Study Title: Youth Mindful Awareness Program (YMAP): Intervention Study
Version Date: November 20, 2021 (parent) Vanderbilt

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	**Vanderbilt University**
Site Principal Investigator:	Judy Garber, Ph.D.
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Site Study Coordinator	Jennifer Fuller, M.A.
Site Study Coordinator Contact	Jennifer.Fuller@Vanderbilt.edu; YMAP.VU@gmail.com 615-343-8714 or 615-669-2125

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study: The procedures used in this study pose minimal risk or discomfort to participants. Completing the online measures takes time (about 30 minutes) and may be tiring or boring but poses little risk. Interviews take about 60 to 90 minutes. To minimize fatigue or boredom, participants will be able to take breaks and return to the survey by saving their responses as indicated. Questions about mood (e.g., happy, sad, angry, nervous), anxiety, worries, or problem behaviors may be considered distressing or embarrassing for some participants. To minimize distress related to any questions, participants will be informed that responses are voluntary, and they can choose to not answer any question. Risks surrounding loss of confidentiality of participants will be controlled for by coding data with a participant number ID unrelated to the person's name, address, or phone number. Data will be stored on secure servers and in locked filing cabinets. Access to data is limited to only key study personnel.

Payments for time spent taking part in this study: Participants in the *Intervention Study* will be compensated up to $250 based on completion of the evaluations as described below.

Initial Survey. Participants will be compensated $5 for completing the brief initial online survey.

Interview and Other Online Measures. Participants will be compensated $20 for completing the interview and other online measures (on REDCap; computer tasks from The Many Brains Project) before the program. Participants will receive another $25 for completing the interview and online measures and computer tasks at the end of the program (about 10-12 weeks after the first assessment).

Mini Mood Log. The *Mini Mood Log* (on Qualtrics) involves 4 brief assessments per day over 5 days (Sunday – Thursday). The Mini Mood Logs are administered 2 times in the study: before and post. For each set of *Mini Mood Logs*, participants will be compensated up to $70. At each *Mini Mood* Log administration, participants complete 4 surveys/day for 5 days (total of 20).

The payments for each *Mini Mood Log* period are as follows:

- 1-4 Entries = $5
- 4-7 Entries (at least 20% completed) = $10
- 8-11 Entries (at least 40% completed) = $20
- 12-15 Entries (at least 60% completed) = $30
- 16-17 Entries (at least 80% completed) = $40
- 18+ Entries (90% to100% completed) = $50

Participants will be paid an additional $20 for completing at least 16 daily *Mini Mood Log* entries at each time point. The payment amount depends on the number of *Mini Mood Log* entries received on time. An *on-time* entry means that the Mini Mood Log is completed on the same day it is received and before the next Mini Mood Log is texted. Thus, if more than one Mini Mood Log is completed at the same time only one will be counted; the final Mini Mood Log for each day must be completed before going to bed each day.

Payment is provided at the end of the *Mini Mood Log* data collection week. If they miss four or more data entries for the *Mini Mood Log* week, they will have the opportunity to complete 4 additional entries on Friday of that week. For the whole study, participants can be compensated up to $140 for completing the *Mini Mood Logs* ($70 for each of two times).

Weekly Assessments Participants will complete a brief online assessment (10 minutes) weekly about mood and anxiety for which they will be compensated $5 for each survey completed. Reminders will be sent regarding these weekly assessments. Payment for completing the first 4 weekly surveys (up to $20) will be added to the payment for the midpoint evaluation. Payment for completing the last four weekly surveys will be added to payment after the post-assessment (up to another $20 for 4 survey weeks). Two months after the post interview, youth will complete the same brief set of online measures that they completed weekly.

Compensation across the whole study. Payments for the YMAP *Intervention Study* will be in the form of electronic gift cards. Participants will be sent an e-gift card at four points over the course of the study and can be compensated up to $250 for completion of all evaluations

(1) **After the First Evaluation (Baseline):** up to $95
   a. Initial Survey: $5
   b. Interview and Online Measures: $20
   c. Mini Mood Log: up to $70

(2) **After Midpoint Evaluation**: up to $30
   a. $10 for online measures
   b. Up to $20 for completion of the 4 prior weekly assessments

(3) **After Post-Intervention Evaluation**: up to $115
   a. Interview and Online Measures: $25
   b. Mini Mood Log: up to $70
   c. Up to $20 for completion of the 4 prior weekly assessments

(4) **Follow-up measures** two months after post interview: $10

Parents receive $10.00 for completing the online measures at baseline and $10.00 for completing the measures again at the post-intervention assessment.

Costs to you if you take part in this study: There is no cost to you for taking part in this study.

Contact Information. If you have questions about this research study or research-related injury, please contact the principal investigator, Judy Garber, Ph.D. at 615-343-8714 or 615-669-2125 or email at judy.garber@vanderbilt.edu. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please call the Vanderbilt University Institutional Review Board Office at 615-322-2918 or toll free at 866-224-8273.

Confidentiality: All efforts, within reason, will be made to keep confidential your and your child's personal information in the research record, but total confidentiality cannot be guaranteed. The research files at Vanderbilt University keep the following identifiers *separate* from your research data: you and your child's name, address, phone number, e-mail address, date of birth, and a unique study ID number.

- A list that matches your child's study code number and identifiers will be kept in a password protected file on a secure server at Vanderbilt University, accessible only to core research staff. Data obtained through the study will be stored with a code number in a secure electronic data management system.
- This signed consent form will be stored in a locked file in the investigator's lab separate from any of the data.
- This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.
- We are required by law to report cases of abuse or neglect.

- During the research, if we learn that your child is having thoughts about suicide or about hurting him/herself or others, the research staff will ask more questions about these thoughts. Based on your child's responses, the staff may provide you with help to obtain appropriate services. This may include:
  - working with you and your child to contact your child's physician
  - contacting another health professional to discuss these concerns
  - working with you and your child on a safety plan that may include getting your child to a hospital or ER.
- The interviews will be audio and video recorded for the purpose of evaluating interviewer reliability. We also will audio and video record the coached intervention sessions to ensure that the intervention is delivered with fidelity and for supervision of the coach. Your child may decline these recordings at any time and continue in the study. Digital files will be stored on password-protected, secured server, labeled by code number only and will be erased five years after study completion.
- Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies by putting it into scientific databases. Your child's *de-identified*, coded research information may be put in one or more databases and used for future research. Information stored in these databases will not include any identifying information such as your or your child's name, address, telephone number, or date of birth. Your child's research data will only be available to researchers who have received approval from data access committees or Institutional Review Boards. Some of these databases are maintained by Vanderbilt University, some are maintained by the federal government, and some are maintained by other institutions.
- If any publications or presentations result from the research, no personally identifiable information will be shared. Seven years after completion of analysis of data from this study, documents with your child's identifying information will be destroyed and we will no longer be able to link your child's data to his/her identity. Your child's de-identified research data will be maintained indefinitely to verify the integrity of the data and validity of results.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily agree to participate and choose to allow my child to take part in this study.

Date **SIGNATURE** of parent/legal guardian **PRINT NAME** of parent/legal guardian

Consent obtained by: Date Signature

Time Printed Name and Title