STUDY TITLE: Mind over Mood

R61 PHASE: Social Cognitive Training to Enhance the Efficacy of CBT for Depression in Youth: A Developmental Approach

STUDY IRB NUMBER # 190077

PRINCIPAL INVESTIGATOR
Judy Garber, PhD., Vanderbilt University, Department of Psychology and Human Development

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Principal Investigator: Judy Garber, PhD
Study Title: *Mind over Mood*
Institution/Hospital: Vanderbilt University
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Name of child participant (print): _____ Age: _____

The following information is provided to inform you about the research project and you and your child's participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You and your child will be given an opportunity to ask questions, which will be answered. Also, you and your child will be given a copy of this consent form.

You and your child's participation in this research study is voluntary. You may choose not to participate and may receive alternative treatments without affecting your healthcare/services or other rights. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you and your child will be notified so that you can make an informed decision whether or not to continue your participation in the study.

Purpose of the study: The purpose of the study is to compare the effects of two different treatments for depression. Both treatments involve cognitive behavioral therapy (CBT). CBT includes developing skills for coping with stress, learning to examine thoughts, and problem solving. CBT is a common treatment for depression that can be helpful to many people, but it does not work for everyone. Therefore, we are testing whether adding another skill – perspective taking (seeing another's point of view) can further improve the effects of CBT on reducing depression.

Information learned from this study may help doctors and therapists provide better treatments for youth with depression. You and your child are being asked to participate in this research study because your child may be experiencing symptoms of depression.

You and your child do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You 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 still want to be in this study.

Procedures to be followed and approximate duration of the study: This research study will last for about 14 weeks. You and your child will first be asked to complete an interview about your child's feelings and behaviors and to respond to questions and surveys on a computer. The interviewer is a Ph.D. student or Masters-level research assistant. You also will be asked to complete questionnaires about your own feelings. Interviews will be audiotaped for review for quality control of the interviewer. You and your child have the right to skip any questions that you do not want to answer.

If your child is eligible and willing to continue to participate in the study, your child will be randomly assigned (like a coin toss) to either CBT.1 or CBT.2. Both are individual treatment with a Masters level therapist for up to 12 sessions. During this time, your child will be asked to complete a measure at each session in order to monitor her/his symptoms. In addition, in sessions 4 and 8, s/he will be asked to complete measures about social relationships. Finally, at the end of treatment (after session 12), your child will complete an interview and questionnaire battery similar to the first assessment.

Treatment appointments will be scheduled at a time that is mutually agreed upon among you, your child, and the therapist, most likely afternoons or early evenings. If your child is taking medications, he/she will be able to continue throughout his/her time in the study.

Visit 1 (Assessment)

- Visit our research lab at Vanderbilt University to complete the interview and questionnaires. This assessment will determine eligibility for the study.
- Interviews will be audio recorded to ensure that our interviewers are getting information correctly.
- This visit will take about 2.5-3 hours to complete.

Treatment Sessions 1-12

- Your child will be asked to attend up to 12 individual therapy sessions that will last approximately 50 minutes each time. Your child will be taught skills for coping with stress, assertive communication, engaging in positive activities, realistic thinking, and problem solving.

- These sessions will be audio-recorded to ensure that therapists cover the material accurately.
- Your child will be asked to attend all sessions. If needed, we will do make-up sessions by telephone or by having a longer session the next time.
- To monitor your child's progress, every week throughout treatment, your child will be asked to complete a brief questionnaire about his/her recent mood, thoughts, and behaviors.
- Your child will receive 12 individual therapy sessions as part of the study. Additional sessions beyond 12 will not be considered part of the research protocol.
- In sessions 4 and 8, your child will complete measures about social relationships (15 minutes).

Assessment Visit 2

- This visit will occur at Vanderbilt University during the week following the last treatment session and will involve a follow-up interview and questionnaires similar to what was done at the Assessment Visit 1.
- Interviews will be audio recorded to ensure that the interviews are being done correctly.
- This visit will take about 2.5-3 hours to complete.

Expected costs of tests and procedures that are only being done for the research study:

- You, your child, and your medical insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your child's condition.
- The research-related tests and procedures that will be provided to your child include:
  - Individual treatment for depression for 12 sessions
  - Visits to our offices for research-related purposes (e.g. meetings, assessments, research study therapy sessions)
  - Clinical and diagnostic assessments and interviews
- If you have any questions about costs and insurance, please ask the principal investigator or a member of the research team.

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 the participants. Questionnaire and interviews are time consuming and may be tiring o boring, but pose little risk. To minimize fatigue or boredom, participants will be able to take breaks as needed during the assessment. Questions about alcohol/drug use and suicidal ideation may be considered distressing for some participants. Interviewers will be experienced PhD students or Masters-level students, under the supervision of a PhD level clinician (the PI). To minimize distress related to any questions, participants will be informed that all responses are voluntary and they can choose not to answer any question.

The typical risks surrounding loss of confidentiality of participants will be controlled for by coding data with participant ID numbers, storing data on secure servers and forms in locked filing cabinets, and limiting access to data to only key study personnel. Study staff will not divulge any information about interviews or other tests to non-study staff.

Suicidality: Participants will be carefully screened for suicidality at the initial assessment and throughout treatment. We will administer a standard semi-structured diagnostic interview; interviewers are clinical psychology PhD students or Master's level students under the supervision of the PI, a licensed clinical psychologist. This interview includes questions to evaluate lifetime history of suicidal ideation, intent, plans, attempts, and self-harm behaviors. "Severe suicidality" is defined as current suicidal intent or plans and/or a recent (past month) suicide attempt using potentially lethal means. Youth meeting criteria for severe suicidality will be excluded from the study and provided with mental health resources and a safety plan (as needed). The interviewer will explain to the participant the need for services to ensure that his/her symptoms are more closely monitored than we are able to do in this study, and the interviewer will provide a list of mental health resources to the participant and caregiver. The interviewer will contact the study PI who will try to meet with the family in person or provide support by phone. If the participant endorses immediate plans to harm him/herself, the interviewer will discuss with both the participant and caregiver (as described in the consent process as a limit of confidentiality) and work with them to complete a safety plan, which may include visiting the emergency room for immediate evaluation. Throughout treatment, participants will complete a weekly measure of depressive symptoms.

If the participant endorses suicidal ideation, then the therapist will assess further for serious thoughts of killing self, plans, or attempts in past week with the brief suicidality assessment (BSA). Therapists will review responses immediately and address them in the therapy session that day. Endorsing any of the 3 yes/no items on the BSA will warrant further evaluation of current suicidal intent, plan, or attempt. If a participant meets current criteria for "severe suicidality," as defined above, similar steps will be followed in terms of discussing the need for more appropriate services, providing the participant and caregiver with appropriate referrals and safety plan, and contacting the PI. The participant and caregiver will be encouraged to seek additional individual services, but also may continue in therapy provided by this study while waiting to connect with additional services, if the participant and research staff agree that this would be beneficial for the participant. This decision will be made through discussion with the participant and caregiver, therapist, and supervisor and will focus on the best course of action for the participant's well-being (e.g., terminating participation in order to focus on more intense individual services or continuing until additional services are available).

Confidentiality: All efforts, within reason, will be made to keep your and your child's personal information in the research record confidential, but total confidentiality cannot be guaranteed. Our research files at Vanderbilt include these identifiers that are kept 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 and your child's study code number and identifiers will be kept in a password protected file on a secure server through Vanderbilt, 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.
- Your child's research records will be labeled only with the study ID number and kept separate from any documents containing identifying information.
- This signed consent form will be stored in a locked file in the investigator's lab separate from any of the data.
- This study has support from the National Institutes of Health (NIH). 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. The Certificate does not prevent us from disclosing your information if we learn of possible harm to you, your child, or others, or if you need medical help. We will disclose to the proper authority as required by law any information you or your child share with us concerning child physical or sexual abuse, child neglect, or imminent risk of harm to self or others. Disclosures that you consent to in this document are not protected, which includes sharing research data for this study or future research. Disclosures that you make yourself are also not protected.
- 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 and your child's responses, the staff may provide you with help to obtain additional or more appropriate treatment. This may include:
  - working with you 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 emergency room.
- 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 and 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 and/or Institutional Review Boards. Some of these databases are maintained by Vanderbilt, some are maintained by the federal government, and some are maintained by other institutions.
- If any publication or presentation resulting from the research, no personally identifiable information will be shared. Five 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 in order to verify the integrity of the data and validity of results.

Study Results: Results from this study will be available to you upon publication of the findings.

Compensation in case of study-related injury: If you or your child are injured because being in this study, you can get reasonable and necessary medical care for your injury at Vanderbilt without charge to you. There are no plans for Vanderbilt to pay for the costs of care beyond your injury, or to give you money for such injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that might result from this study.** Information gained from the study may advance our understanding how best to treat depression in teens. This may help us to make treatments that are more effective for other teens experiencing depression.
b) **The benefits your child might get from being in this study.** There is no guarantee that your child will benefit from taking part in this study. Participating in therapy may lead to improvement in symptoms of depression, and your child may learn ways to help to cope with depression in the future.

Alternative treatments available:

- You and your child do not have to take part in this study in order for your child to be treated for his/her condition. Instead of participating in this research, your child could:
  - Receive outside treatment, including therapy, medication, or other treatments for depression.
  - Be part of a different research study, if one is available.
  - Choose not to be treated.
- Before you and your child decide if you want to be in this research study, we will discuss other choices that are available to you. We will tell you and your child about the possible benefits and risks of these choices.

Compensation for participation:

- Your family will be paid up to $120 for completing all parts of the study as follows:
  $50 for the first assessment (pre-treatment: to determine eligibility)
- If eligible and your child participates in the study, then
  $50 for the last assessment (post treatment)
  $10.00 for completing the measures at session 4
  $10.00 for completing the measures at session 8
  - Payments will be made through cash or gift card (e.g., Amazon), which will be given out after completion of the assessment.

Circumstances under which the Principal Investigator may withdraw your child from study participation: The principal investigator (PI) may recommend that your child be taken out of the research study in order to ensure safety and well-being. Some reasons include:

- It is determined (by the PI or therapist) that your child is not receiving the appropriate treatment at this time
- Your child's condition has become worse, your child reports severe suicidality or is deemed to be a risk to him/herself or others. Your child may require more intensive treatment. In either case, the research team will discuss this with you and your child and will provide you with other clinical resources, as needed.

What happens if you or your child choose to withdraw from study participation? If you or your child decide to stop being part of the study, you should tell the study coordinator, therapist, interviewer, or principal investigator. Deciding to not be part of the study will not change your child's regular medical care in any way, and you and your child will be compensated for the assessments you completed.

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

Contact Information. If you have questions about this research study or possibly injury, please contact the principal investigator, Judy Garber, Ph.D. at judy.garber@vanderbilt.edu or (615)343-8714. 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 contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Date of IRB Approval: 06/02/2019

Privacy: All efforts, within reason, will be made to keep your and your child's information private. Using or sharing ("disclosure") such data must follow *federal privacy rules*. By signing the consent for this research study, you are agreeing ("authorization") to the uses and sharing of your child's data as described below.

Vanderbilt University may share the results of your child's study to the following groups: the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, or the study sponsor (National Institute of Health). Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your and your child's research data private. Your or your child's data will be shared with the appropriate authority as required by law if you, your child, or someone else is in danger of being harmed, or your child has experienced physical or sexual abuse or neglect.

Data Sharing. The sponsor and/or Vanderbilt may give or sell your child's health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. Garber and her staff will comply with all laws regarding the privacy of such information. There are no plans to pay you or your child for the use or transfer of this de-identified information.

The study results will be kept in your child's research record for at least seven years after analyses of the study data are finished. Unless told otherwise, your consent to use or share your child's de-identified data does not expire. If you change your mind, please contact Dr. Garber in writing and let her know that you withdraw your consent. Her mailing address is Department of Psychology & Human Development, Peabody College #552, 230 Appleton Place, Nashville, TN 37203-5721. At that time, we will stop getting any more data about your child, but the data we stored before you withdrew your consent may still be used for reporting and research quality.

If you or your child decide not to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans, or affect your child's ability to get benefits. We will give you a copy of this consent form.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate and agree to my child participating.

Date	PRINT NAME of parent/caregiver	SIGNATURE of parent/caregiver

Consent obtained by:

Date	Signature
	Printed Name and Title

STATEMENT BY PERSON AGREEING TO BE CONTACTED FOR OTHER STUDIES

Finally, we are interested in contacting you by telephone, mail, or email about future studies we will be conducting on psychological issues related to depression, stress and coping, and parenting. You and your family are under no obligation to participate in future studies, and you have the option of whether you wish to be contacted about these studies. Also, you may discontinue future contact by the research team any time you wish.

☐ I would like to be contacted to hear about other studies. I understand that I can decline after being contacted.

☐ I do not want to be contacted about other studies

Date	Signature of parent/caregiver

Date of IRB Approval: 06/02/2019

Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Judy Garber, PhD
Study Title: *Mind over Mood*
Institution/Hospital: Vanderbilt University

Version Date: 01/20/2019

This assent document applies to children ages 12-17

Name of participant _____ Age___

Below are the answers to some questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask. You will be given a copy of this assent form. Your participation in this study is voluntary. You are free to withdraw from the study at any time.

1. **Why are you doing this research?** The purpose of the study is to compare the effects of two different treatments for depression. Both treatments involve cognitive behavioral therapy (CBT). CBT includes developing skills for coping with stress, learning to examine thoughts, and problem solving. CBT is a common treatment for depression that can be helpful to many people, but it does not work for everyone. Therefore we are testing whether adding another skill – perspective taking (seeing another's point of view) can further improve the effects of CBT on reducing depression. You are being asked to participate in this research study because you are a teen who may be experiencing symptoms of depression.

2. **What will I do and how long will it take?** Participation in the entire study will take about 14 weeks from the first to the last evaluation.

Assessment Visit 1
- Visit our research lab at Vanderbilt University to complete the interview and questionnaires. This assessment will determine eligibility for the study.
- Interviews will be audio recorded to ensure that our interviewers are getting information correctly.
- This visit will take about $2^{1/2}$ - 3 hours to complete.

Treatment Sessions 1-12
- You will be asked to come individual therapy sessions that will last approximately 50 minutes each time. You will be taught skills for coping with stress, assertive communication, engaging in positive activities, realistic thinking, and problem solving.
- These sessions will be audio-recorded to ensure that therapists cover the material accurately.
- You will be asked to attend all sessions. If needed, we will do make-up sessions by telephone or by having a longer session the next time.
- To monitor your progress, every week throughout treatment, you will be asked to complete a brief questionnaire about your recent mood, thoughts, and behaviors.
- You will receive 12 individual therapy sessions as part of the study. Additional sessions beyond 12 are not considered part of the research protocol.
- In sessions 4 and 8, you will complete measures about social relationships (15 minutes).

Assessment Visit 2
- This visit will occur at Vanderbilt University during the week following the last treatment session and will involve a follow-up interview and questionnaires similar to what was done at the Assessment Visit 1.
- Interviews will be audio recorded to ensure that the interviews are being done correctly.
- This visit will take about $2^{1/2}$ - 3 hours to complete.

Compensation for the assessments: Your family will be paid up to $120 for completing all parts of the study as follows: $50 for the first assessment. If eligible and you participate, then $50 for the last assessment (post treatment); you also will receive $10 for completing measures in sessions 4 and 8.

3. **Do I have to be in this research study and can I stop if I want to?** You do not have to take part in this study if you don't want to. You can stop the study at any time. Just let the therapist, research assistant, or principal investigator know; they can discuss the next steps with you.

4. **Could it make me sick?** There are few risks to being in the study. In the initial assessment, some of the questions are personal and may cause mild distress. Your responses are voluntary and you may choose not to answer a question.

   You will work closely with research staff and clinicians throughout the study. If it seems as though your symptoms have gotten worse, we will discuss options with you and your parent, including providing a list of resources for other or additional treatment, if needed. If your symptoms worsen and we believe there may be a risk of harm to yourself or others, we may need to get other professionals involved in order to ensure safety and to determine that you are getting the most appropriate treatment.

5. **Will anyone know that I am in this research study?** We keep all of your information private by giving you a unique ID code. A list that matches your code number and your name will be kept in a password-protected file that only the main research staff can access. We will not discuss your involvement in the study with others except if you are at imminent risk of harming yourself or others, we may need to report this. In addition, we are required by law to report suspected child abuse or neglect; in some cases, research records may be subpoenaed for legal purposes.

6. **How will this research help me or other people?** There is no guarantee that you will get better from taking part in this study; however, participating in therapy may lower your feelings of depression or irritability and you might learn new coping skills for managing sadness, irritability, or apathy. Previous research has found that this treatment is effective for many teens with depression.

   Information gained from the study may advance our understanding of treatments for teen depression, leading to improved therapy and better selection of treatment options.

7. **Can I do something else instead of this research?** Yes. You do not have to take part in this study. If you decide that you would like to stop being part of the study, please tell the interviewer, therapist, or principal investigator. Instead of participating in this research, you could:
   - receive treatment elsewhere, including CBT, medication, or other treatments for depression.
   - be part of a different research study, if one is available.
   - choose not to receive treatment.

   Before you decide if you want to be in this study, we will discuss options that are available to you.

8. **Who do I talk to if I have questions?** If you have any questions about this research study, please feel free to contact the study director, Dr. Judy Garber, judy.garber@vanderbilt.edu, 615-343-8714.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____
Signature Printed Name and Title