STUDY PROTOCOL

STUDY TITLE
Youth Mindful Awareness Program (YMAP)

R61 PHASE: Targeting negative affect through mindfulness training in youth at risk for internalizing problems

STUDY IRB NUMBER
Vanderbilt IRB **#202263** "SIRB: Youth Mindful Awareness Program"

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1.0 Background

Mood problems in youth are serious public health concerns for which more targeted interventions are needed. Rates of anxiety and depression in youth are substantial, causing a major unmet need for effective interventions. Although some progress has been made in preventing these mood problems in adolescents, further research is needed that targets theoretically and empirically supported risk processes. An important risk factor found to increase the likelihood of anxiety and depression is negative affectivity - a propensity to experience and express more frequent, intense, and enduring negative emotional states.

2.0 Rationale and Specific Aims

The ***Intervention Study*** builds upon findings from our prior longitudinal study in which we found that elevated levels of negative affectivity during adolescence prospectively predicted internalizing problems (Zinbarg et al., 2016), and this relation was mediated by changes in negative affect (NA) measured with ecological momentary assessment (EMA) (Adam et al., 2023). The *Intervention Study* aims to test whether an online, coached mindfulness intervention as compared to an assessment-only control condition reduces negative affect as measured with EMA, in 450 adolescents (ages 12-17) who vary in their levels of NA. EMA will measure average daily mood, collected four times a day across seven days at pre- and post-intervention. In the R33, participants will be randomly assigned (like flipping a coin) to one of three conditions – (a) mindfulness, (b) support active comparator or (c) no intervention. We will compare youth randomized to the three conditions regarding NA, internalizing symptoms and disorders, and functioning at baseline, post-intervention, and 6-month follow-up. After the last assessment, all participants will be offered information about the other programs they did not receive. This will let us examine the effects of the programs, while still giving all youth access to them.

3.0 Inclusion/Exclusion Criteria

Individuals interested in participating in the Intervention Study will be interviewed about psychiatric disorders. No race or ethnic group or gender will be excluded.

1. **Inclusion criteria for the Intervention Study are:**
   a. Participants are ages 12 through 17 years old
   b. Participants have access to a smartphone, tablet, or other mobile device on which they can access the intervention materials and complete EMA reports. Youth without a device will be provided with one for their time in the study.
2. **Exclusion criteria for participation in the Intervention Study are:**
   a. current diagnosis of DSM-5 anxiety or depressive disorder with severe clinical impairment
   b. current alcohol or substance use disorder
   c. current serious suicidality
   d. lifetime diagnosis of bipolar disorder, schizophrenia, autism, conduct disorder, or developmental delay.
   e. reading level below 4th grade as reported by the parent or teen
   f. teen does not speak English at a level that would allow them to participate in the intervention and assessments

4.0 Enrollment/Randomization

4.1 Enrollment

Intervention Study Enrollment *(N=450; 150 per site)*: Parents of interested teens will contact the study team by telephone, text, email, or an online REDCap link. Study team members answer parents' and teens' questions and will send a link to the e-consent form to the parent. Teens for whom parent consent is obtained, then will be sent a separate REDCap link to their e-assent and study questionnaires; they also will be interviewed about their psychiatric symptoms. Youth who meet the inclusion and exclusion criteria, will be asked to complete the EMA procedure. After the EMA, youth will be randomized to one of the three conditions.

4.2 Randomization.

For the R33 *Intervention Study*, youth will be randomly assigned by the site project coordinator to one of three conditions – (a) mindfulness, (b) Active Support, and (c) No intervention. Randomization will be balanced on sex, age, and race/ethnicity using a modification of Efron's biased coin toss procedure (Begg & Iglewicz, 1980; Efron, 1971). The purpose of the stratification is to yield a similar proportion within the intervention and control conditions. For example, if 70% of participants are female in the intervention condition, then we will aim for 70% female in the other conditions. Participants will know their assignment at the point they are randomized. The independent interviewers will not know to which condition participants are assigned.

5.0 Study Procedures

5.1 Recruitment Methods. *Recruitment* will be conducted through the following methods - flyers, letters, social media, and listservs. Information about how to contact the study team will be included on all recruitment methods. Once participants contact the study team, we will answer their questions and will provide them with a confidential, unique link to the REDCap consent and assent. *All study recruitment will be online and only open to those living in California, Tennessee, and Illinois, US.*

1. A study-specific website URL: *Youth-Mindful-Awareness-Program.org* will be included in all recruitment materials that target parents of youth ages 12-17. The website and recruitment materials provide information for interested parents about how to contact the study staff through email or phone to obtain more information about how their teen can participate in the studies, or they can complete an online REDCap contact form.
2. Study flyers will be distributed to community organizations via. Email or dropped off in person. If community organizations have capacity, we will ask if they also can post the study flyers on their websites, social media, or email listservs. Interested people will contact the study email, phone number, or online form.
   a. Example: Northwestern University will contact community organizations in Chicago and Evanston such as Back of the Yards Neighborhood Council, Hyde Park Neighborhood Club, Evanston Public Libraries, McGaw YMCA, Evanston Families, Evanston Youth Outreach.
   b. Example: Vanderbilt University will send out flyers and announcements through the Vanderbilt University listserv/Research Match, pediatrician offices, YMCAs, and public libraries.
3. Study-specific social media will be created (Instagram, Facebook, Twitter) where study flyers will be posted. These social media posts will be re-posted and sent to community organizations who will repost on their social media or share within their own email lists. Parents of teens who are interested in the study will contact the study team. If we are not able to meet our recruitment goal, we will pursue social media paid advertising (e.g., Instagram & Facebook) restricting by age (12-17) and location (i.e., state).
   a. Example short-posts: Please visit *Youth-Mindful-Awareness-Project.org* to learn more." (b) *Intervention Study* – "Do you have a child between the ages of 12-17? Your child may be eligible to participate in a study about decreasing stress and improving well-being. Please visit *Youth-Mindful-Awareness-Project.org* to learn more."
   b. Facebook Groups: Evanston Mamas FB, District65 Parents and Guardians, Raising Children in Evanston.
4. Flyers/Ads will be posted on Craigslist and similar free gig apps and websites
5. The study team will check with listserv adstrators to determine if they can crowdsource via listservs.
6. At the UCLA site, participants will be recruited in collaboration with a high school in El Centro, CA where parents will be sent a letter and study flyers through the school. Interested parents will contact the study email, phone number, or online form. Permission has been granted for recruitment at this high school. UCLA also will recruit through a Registry
7. At Vanderbilt University, mass email distribution will be used. In addition, a listing will be placed on the Kennedy Center Study Finder and ResearchMatch websites. ResearchMatch.org also will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (Research Match - IRB 090207).
8. All sites will use a recruitment company call BuildClinical that recruits broadly

5.2 Consent/Assent Procedures

We will obtain separate parent consent, adolescent (ages 13-17) and child assent (age 12) using an e-consent on REDCap. A study team member will be available to explain the *Intervention Study* to parents and youth and will answer all their questions prior to beginning the study. Parents or teens who prefer to receive a hard copy of the consent form will be mailed the form with a stamped, addressed envelope in which to return the signed form. A separate assent form will be given to 12-year-old participants; the 13- to 17-year-olds will be asked to sign an assent form.

Parents and children whose primary language is not English: We are not planning to enroll children whose primary language is not English. It is likely, however, that for some parents/guardians, Spanish will be their primary language. The e-consent procedure will give parents the option to use the English or Spanish version of the consent form. Members of the research team who are fluent in Spanish will be available to answer questions from Spanish speaking parents.

Study Consent: For parents/guardians and youth interested in the *Intervention Study*, online e-consents through a link to REDCap will be obtained from a parent/guardian and from the teen prior to beginning the interview with the teen. A copy of the consent form will be emailed to parents along with a link to a REDCap consent form. After reading the consent form, parents will type their name and date, and submit the form electronically. Teens for whom parents have consented will be given an e-assent form to review with a project staff person. The authorized research staff obtaining consent will sign and date the form after the participant has submitted it online and prior to the participant starting the interview. Parents will be offered a Spanish or English version of the consent form either as an e-consent or as a hard copy mailed to them. This will accommodate all families who may have different types of technology/internet access. Participants who assented for study participation as minors (<18 years of age) but who turn 18 during the course of the study will be asked to provide consent for continued study participation when they turn 18 years old."

5.3 Procedures

5.3.A. Overview & Timeline: The following procedures outlined for the Intervention Study will take place over the course of approximately 12 weeks. The **Intervention Study Procedures & Frequency Table** (Appendix A) describes the activities to be conducted. The **Intervention Study Overview Flowchart** (Appendix B**)** shows the procedures in chronological order for each condition.

5.3.A.1. Assessments

***Baseline Interviews and Questionnaires*:** Youth will participate in an interview (about 1 hour) to assess inclusion/exclusion criteria. Interviews will be conducted remotely (e.g., Zoom; telephone) and will be audio recorded for the purpose of evaluating inter-rater reliability. Interviewers will be research staff and psychology graduate students trained and supervised by the PIs at each site (Dr. Garber, Vanderbilt; Dr. Zinbarg, Northwestern; Dr. Chavira, UCLA). The Schedule of Affective Disorders and Schizophrenia for School-aged Children (KSADS), an established diagnostic interview, will be used to assess DSM disorders in participants. Youth also will be interviewed about their service utilization outside the study using the CASA (Child and Adolescent Services Assessment). After the interview, participants who meet inclusion and exclusion criteria will be invited to continue to the next part of the study. Participants not eligible for the study will be thanked for their participation and compensated for completed activities. All participants will be provided with an information sheet that contains referrals to health care service providers in the area.

Questionnaires: Table 1 presents the measures, number of items, informant, and time points.

Table 1	**Intervention Study**				
	Baseline	**Weekly**	**Mid**	**Post**	**Follow-up**
Youth Self-report Measures					
Demographics	✓				
Negative Affect (NA-15)	✓		✓	✓	✓
Patient Health Questionnaire (PHQ13)					
Patient Health Questionnaire (PHQ14)	✓	✓	✓	✓	✓
Generalized Anxiety Disorder (GAD7)	✓	✓	✓	✓	✓
Mood & Feelings	✓	✓	✓	✓	✓
Stressful Life Events (SLE)					
Distress Tolerance Scale (DTS)	✓		✓	✓	✓
Short Five Facet Mindfulness Questionnaire (S-FFMQ)	✓		✓	✓	✓
Everyday Discrimination (EvDisc)	✓			✓	✓
Sleep Scales	✓			✓	✓
Loneliness Scale (LS)	✓			✓	✓
Rumination Scale for Children (Rum-C)	✓			✓	✓
Strengths & Difficulties Questionnaire (SDQ)	✓			✓	✓
Screen for Child Anxiety Related Disorders (SCARED)	✓			✓	✓
Positive and Negative Affect Schedule (PANAS-X)	✓			✓	✓
Self-acceptance questionnaire (SAQ)	✓			✓	✓
Life Events Checklist (LEQ)	✓			✓	✓
Conflict Behavior Questionnaire (CBQ)	✓			✓	✓
Gratitude Scale	✓			✓	✓
Barriers to Care	✓			✓	✓
Childhood Trauma Questionnaire (CTQ)	✓				
Working Alliance Inventory (WAI)			✓	✓	✓
Parent Report					
Strengths & Difficulties Questionnaire (SDQ)	✓			✓	
SCARED-P (completed by parent about child)	✓			✓	

PHQ14-Parent about Child	✓			✓	
Conflict Behavior Questionnaire (CBQ)	✓			✓	
PHQ13 & GAD7 about self	✓			✓	
Positive and Negative Affect Schedule (PANAS-X)	✓			✓	
EMA – Ecological Momentary Assessment: Mood Log	✓			✓	✓
Interviews					
Schedule of Affective Disorders and Schizophrenia for School-aged Children (KSADS)	✓			✓	✓
Child and Adolescent Services Assessment (CASA)	✓			✓	✓

Ecological Momentary Assessment (EMA): The EMA involves participants completing an EMA survey on Qualtrics for 7 consecutive days. If they miss five or more EMA responses, they will be given the opportunity to make up missed responses by adding a day. Participants will receive a text message four times a day for seven days. The number of questions vary by the time of day: morning and night surveys are a little longer than the two during the day. These take 5 to 10 minutes to complete. Participants will complete the EMA prior to the intervention and at post-intervention (week 10).

5.3.B.2. Procedures -- All Participants

1. Interested parents will contact the study team via email, text, phone, or a link on REDCap. Study staff will respond to the inquiry and provide information about the study.
2. First, each participant will be sent a unique link to REDCap to complete questionnaires about mood, symptoms, and functioning. Participants who are unable to access the measures online will be mailed paper versions and return the completed measures in a stamped, addressed envelope provided to them.
3. Next, participants will complete the EMA (4 times per day over 7 days).
4. Participants will be randomized to one of the three conditions: mindfulness, supportive active control, or no intervention control.
5. All participants will complete the PHQ14, GAD7, and affect measure weekly throughout the study.
6. Four weeks after the week 5 assessments (week 10), participants will complete several midpoint surveys.
7. After completing the endpoint EMA, participants will be interviewed again about their symptoms and functioning (via Zoom) and will complete the questionnaires on REDCap. A unique link will be sent to each participant. Participants who are unable to access the measures online will be mailed paper versions, which they can return in a stamped, addressed envelope.
8. Interviews will be audio recorded so that we can conduct quality checks of the interviewers and test inter-rater reliability. Participants who prefer not to be audio recorded may continue to participate without recording.
   a. Interviews will be conducted by staff and psychology graduate students who will be trained and supervised by the PIs at each site (Dr. Garber, Vanderbilt; Dr. Zinbarg, Northwestern; Dr. Chavira, UCLA). Established structured diagnostic interviews will be used to assess DSM disorders using the Schedule of Affective Disorders and Schizophrenia for School-aged Children (KSADS; Kaufman et al., 1997)
   b. In addition, teens will be interviewed about their service utilization outside the study using the CASA (Child and Adolescent Services Assessment; Farmer, Angold, Burns, & Costello, 1994).

5.3.B.3. Additional Intervention Condition Procedures

1. Participants will be instructed in downloading the intervention (i.e., *mindfulness; active support*) program materials and Zoom on their smartphone or tablet. If they do not have access to technology, a device to access the app will be provided to them for the time they are in the study.
2. Participants will meet with their coach for 30-40 minutes for 9 weeks over Zoom.
3. The *intervention* programs guide participants through exercises. Coaches will introduce the new exercises each week. Coaching sessions will be audio/video recorded to ensure intervention quality and fidelity to the study protocol. Participants who prefer not to be recorded may continue to participate without recording.
4. [Weeks 6-9] After completion of mid-point surveys, participants will resume weekly meetings with coaches and will continue to complete tasks using the program to which they were assigned.
5. After the final coaching session, participants will complete the post-intervention EMA, interview, and questionnaires.

5.3.B.4. Financial Compensation.

Participants in the *Intervention Study* will be compensated up to $300 based on completion of evaluations.

Payments for time spent taking part in this study: Participants in the will be compensated up to $300 based on completion of the evaluations as described below.

1. ***Interview and Online Measures.*** Participants will be compensated $30 for completing the interview and other online measures before the program. Participants will receive another $25 for completing the interview and online measures at the end of the program (about 10-12 weeks after the first assessment).
2. ***Mood Log.*** The Mood Log (on Qualtrics) involves 4 brief assessments per day over 7 days. The Mood Logs are adstered 2 times in the study: before and post (about 10 weeks later). For each set of Mood Logs, participants will be paid up to $50. At each Mood Log adstration, participants complete 4 surveys a day for 7 days (total of 28).

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

- 1-5 Entries = $5
- 6-10 Entries = $10
- 11-15 Entries) = $20
- 16-20 Entries = $30
- 21-24 Entries = $40
- 25-28 Entries = $50

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

Payment will be made after the end of the *Mood Log* data collection week. If they miss four or more data entries for the Mood Log week, they will have the opportunity to complete 4 additional entries on an additional day of that week. Across the whole study, participants can be compensated up to $120 for completing the *Mood Logs*.

Weekly Assessments. Participants will complete a brief 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-evaluation (up to another $20 for 4 survey weeks). Six months after the post interview, youth again will complete the online surveys and an interview.

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 up to four points over the course of the study and can be compensated up to $300 for completion of all evaluations.

(1) After the First Evaluation (Baseline): up to $90
   a. Initial Survey: $10
   b. Interview and Online Measures: $30
   c. Mood Log: up to $50

(2) After midpoint evaluation: up to $30
   a. $10 for questionnaires
   b. Up to $20 for completion of the 4 prior weekly assessments

(3) After post-evaluation: up to $130
   a. Interview and Online Measures: $40
   b. *Mood Log:* up to $70
   c. Up to $20 for completion of the 4 prior weekly assessments

(4) Follow-up online measures six months after post interview: $50

Parents will receive $10 for completing online measures at baseline and $20 for completing the measures at the post evaluation for a total of $30.

5.4 Research Locations and Materials

These research studies are being conducted at Vanderbilt University (Nashville, TN), University of California Los Angeles (Los Angeles, CA), and Northwestern University (Evanston, IL). All research activities will take place

online using the following platforms: REDCap, Qualtrics, Zoom, and Microsoft TEAMS. Participants will use their personal smartphone or tablet to access the intervention materials. Participants who do not have access to a phone or tablet will be provided a phone during their time in the study.

5.5 Multi-Site Coordination

Vanderbilt University, the coordinating center, is the IRB of record for all institutions engaged in this study. Each institution will conduct the same study protocol and will be responsible for recruitment, consent, and data collection at their site. The Northwestern University site will oversee data analysis of de-identified data (ID numbers will be used for participants).

To facilitate coordination of activities among collaborating sites, the research team (PIs, Research Coordinators, RAs) meet on Zoom weekly to communicate about adherence to the protocol and to troubleshoot any issues that arise. In addition, there will be a weekly Zoom meeting among the site Project Coordinators to ensure that the protocols are being followed. Similar procedures for using Zoom, scheduling appointments, and saving files will be implemented across sites.

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

6.1. Data and safety monitoring plan general description: The PIs at each site will monitor the accuracy (reliability and validity) of all data collected. All measures have been selected based in part on their established levels of reliability and validity. All data will be checked for errors prior to any analysis. In addition, the weekly measures will be monitored by study staff for reports by participants about harm to self. If reported by a participant, the *Critical Incident Protocol* will be implemented.

Assessment data will be obtained through REDCap online electronic forms and on standard paper-and-pencil forms as needed; all interviews will be digitally audio/video recorded, and responses will be recorded on REDCap forms. Data will be reviewed by the site research coordinators for missing data or outlying values and these questions will be referred to the relevant interviewer. All data collected on paper will be double entered, checked for accuracy, and all entry errors will be corrected. All data will be stored in a secure, shared Box folder with locked sharing permissions using the SAFER add-on. Participants will be identified by alphanumeric codes only; names and other possible identifiers will not be included in the electronic database. Identification numbers do not reveal the identity of participants (e.g., no birth dates, initials, social security numbers). An archival record of all data collected that has passed through the above-noted checks will be maintained on a secured server. Each site will be responsible for data security and confidentiality. At each stage of data collection and maintenance, all identifying information is shared from data archives; any hard copies of data that could identify subjects are stored in locked file cabinets with restricted access, and participant files are password protected. Data transferred from one site to the other will be de-identified, will not contain PHI, and will be transferred electronically using secured file transfer protocols.

6.2. Data Safety Monitoring Board: A Data and Safety Monitoring Board (DSMB) will monitor the clinical trial at the three sites and serve as a reporting body to the NIH as well as to the respective IRBs. The primary role of the DSMB is to monitor the safety of participants in both the intervention and the control conditions, receive reports of all adverse events in a timely and consistent fashion, and check the validity and integrity of the data. The DSMB is composed of three members, none directly involved in the project or employed by the participating institutions. The DSMB consists of experts knowledgeable in several areas relevant to this study including interventions for internalizing symptoms in children and adolescents (Anne Marie Albano, Ph.D.), implementation and evaluation of mindfulness interventions (Philippe Goldin, Ph.D.) and biostatistics (David Rosenfield, Ph.D.). The DSMB will first approve the protocol and subsequently conduct annual reviews to determine whether participant safety has been adequately safeguarded and enrollment goals have been met. The DSMB will be kept apprised of any serious adverse events when they occur and will serve as the final arbiters of whether individual participants should be removed from the protocol. Although the coaches, in consultation with the clinically responsible PIs, are empowered to take whatever immediate action is necessary to safeguard the welfare of individual participants, the DSMB also will be called upon to render judgments if any serious clinical problems (e.g., serious suicidal intent) occur.

Data monitoring and participant safety: The DSMB will meet first to approve the protocol and subsequently conduct annual reviews to determine whether participant safety has been adequately safeguarded and enrollment goals have been met. The DSMB will be informed of any protocol-related serious adverse events; when they occur. The DSMB will serve as the final arbiters of whether individual participants should be removed from the

study. Although the coaches, in consultation with the clinically responsible PIs are empowered to take whatever immediate action is necessary to safeguard the welfare of individual participants, the DSMB also will be called upon to render judgments when any serious clinical problems (e.g., serious suicidal intent) occur. Psychiatric or other life crises that are high risk and imminent will be acted upon immediately with staff linking participants to appropriate crisis services. These are reviewed immediately with the clinically responsible PI. Lower risk and less imminent crises are reviewed within 48 hours by the clinically responsible PI. Interim analyses will be conducted at each annual review for safety only, not effectiveness. Assuming there are no safety issues, we will prepare the data for analysis. Early termination typically is not an issue in a prevention study unless iatrogenic effects of the intervention are observed.

6.3. Critical Incident Protocol & Reporting of Adverse Events: Please see **Critical Incident Protocol.** In the *Intervention Study,* we will collect interview and questionnaire data that could indicate potential harm to participants (e.g., participants expressing intent to harm self or others, or data indicating child, spousal, elder or other forms of abuse or neglect). The *Critical Incident Protocol* will be triggered if a participant reveals information indicating possible or actual harm to themselves or others. Information collected by questionnaires will be monitored by research staff within a day of data collection. All adverse events or unanticipated problems involving risk to participants or others will be reported to the appropriate agency as required including the IRB, specific state agencies and stakeholders (IL, TN, CA), the Data Safety and Monitoring Board, and the National Institute of Mental Health. The clinically responsible PIs at each site (Garber at Vanderbilt; Zinbarg at Northwestern; Chavira and Craske at UCLA) will monitor and report any adverse events. The PIs also will supervise all study staff, interviewers, and coaches to ensure that all required protocol procedures are followed.

6.4. Potential Risks to Participants

The studies have mal risk to participants. The studies consist of interviews and surveys to research individual and group characteristics.

6.4.A. A risk that can occur from being in the *Intervention Study* is discomfort or embarrassment from the participant answering personal questions on surveys and interviews. Answers from participants are confidential and will be seen only by research staff. The interventions are manualized and all coaches will be trained and supervised by the PIs at each site; graduate students will be trained and will provide supervision of coaches as well.

Another possible risk is the breach of confidentiality. Data files used for analysis will not contain any identifiable information. If there is a breach of confidentiality, participants will be informed. There is also a low probability that participants will have a loss of privacy (name & email) if the online program is compromised.

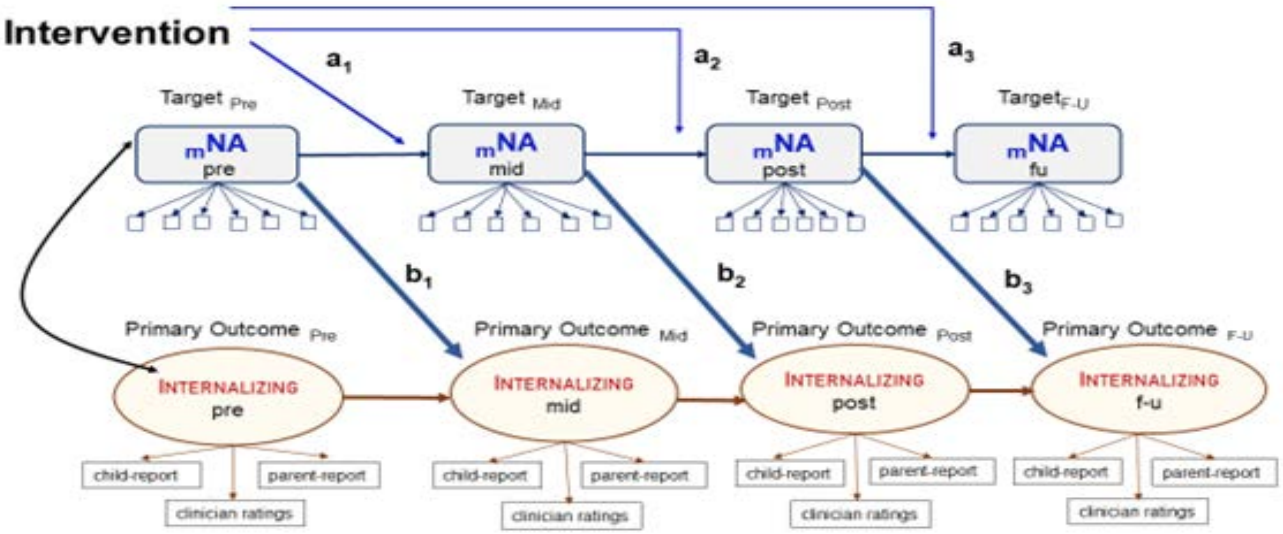
The risks are mal for participants assigned to the mood monitoring condition. These youth will be monitored for symptoms as often as those in the intervention condition. Moreover, given that this is a prevention trial, no participant currently meets diagnostic criteria for a mood or anxiety disorder with serious clinical impairment. Thus, treatment is not being withheld. All participants are free to seek other non-study professional services and will be encouraged to engage in standard care mental health services as needed. All participants will be offered the opportunity to receive the other program materials after their follow-up assessment is completed.

7.0 Study Withdrawal/Discontinuation

Participants can withdraw from the study by the participant or parent letting study personnel know in writing that they would like to stop study participation. The address to which a letter can be sent is listed in the consent form. Participants who want to stop the mindfulness program can still participate in the assessments and will be compensated. Participants who choose to withdraw will be compensated for all study tasks that they have completed up until that point. Study data collected up to the point of withdrawal will be maintained.

8.0 Statistical Considerations

The figure below depicts the structural equation model (SEM) analysis of the data from this study (through Post) and the R33 study that will follow it (through Follow-up, f-u). We will conduct an inferential test of the critical a_2 path – representing the effect of intervention on our primary target variable, momentary negative affect (mNA) - from our SEM analysis. We conducted a power analysis using G*Power and with a post-treatment sample size of 102 and a medium effect size for the a_2 path (i.e., a .50 standard deviation post-treatment condition effect), alpha = .05 and a one-tailed test, we will have power of .81. Our initial sample size for the R61 was 126 (42 per site, 21 per condition per site) so that even with close to 20% attrition, we will still end up with 102 at post-treatment.



9.0 Privacy/Confidentiality Issues

This study is supported by the National Institute of Health and therefore has a certificate of confidentiality through NIH.

Data Storage: Non-audio/video digital files, including survey data, will be stored in a password-protected, secured Box folder, labeled by code number only and will be stored indefinitely. Data Storage will not be permitted on personal computers. The Box folder is password-protected. All files will be labeled by date, session number, and participant code and will not include any identifying information (e.g., name, initials, birth date). The Box Folder with SAFER will be accessed by research team members only. The SAFER folder will have two adstrators that will be able to manage the levels of access study personnel have to sensitive data. The de-identified survey data will be stored indefinitely.

Audio/Video Recording: Assessment interviews will be audio recorded for evaluating inter-rater reliability and coached intervention sessions will be audio and video recorded to ensure that the intervention is delivered with fidelity and for supervision. Audio and video recordings will be labeled using date, session number, and participant code. The file naming system will not include any personal identifiers (e.g., participant name, age, address). The audio and video recordings will be stored on a secure Box folder with SAFER add-on that is only accessible by the study personnel. Audio and video recordings will be stored up to 7 years after the study is published; no one outside of the study team will have access to the recordings. Recordings will be shared outside the research team only if the participant gives express consent on a separate consent form.

10.0 Follow-up and Record Retention

Deidentified participant data from surveys will be stored indefinitely in a secure Box folder with the SAFER add-on. and will only be shared outwardly with express consent from study participants. All study data will be maintained indefinitely by the PIs of the coordinating and data centers (Judy Garber at Vanderbilt University, Richard Zinbarg at Northwestern University, respectively). De-identified data will be shared according to the requirements of the National Institute of Mental Health.

APPENDIX A: Study Procedures and Frequency of Activities

Procedures (Participant Activities)	Frequency
Questionnaires to assess negative affect, symptoms, and functioning. Surveys will be conducted on REDCap.	Four times (pre-, mid-, post-intervention, and follow-up). Survey Length: Approximately 50 minutes
Interview to assess psychiatric diagnoses: Interviews will be conducted on Zoom or phone.	Three times (pre- and post-intervention, and follow-up). Interview Length: About 60 minutes
EMA - Ecological Momentary Assessment: EMA surveys will be conducted via an individualized link on Qualtrics	EMA occurs two times (pre- and post-intervention). Survey length: Each EMA response takes about 5-10 minutes (4 per day for 7 days)
Weekly Assessment: Measures of mood related symptoms will be adstered once a week. Weekly measures will be completed via. REDCap.	Completed weekly. Survey Length: 10 minutes
Participants in the Mindfulness condition will complete online activities on their own between coaching sessions for 5 minutes a day in week 1, 10 minutes a day in weeks 2-5, and 15 minutes a day in weeks 6-9. Participants in the Awareness condition will complete writing activities four days a week for 10 to 15 minutes each time.	Participants will be asked to access the online activities over the 9 weeks of the program.
Coached Sessions - Participants will work with a coach on program activities. Coaches will train participants in the YMAP mindfulness or awareness activities that they complete weekly.	There will be 9 coaching sessions (once per week) during the Intervention Study. Coaching Session Length: 30-40 minutes.

APPENDIX B: Procedures Flowchart