwhelmed, I can find a calm place inside.	0	1	2	3	4	5
When I bring awareness to my body, I feel a sense of calm.	0	1	2	3	4	5
I can use my breath to reduce tension.	0	1	2	3	4	5
When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	0	1	2	3	4	5
I listen for information from my body about my emotional state.	0	1	2	3	4	5
When I am upset, I take time to explore how my body feels.	0	1	2	3	4	5
I listen to my body to inform me about what to do.	0	1	2	3	4	5
I am at home in my body.	0	1	2	3	4	5
I feel my body is a safe place.	0	1	2	3	4	5
I trust my body sensations.	0	1	2	3	4	5

7. Over the last week, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge.	1	2	3	4
Not being able to stop or control worrying.	1	2	3	4
Worrying too much about different things.	1	2	3	4
Trouble relaxing.	1	2	3	4
Being so restless it is hard to sit still.	1	2	3	4
Becoming easily annoyed or irritable.	1	2	3	4
Feeling afraid, as if something awful might happen.	1	2	3	4