

Institutional Review Board
INFORMED CONSENT DOCUMENT FOR RESEARCH -- MASTER CONSENT

Study Title: Youth Mindful Awareness Program (YMAP): Intervention Study
Version Date: May 1, 2022 (parent)

Part 1 of 2: MASTER CONSENT

Full Name of **Child** Participant: _____ **Child's Age:** _____

You and your child are being invited to take part in a research study. This is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information. It includes information specific to the study site where you and your child are being asked to enroll. Both parts together are the legal consent for that must be provided to you.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If something is not clear, please ask someone to answer any question you have.

Key information about this study:

We are conducting a study to test the effects of a mindfulness program on teens' well-being. We are especially interested in how youth of different ages (12-17) and from different areas of the country respond to the program. This information will tell us about how well the program teaches teens skills for managing their moods.

Participation in the study might not benefit your child directly. Youth will be randomly assigned (like flipping a coin) to one of two groups. One group will participate in the mindfulness program after the first assessment. The other group will receive access to the program after the post assessment (about 12 weeks after the first one). This will let us examine the effect of the program, while still giving all youth access to it.

This study involves minimal (little or no) risk or discomfort to participants. The first and post assessments each take about two hours. They will be scheduled at a time that works best for your child. We will ask questions about mood, sleep, anxiety, appetite, concentration, friends, and school. Some of these questions may be upsetting or embarrassing. Your child can choose not to answer any question. Youth also will complete a *daily assessment* at the beginning and end of the program. These questions are asked four times a day for five days in a row. They take about five minutes each time and ask about stress and moods in the moment.

Parents will be asked to complete a few measures about their own and their child's health, well-being, and adjustment (about 30 minutes). These will be completed before and after the program.

The mindfulness program involves meeting remotely (e.g., by Zoom) with a coach once weekly for 9 weeks. The coach introduces the mindfulness skills, reviews the use of the program, and answers any questions about it. These weekly meetings take about 30-40 minutes.

All participating teens are compensated up to \$250 for completion of all study assessments.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed).

You and your child are being invited to take part in a research study because we are studying adolescents in your child's age range. Participation in the study is completely voluntary. We are interested in learning how well an mindfulness program can help teens manage their moods and promote well-being. You or your child may choose not to be in this study and get other treatments without changing your child's healthcare, services, or other rights. You and your child can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you and your child still want to be in this study.

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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 and interviews take time; this is time during which you and your child could be doing other things. The assessments may be tiring or boring but pose little risk. 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 embarrassing or upsetting for some participants. To minimize distress related to the 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.

Risks that are not known: No known risks are associated with completing the assessments other than possibly being tired or bored. To our knowledge, using the program also involves no risk. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want you and your child to be in this study.

Good effects that might result from this study: (i.e., the benefits to science and humankind that might result from this study). Information gained from this study may advance our understanding of whether a mindfulness program improves well-being in teens. There is no guarantee that your child will benefit from taking part in the study.

Procedures to be followed: Participating youth will be provided with individualized links to assessments that will be completed online, which include an initial survey and two sets of online measures. The initial survey includes questions about mood (angry, happy, nervous, sad) and anxiety, and takes 10-15 minutes to complete. Next, part 1 of the Online Measures includes questions about mood, stress, loneliness, and mindfulness, and takes about 40 minutes. Part 2 of the online measures includes short computer tasks (like online games) that take about 20 minutes. In addition, we will interview your child remotely (by phone or Zoom) about their well-being, sleep, appetite, sadness, anxiety, concentration, worry, and trauma (e.g., abuse). We also will ask about behaviors such as lying or behaviors that would be considered illegal (e.g., stealing). Parents will complete measures about their own and their child's physical and mental health, well-being, and adjustment (about 30 minutes). The initial survey is completed before the program. The other parts of the assessments described here take place before and after the program.

All participating youth will complete daily assessments (called *Mini Mood Logs*) online using a phone or tablet at the beginning and end of the ten weeks. Each time, questions (5-10 minutes) will be asked four times a day across five days in a row. Youth will respond to questions about what they are doing, feeling, and thinking in the moment. All youth also will complete a brief set of questions about their mood weekly and again, two months after the post interview.

The Table below shows the amount of time for the different parts of the assessments. After the first evaluation, youth for whom the program is a good fit will be randomly assigned (e.g., like flipping a coin) to one of two groups. One group will receive the mindfulness program (described below) after the first assessment. The other group will be provided with access to the program after the post assessment, about 12 weeks later.

Date of IRB Approval: 01/27/2023
Date of Expiration: 01/26/2024

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Table 1. Assessment Schedule	Time	Pre	Weekly	Mid	Post	Follow-up*
Youth						
Initial Survey Interview	10-15 minutes 1 hour	✓ ✓			✓	
Online Measures Part 1 (questionnaires) Online Measures Part 2 (tasks)	40 min 20 min	✓ ✓		✓	✓ ✓	
Mood measures Mood Log [4 times a day; 5 days each time]	10 min 5-10 min, 4 times/day	✓	✓		✓	✓
Parent	30 minutes	✓			✓	

*Follow-up measures are completed 2 months after the post interview

What is the Youth Mindful Awareness Program (YMAP)? YMAP is based on a program called *MyLife (Stop, Breathe, Think)*. Youth will meet remotely (by Zoom) with a trained coach once a week for 9 weeks. During these 30–40-minute meetings, the coach will introduce new skills. The coach also will help youth learn to use the program and will answer their questions about the program. Between meetings, teens will practice the skills on their own for about 5–15 minutes a day.

Mindfulness programs teach teens to become more aware of what is happening in and around them. Through mindfulness activities such as calm breathing, listening, acceptance, and compassion, teens can become more aware of their thoughts and feelings and learn to manage them more effectively. Mindfulness also can help teens improve the way they relate to the people in their lives and become kinder to themselves and others.

What will happen if you decide to stop being in this study? You or your child may decide to stop at any time. If you or your child decides to stop being part of the study, you should tell the study staff. To do so, contact the principal investigator or study coordinator. Deciding to not be part of the study will not change your or your child's relationship with the research university. You and your child will receive compensation for assessments completed and may keep all compensation for assessments completed up to the point of stopping participation.

Clinical Trials Registry. A description of this clinical trial is available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you or your child. The website will only include a summary of the results. You can search this website at any time.

Privacy: Information collected as part of this study about you or your child may be made available to others to use for research. To protect your privacy, we will not release your or your child's name or any information that would identify you or your child. In any reports of this research, we will not include any information that would make it possible to personally identify you or your child. You will not receive any benefit as a result of the measures collected. The information obtained from you and your child may help us or other researchers learn more about the causes, risks, treatments, or prevention of health problems in youth. Research assessments will be audio or video recorded for the purpose of evaluating interviewer reliability. Sometimes a supervisor might attend the meeting to observe the interviewer for training purposes. We also will audio or video record the coached sessions to ensure that the intervention is delivered with fidelity and for supervision. Digital files will be stored on password-protected, secured servers, labeled by code number only and will be erased five years after study completion.

Study Results: Results from this study will be available to you and your child upon request after publication of the findings. No information about individual responses will be shared with you or your child.

Please go to the next page for Part 2 of 2: STUDY SITE INFORMATION

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