DOCUMENT:

INFORMED CONSENT AND ASSENT

OFFICIAL STUDY TITLE:

TREATMENTS FOR IMPROVING MOOD IN DEPRESSED TEENS

(TEEN THRIVE-3)

R34AT009886

NCT NUMBER:

NCT003831360

DOCUMENT DATE:

(12/10/2020)

ASSENT FOR PARTICIPATION IN A RESEARCH PROJECT

BUTLER HOSPITAL AND BROWN UNIVERSITY

Treatments for Improving Mood in Depressed Teens—RCT

Research Project Summary

A research study is a way to learn more about people. We are doing a research study to understand how two different groups may help teens with depression. These two groups are: video-based group cognitive-behavioral therapy for depression, or video-based yoga classes. We hope that results of this research can help us understand and expand treatment options for depressed teens. You have been asked to participate because you have been feeling sad or down recently.

If you decide you want to be part of the study, your participation in the study will last 6 months. After starting the study, the amount of time that you spend on study treatments may amount to 3 hours per week for the first 3 months. We will also ask you to complete questionnaires and interviews. These study procedures are described in more detail below.

Description of Procedures

1. **Initial Interview.** First, you will have an initial meeting with study staff via secure videoconference. During this meeting, we will ask you questions about your mood, alcohol and drug use, unusual experiences that you might have, eating habits, and other treatments for depression. We will also ask you to complete questionnaires about your thoughts about yourself, your ability to get things done at home and school, and your level of exercise. This meeting will take 2-3 hours.

   We will use results from this meeting to determine whether the study is a good match for you. If so, we will need to make sure it is medically safe for you to be in a yoga class by asking for a note from your doctor. If your primary care provider agrees, you will be able to be in the study. If you have a mental health care provider, we will also let them know that you would like to participate in this study. We must be able to contact these providers in order for you to participate in the study. We will send these releases to your parent and ask that they return them to us via email, fax, or mail.

2. **Random Assignment.** You will be randomly assigned to 1 of 2 treatment groups. You will have a 1/2 chance of being assigned to take yoga classes, and a 1/2 chance of being assigned to group cognitive-behavioral therapy. The words “random assignment” means that we will use a method similar to flipping a coin to find out which group you will be in.

3. **Treatments during the study.**

   Group Cognitive-Behavioral Therapy (CBT). This program will involve a series of groups that focus on ways to cope with depression. We will ask you to first have a 30-minute individual meeting via videoconference with one of the group leaders. Then, you will be invited to attend one 45-minute session via videoconference every week for 12 weeks. The group leaders will introduce new skills, including ways to identify and set important goals, how to cope with low motivation to do things, ways to communicate with peers and others, problem-solving, and how to manage thoughts related to depression. The group leaders will encourage you to use what

you discuss in the group to make healthy changes to your life. We will mail or drop off a workbook at your house for you to use.

Yoga. Yoga involves stretching and breathing exercises. This yoga program will be designed to be safe for people who are new to yoga and who may not be physically fit. As part of this program, we will ask you to attend an individual session with a yoga teacher via videoconference, and then invite you to attend one 45-minute yoga class via videoconference each week for 12 weeks. The yoga teacher will also give you guidance on how to practice yoga on your own. We will mail or drop off yoga supplies at your house for you to use.

4. **Weekly questionnaire.** Every week during the first 12 weeks, we will ask you to complete a brief questionnaire that asks about home yoga practice or use of skills in the CBT group.

5. **Monthly interviews and questionnaires.** Approximately 1 month after you start the study, we will meet with you via videoconference to ask you about your mood, your thoughts about yourself, your ability to get things done at home and school, and your level of exercise. You will also complete questionnaires on our secure data collection system called REDCap. This interview and questionnaires will take about 30 minutes. We will ask you to complete these interviews and questionnaires 2 months and 3 months after starting the study as well. At 3 months, we will also ask you to answer a series of questions about your opinion of the group you attended. We will ask you to complete similar interviews and questionnaires, via videoconference, again 3 months after classes end.

6. **Audio Recording.** During the study, we will audio record all interviews and classes. We do this to make sure that study staff are following study procedures in the correct way, and also to make sure that we have correctly recorded information that you share with us. We will tell you whenever we plan to audio record. You or your parent may refuse audio recording of interviews at any time and still participate in the study. We will ask for your permission to audio record assessments at the end of this assent form.

Communications with Study Staff

We will ask you and your parent about how you would like research staff to contact you. This may include telephone, mail, email, or text message. In order for you to participate, we will need to be able to send links to videoconferences and online questionnaires to you.

How do telephone calls with researchers work? When research staff tries to contact you by phone, they will be careful about messages they leave. They will not discuss the reason for the phone call with anyone other than you or your parent.

How do texts with researchers work? Texts from the study staff will be sent from a phone that is only used for this research study. Research staff will not be constantly checking the phone, but it will be checked periodically during regular office hours. You can respond to messages from researchers by sending them text messages, but you should not send private health information.

How do emails with researchers work? Emails from the study staff will be sent from a Care New England (carene.org) email address or from our REDCap system for secure data collection. Emails from the study staff will include links to a) a REDCap questionnaire; or b) our videoconference portal. The study email address will not be constantly checked for return messages. Emails may NOT be received by researchers on a regular basis.

How do videoconferences with study researchers work? The purpose of the videoconferences is to a) conduct study assessments; or b) conduct online yoga or group CBT meetings. In order to connect to our electronic devices for a videoconference meeting, we will need to send an email message to you. This message will contain instructions and a weblink to navigate the connection to the videoconference system. We will use a HIPAA-compliant videoconferencing system. For the confidentiality of others participating in the video conference as well as your own confidentiality, you MUST attend the conference in a private space in your home, where there are no other people.

You must agree to the following rules of group confidentiality in the telehealth setting:

- The session leader will monitor the session to make sure that the only people connected to the session are the designated group participants.
- All members of the group must agree to keep the group discussion confidential. You must agree to protect the group confidentiality, by not revealing the names of other members of the group, nor what is said and done in the group. You must agree to be in a private space in your home for the meeting. If you violate this confidentiality, you will be removed from the group.
- You may not record any part of the group. The consequence for recording would be removal from the group for violating confidentiality, as well as possible legal consequences. We do this because we want to protect everybody's privacy.

Risks related to texts, emails, and videoconferences. Your participation in this research may be considered health information that should be kept private.

There are risks associated with texts, emails, and videoconferences. There is always a risk that a text or email could be intercepted, read by someone else, or sent to the wrong phone number or email address. If someone else were to read email or text messages sent between our staff and you, or overhear the videoconference meeting with our researchers, they might be able to know that you are in this study.

In addition, CBT and yoga classes are group meetings that include other participants who are enrolled in the study. Although we ask all participants to watch the videoconference privately, and maintain any information discussed in the meeting as confidential, we cannot guarantee that they will do so. It is possible that a group member could record the group without permission to do so.

Steps we take to reduce risk of loss of privacy. We will communicate by text or email to a) schedule and provide reminders for research-related appointments; b) send links to videoconferences; or c) to provide links to our secure data collection system, REDCap. We will not send messages to a group of recipients. Only the research team will have access to your email or text communications, and only the research team will be part of the videoconferences. We will not send email or text messages that contain urgent information or protected health information. We will not send messages that direct you to get medical care. Medical issues should be discussed with the research team over the phone rather than by email or text.

We use a study-specific, password-protected cell phone for texting. We will only communicate by email to send you the information listed above. They will be sent via REDCap or a carene.org email account. Our videoconference system is HIPAA compliant and all meetings will be monitored to make sure only study participants are present.

Email addresses and any other information that personally identifies you will be removed from the final research database when the study is over.

Steps you can take to reduce risk of loss or privacy. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study. If you share a home computer with other family members and you do not want them to know you are participating in this study, make sure to provide an email address that only you can access. Keep in mind that a school (or employer, if relevant) may have access to any email communications sent or received on a school or work computer. Additionally, when using any public computer or a smartphone that might be found or used by others, you should be sure to protect your username and password, and make sure to logout before moving away from the computer screen.

Contacting research staff by text or email. It is possible that a message you send via text or email will go unnoticed or will not be read by the research team for days or weeks. Therefore, please use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, concerns about effects of study procedures, etc.) should NOT be communicated by text or email. Instead, please call our office at 401-430-5258.

Risks

There are some things about this study you should know.

A possible risk is loss of confidentiality if someone sees your responses on questionnaires, including on our data collection system REDCap. However, we will keep all information you give us confidential, and store information on secure computer servers and in locked file cabinets. REDCap, our data collection system, has been designed to be a secure system.

You may find certain questions uncomfortable to answer. We will do our best to help you be comfortable, and you may decide not to answer any questions.

If you are in the yoga classes, it is possible that you may experience an injury such as a muscle strain. During video-based classes, the yoga teacher is not in the room with the participants, which makes it harder for them to see any subtle signs of distress. In order to reduce this risk of injury, yoga teachers will first have a 1:1 meeting with you before you start group classes. This will give them a chance to talk with you and understand any physical concerns you might have and provide advice about how to manage them. Second, teachers will also suggest modifications during class for each person's individual needs and abilities. Third, teachers will only use postures and practices that have been successfully done in in-person classes with people in this age range. Finally, we ask that you follow the yoga teacher's instructions and let them know if you experience any pain or difficulties during classes.

Female Participants Please Note: Although prenatal yoga can be helpful for women who are pregnant, we do not recommend being in a regular yoga class during pregnancy. Please let us know if you become pregnant during the study. We will ask you not to participate in yoga classes if you become pregnant, although we may continue study interviews and questionnaires. If you do not want us to share information about your pregnancy with your parent, we will not. We will encourage you to talk to your parent. We will give you information about healthcare providers who take care of pregnant women if needed.

Benefits

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. You may find that participation in the study helps you to feel happier or healthier. However, it is also possible that participation in the study will not change how you feel or your health status.

Economic Considerations

If you are eligible for this study, you will be paid for completing interviews and questionnaires and other assessments, regardless of how many classes or groups you completed during the course of the study. The total amount you may receive in this study is $140. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30
End of month 6	$40

Alternative Treatments/Alternative to Participation

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you.

Confidentiality

If you tell the researchers something that makes us think you might harm yourself or someone else, or that someone is harming you, we will take steps to help you. We will tell your parent this information (unless we think that puts you in more danger). We may contact your primary care provider or other health providers.

No other information will be shared with your parent while the study is ongoing, although your parent may ask for some of the information once the study has ended.

Overall, information that we collect in this study will be protected and kept confidential in the same way that other medical information is kept confidential.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

We ask all participants to treat any information they learn about other members of their yoga class or CBT group as confidential. However, we cannot guarantee that all participants will do so.

Voluntary Participation

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parent knows about the study and must sign a consent form if you are under 18 years of age.

Questions

You should ask your parent or our staff members any questions you have about participating during your scheduled videoconference meeting. You should take as much time as you need to make your decision.

THIS FORM IS VALID UNTIL

DATE: January 31, 2022

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

Acknowledgements for REDCAP

All of my questions about this study have been answered to my satisfaction. (YES/ NO)

[*answer must be yes to continue*]

I give my assent to participate in this study. (YES/NO)

[*answer must be yes to continue*]

I agree to have my assessment(s) audio recorded. This will be used for research and training purposes only. (YES/NO)

I acknowledge risks related to the use of email associated with my participation, and I agree to allow researchers to send me emails, as described in the assent form. (YES/NO)

[*answer must be yes to continue*]

Please indicate the email address researchers should use to contact you:

Please re-enter the email address:

I acknowledge risks related to use of text associated with my participation, and I agree to allow researchers to send me texts, as described in the assent form. (YES/NO)

Please indicate the cell phone number researchers should use to contact you:

Please re-enter the cell phone number:

I acknowledge risks related to use of videoconference associated with my participation, and I agree to participate in research videoconferences, as described in the assent form. (YES/NO)

[*answer must be yes to continue*]

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—RCT

Sponsorship

This study is being paid for by a grant from the National Center for Complementary and Integrative Health.

Research Project Summary

You are being invited to participate in this study because you have indicated that you experience sad or depressed mood. Participation in the study will last 6 months. During the first three months, you will be randomized to one of two groups: 12 weeks of weekly video-based group cognitive-behavioral therapy for depression, or 12 weeks of video-based yoga classes. The amount of time that you spend on study treatments may amount to 3 hours per week during this initial 3-month period. Throughout the entire 6 months, there will also be periodic assessments which will last 1-2 hours each time. You will be paid for study participation. Major risks of participation include loss of confidentiality and minor injury if you attend yoga classes. Study staff will take steps to reduce these risks.

You should know about the risks and benefits of this study to make a wise decision about whether to be a part of it. This consent form gives you information about the study. A member of the research team will also discuss this information with you. This discussion will cover why and how we are doing this study, any possible risks and benefits of participation, and possible different ways to help you get the care you need. Once you understand what the study is about, we will ask you if you wish to be in the study. If so, we will ask you to sign this consent form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

Description of Procedures

1. **Initial Interview.** First, you will have an initial meeting with study staff via secure videoconference. During this meeting, we will ask you questions about your mood, substance use, unusual experiences that you might have, eating habits, and other treatments for depression. We will also ask you to complete questionnaires about your thoughts about yourself, your ability to get things done at home and school, and your level of exercise. This meeting will take 2-3 hours.

   We will use results from this meeting to determine whether the study is a good match for you. If so, we will contact your primary care provider in order to find out whether it is medically safe for you to be in a yoga class. If your primary care provider agrees, you will be able to be in the study. (If you have up-to-date documentation that you may participate in physical education classes, this is an acceptable substitute for medical clearance that is specific to this study). If you have an outside mental health provider, we will also let them know that you would like to participate in this study. We will ask you to sign releases of information to contact these providers. We must be able to contact these providers in order for you to participate in the study. We will send these releases to you and ask that you return them to us via email, fax, or mail.

2. **Random Assignment.** If you are eligible for the study, you will be randomly assigned to 1 of 2 treatment groups. You will have a 1/2 chance of being assigned to take yoga classes, and a 1/2 chance of being assigned to group cognitive-behavioral therapy. The words "random assignment" means that we will use a method similar to flipping a coin to find out which group you will be in.

3. **Treatments during the study.**

   Group Cognitive-Behavioral Therapy (CBT). This program will involve a series of groups that focus on ways to cope with depression. We will ask you to first have a 30-minute individual meeting via videoconference with one of the group leaders. Then, you will be invited to attend one 45-minute session via videoconference every week for 12 weeks. The behavioral health specialists who leads this group will introduce new skills, including ways to identify and set important goals, how to cope with low motivation to do things, ways to communicate with peers and others, problem-solving, and how to manage thoughts related to depression. The behavioral health specialists will encourage you to use what they discuss in the group to make healthy changes to your life. We will mail or drop off a workbook at your house for you to use.

   Yoga. Yoga involves stretching and breathing exercises. This yoga program will be designed to be safe for people who are new to yoga and who may not be physically fit. As part of this program, we will ask you to attend an individual session with a yoga teacher via videoconference, and then invite you to attend one 45-minute yoga class via videoconference each week for 12 weeks. The yoga teacher will also give you guidance on how to practice yoga on your own. We will mail or drop off yoga supplies at your house for you to use.

4. **Weekly questionnaire.** Every week during the first 12 weeks, we will ask you to complete a brief questionnaire that asks about home yoga practice or use of skills in the CBT group.

5. **Monthly interviews and questionnaires.** Approximately 1 month after you start the study, we will meet with you via videoconference to ask you about your mood, your thoughts about yourself, your ability to get things done at home and school, and your level of exercise. You will also complete questionnaires on our secure data collection system called REDCap. This interview and questionnaires will take about 30 minutes. We will ask you to complete these interviews and questionnaires 2 months and 3 months after starting the study as well. At 3 months, we will also ask you to answer a series of questions about your opinion of the group you attended. We will ask you to complete similar interviews and questionnaires, via videoconference and REDCap, again 3 months after classes end.

6. **Audio Recording.** During the study, we will audio record all interviews and classes. We do this to make sure that study staff are following study procedures in the correct way, and also to make sure that we have correctly recorded information that you share with us. We will tell you whenever we plan to audio record. You may refuse audio recording of interviews at any time and still participate in the study. We will ask for you to indicate whether you give permission for audio recording assessments at the end of this consent form.

   Please note that all yoga and CBT classes will be audio recorded; by signing this consent form you give us permission to do this.

Communications with Study Staff

You will be asked about your preferences for how research staff contact you. This may include telephone, mail, email, or text message. In order for you to participate, we will need to be able to send links to videoconferences and online questionnaires to you.

How do telephone communications with researchers work? When research staff contacts you via phone for appointment reminders, they will be as discrete as possible. If they contact you by phone, they will not discuss the reason for the phone call with anyone other than you.

How do text communications with researchers work? Texts from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages constantly, but it will be checked periodically during regular office hours. You can respond to messages from researchers by sending them text messages, but you should not send private health information.

How do email communications with study researchers work? Emails from the study staff will be sent from a Care New England (careen.org) email address or from our REDCap system for secure data collection. Emails from the study staff will include links to a) a REDCap questionnaire; or b) our videoconference portal. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

How do videoconferences with study researchers work? The purpose of the videoconferences is to a) conduct study assessments; or b) conduct online yoga or group CBT meetings. In order to connect our electronic devices for a videoconference meeting, we will need to send an email message to you. This message will contain instructions and a weblink to navigate the connection to the videoconference system. We will use a HIPAA-compliant videoconferencing system. For the confidentiality of others participating in the video conference as well as your own confidentiality, you MUST attend the conference in a private space in your home, where there are no other people.

You must agree to the following rules of group confidentiality in the telehealth setting:

- The session leader will monitor the session to make sure that the only people connected to the session are the designated group participants.
- All members of the group must agree to keep the group discussion confidential. You must agree to protect the group confidentiality, by not revealing the names of other members of the group, nor what is said and done in the group. You must agree to be in a private space in your home for the meeting. If you violate this confidentiality, you will be removed from the group.
- You may not record any part of the group. The consequence for recording would be removal from the group for violating confidentiality, as well as possible legal consequences. We do this because we want to protect everybody's privacy.

Risks related to text and email communication, and videoconferencing. Your participation in this research may be considered health information that should be kept confidential.

There are risks associated with communications by text and email, and videoconferences. There is always a risk that a text or email message could be intercepted or sent to the wrong phone number or email address. If someone else were to intercept or read email or text messages sent between our staff and you, or overhear the videoconference meeting with our researchers, they might be able to know

about your participation in this research study. This, in turn, might reveal some of your private health information, such as medical or psychiatric symptoms. If you choose to send emails with private health information to us, they could be intercepted or sent to the wrong address, with the resulting loss of confidentiality.

In addition, CBT and yoga classes are group meetings that include other participants who are enrolled in the study. Although we ask all participants to watch the videoconference privately, and maintain any information discussed in the meeting as confidential, we cannot guarantee that they will do so. It is possible that a group member could record the group without permission to do so.

Steps we take to reduce risk of loss of privacy. We will communicate by text or email to a) schedule and provide reminders for research-related appointments; b) send links to videoconferences; or c) to provide links to our secure data collection system, REDCap. We will not send messages to a group of recipients. Only the research team will have access to your email or text communications, and only the research team will be part of the videoconferences. We will not send email or text messages that contain urgent information or protected health information. We will not send messages that direct you to get medical care. Medical issues should be discussed with the research team over the phone rather than by email or text.

We use a study-specific, password-protected cell phone for texting. Emails will be brief and be used for links that you need. They will be sent via REDCap or a carene.org email account. Data collected on REDCap is stored in a secure fashion. Our videoconference system is HIPAA compliant and all meetings will be monitored to ensure only desired participants are present.

Email addresses and any other information that personally identifies you will be removed from the final research database when the study is over.

Steps you can take to reduce risk of loss or privacy. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study. If you share a home computer with other family members and you do not want them to know you are participating in this study, make sure to provide an email address that only you can access. Keep in mind that an employer or school may have access to any email communications sent or received on a work or school computer, or through email accounts that are set up through software owned by a company or institution. Additionally, when using any public computer or a smartphone that might be found or used by others, you should be sure to protect your username and password, and make sure to logout before moving away from the computer screen.

Contacting research staff by text or email. It is possible that a message you send via text or email will go unnoticed or will not be read by the research team for days or weeks. Therefore, you should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, questions about medications, concerns about effects of study procedures, etc.) should NOT be communicated by text or email. These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-430-5258.

Consent. At the end of this consent form, we will ask whether you consent for us to contact you via text and/or email as described above.

Risks and Inconveniences

Because we will be asking you questions about yourself, one possible risk is breach of confidentiality. We will treat your information as a confidential medical record at Butler Hospital. Information about you will be handled by research staff involved in this study (at Butler Hospital or Brown University) who are trained in the protection of research participants and take steps to ensure confidentiality. However, if you tell us that you have suicidal or homicidal thoughts or plans or are engaged in another behavior that may cause serious health problems, we are obligated to take steps to keep you safe. If you tell us about abuse or neglect of children or elderly persons, we must report that to authorities.

As some of the information that we collect may be done using REDCap, our secure web application for managing online surveys and databases, there is the potential for loss of privacy/confidentiality. The REDCap database will need to include an email address and/or cell phone number in order to send you the survey. As with other methods, any information that you provide to us will only be available to study staff. All data captured in REDCap will be stored and hosted by a secure institutional server; no project data is ever transmitted by REDCap to other institutions or organizations. REDCap has been designed to be compliant with guidelines to minimize loss of privacy surrounding protected health information.

It is possible that you may find some things we ask about to be upsetting and uncomfortable. We will do our best to make sure that you are as comfortable as possible with any questions that we ask. You may refuse to answer any questions.

If you are taking yoga classes, which involves physical exercise, another possible risk is physical injury. In rare cases, dizziness or fainting may occur. This is particularly true because the yoga teacher is not in the room with the participants and so is unlikely to see any subtle signs of distress. We will take several steps to decrease this risk. First, yoga teachers will have a 1:1 meeting with each participant prior to them starting group classes in order to understand and address any physical concerns participants may have and provide advice about how to manage them. Second, during class, yoga teachers will suggest modifications for each person's individual needs and abilities. Third, teachers will only use postures and practices that have been successfully used in in-person yoga classes with people in this age range. Finally, if you have a medical problem or injury when practicing yoga, we will help you to get medical treatment if needed.

Female Participants Please Note: Although prenatal yoga can be beneficial for women who are pregnant, we do not recommend participation in a regular yoga class during pregnancy. We will ask you to let us know if you become pregnant during the study. We will ask you not to participate in yoga classes if you become pregnant, although we may continue study assessments.

There is no guarantee that participating in any of these programs will help you to feel less depressed.

Benefits

1. It is possible that you will experience less depression while you are in this study.

2. We will talk with you approximately every 4 weeks to see how depressed you are feeling. If, at any point, study staff determine that your condition is worsening significantly such that you may need additional treatment, we will contact your other medical providers immediately. We will work with your provider to ensure that you get appropriate care.

Economic Considerations

If you are eligible for this study, you will be paid for completing interviews and questionnaires and other assessments, regardless of how many classes or groups you complete during the course of the study. The total amount you may receive in this study is $140. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30
End of month 6	$40

The study interventions and all of the tests and procedures that will be done only for this research will be paid for by the study funds.

Alternative Treatments/Alternative to Participation

Alternatives to participation in this study include getting standard treatment for depression outside of this research program. Alternative community treatments include antidepressant medications or psychotherapy. Both CBT and yoga are available in non-research settings.

As an alternative to participating, you may choose not to participate in these research procedures and receive care for depression elsewhere. Any care you receive at Butler Hospital will not be affected in any way if you decide not to participate in this research study.

Financial Disclosure

None.

Voluntary Participation

You are free to decide whether or not to participate in this study, and you are free to withdraw from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your current or future interactions with Butler Hospital, Care New England, or Brown University. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

Confidentiality

Personal identifiers will be removed from any identifiable private information about you in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or the legally authorized representative).

General information about this study has been or will be submitted to the federal clinical trial registry databank, which can be accessed on the Internet at www.ClinicalTrials.gov.

You will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information you provide to us will be maintained in accordance with state and federal laws. If you tell us something that makes us believe that you or others have been or may be physically harmed, we will report that information to the appropriate agencies if required by law**.** In Rhode Island, we are required to report child abuse and neglect and elder abuse to state authorities.

To keep your information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your name or address) separately from study data (such as questionnaires that you complete).

Clinically relevant research results will be disclosed to you only if they are needed for your health care.

This research is covered by a **Certificate of Confidentiality**. Unless you give special written permission, the researchers and Butler Hospital cannot give out any information about you that could potentially identify you or be used as evidence in a legal case (including any federal, state, or local civil, criminal, administrative, or legislative case).

The only situations where researchers would share your information with others are:

(1) when a specific law (federal, state, or local) requires that potentially harmful things be reported to the authorities (such as reporting child abuse, elder abuse or spread of communicable diseases);
(2) when you have given permission (consent) for the information to be shared in order to help your medical treatment; or
(3) when your information will be used for other scientific research, as allowed by federal regulations protecting research subjects.

We ask all participants to treat any information they learn about other members of their yoga class or CBT group as confidential. However, we cannot guarantee that all participants will do so.

Authorization for Use/disclosure of Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Butler Hospital and the researchers at Brown University and Butler Hospital conducting this study to use your health information (information that identifies you), for the purpose of conducting the research study described above.

Your health information related to this study may also be shared with and used by individuals outside of Butler Hospital, including:

- Staff for this research project who are Brown University employees
- Yoga instructors and CBT providers who work on this research project
- Your primary care provider. We will ask you to sign a “Release of Information” form giving us permission to reach out to that provider. Your primary care provider will let us know if it is safe for you to begin an exercise program. We may also contact them during the study to discuss any changes in your health status that may impact your ability to engage in exercise.
- Specialty mental health care providers for whom you provide written authorization for release of health information. If there is a change to your mental health status (e.g., you become

more depressed and may need more treatment), we will communicate with your mental health provider about this.

- Other healthcare and public safety professionals, if we are concerned that you are at risk of hurting yourself or others.
- The Safety Monitoring Committee for this study. This committee is composed of 3-5 professionals who are responsible for ensuring that the research we conduct is done safely and properly. Typically, they do not have access to confidential patient information; however, it is possible that this committee would need to audit our research records.

The health information that we may use or share with others for research purposes includes any information that you give us as part of your study participation, and results of any assessments that we do as part of the study.

Your health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions. The U.S. Food and Drug Administration (FDA) may inspect all study records to ensure that the study is being conducted in accordance with FDA regulations.

Butler Hospital is required by law to protect your health information. Individuals outside of Butler that receive health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we cannot guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in or receive research-related treatment in this study.
- Butler Hospital may not withhold treatment or refuse to treat you based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your health information for this research study, you must contact one of the Principal Investigators, Shirley Yen or Lisa Uebelacker, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, researchers may still use the health information about you that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to the personal health information about you collected as part of this research study until the study is completed. At the conclusion of the research and at your request, you will have access to this personal health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital.
- Your health information will be provided to you or to your physician if it is necessary for your care.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members during your scheduled videoconference meeting. You should take as much time as you need to make your decision.

THIS FORM IS VALID UNTIL

DATE: January 31, 2022

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

Acknowledgements for REDCAP

All of my questions about this study have been answered to my satisfaction. (YES/ NO)

[*answer must be yes to continue*]

I give my consent to participate in this study. (YES/NO)

[*answer must be yes to continue*]

I agree to have my assessment(s) audio recorded. This will be used for research and training purposes only. (YES/NO)

I acknowledge risks related to the use of email associated with my participation, and I agree to allow researchers to contact me via email, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]

Please indicate the email address researchers should use to contact you:

Please re-enter the email address:

I acknowledge risks related to use of text associated with my participation, and I agree to allow researchers to contact me via text, as described in the consent form. (YES/NO)

Please indicate the cell phone number researchers should use to contact you:

Please re-enter the cell phone number:

I acknowledge risks related to use of videoconference associated with my participation, and I agree to participate in research videoconferences, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—RCT

Sponsorship

This study is being paid for by a grant from the National Center for Complementary and Integrative Health.

Research Project Summary

Your child is being invited to participate in this study because they have indicated that they experience sad or depressed mood. Participation in the study will last 6 months. During the first three months, your child will be randomized to one of two groups: 12 weeks of weekly video-based group cognitive-behavioral therapy for depression, or 12 weeks of video-based yoga classes. The amount of time that your child spends on study treatments may amount to 3 hours per week during this initial 3-month period. Throughout the entire 6 months, there will also be periodic assessments which will last 1-2 hours each time. Your child will be paid for study participation. Major risks of participation include loss of confidentiality and minor injury from yoga classes. Study staff will take steps to reduce these risks.

You should know about the risks and benefits of this study to make a wise decision about whether to allow your child to be a part of it. This consent form gives you information about the study. A member of the research team will also discuss this information with you. This discussion will cover why and how we are doing this study, any possible risks and benefits, and possible different ways to help your child get the care they need. Once you understand what the study is about, we will ask you if you wish for your child to be in the study. If so, we will ask you to sign this consent form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

Description of Procedures

1. **Initial Interview.** First, your child will have an initial meeting with study staff via secure videoconference. During this meeting, we will ask your child questions about their mood, substance use, unusual experiences that they might have, eating habits, and other treatments for depression. We will also ask your child to complete questionnaires about their thoughts about themselves, their ability to get things done at home and school, and their level of exercise. This meeting will take 2-3 hours.

   We will use results from this meeting to determine whether the study is a good match for your child. If so, we will contact your child's primary care provider in order to find out whether it is medically safe for your child to be in a yoga class. If their primary care provider agrees, your child will be able to be in the study. (If you have up-to-date documentation that your child may participate in physical education classes, this is an acceptable substitute for medical clearance that is specific to this study). If your child has an outside mental health provider, we will also let them know that your child would like to participate in this study. We will ask you to sign releases of information to contact these providers. We must be able to contact these providers in order for your child to participate in the study. We will send these releases to you and ask that you return them to us via email, fax, or mail.

2. **Random Assignment.** If your child is eligible for the study, they will be randomly assigned to 1 of 2 treatment groups. Your child will have a 1/2 chance of being assigned to take yoga classes, and a 1/2 chance of being assigned to group cognitive-behavioral therapy. The words "random assignment" means that we will use a method similar to flipping a coin to find out which group your child will be in.

3. **Treatments during the study.**

   Group Cognitive-Behavioral Therapy (CBT). This program will involve a series of groups that focus on ways to cope with depression. We will ask your child to first have a 30-minute individual meeting via videoconference with one of the group leaders. Then, they will be invited to attend one 45-minute session via videoconference every week for 12 weeks. The behavioral health specialists who lead this group will introduce new skills, including ways to identify and set important goals, how to cope with low motivation to do things, ways to communicate with peers and others, problem-solving, and how to manage thoughts related to depression. The behavioral health specialists will encourage your child to use what they discuss in the group to make healthy changes to your life. We will mail or drop off a workbook at your house for your child to use.

   Yoga. Yoga involves stretching and breathing exercises. This yoga program will be designed to be safe for people who are new to yoga and who may not be physically fit. As part of this program, we will ask your child to attend an individual session with a yoga teacher via videoconference, and then invite them to attend one 45-minute yoga class via videoconference each week for 12 weeks. The yoga teacher will also give your child guidance on how to practice yoga on their own. We will mail or drop off yoga supplies at your house for your child to use.

4. **Weekly questionnaire.** Every week during the first 12 weeks, we will ask your child to complete a brief questionnaire that asks about home yoga practice or use of skills in the CBT group.

5. **Monthly interviews and questionnaires.** Approximately 1 month after your child starts the study, we will meet with your child via videoconference to ask your child about their mood, their thoughts about themselves, their ability to get things done at home and school, and their level of exercise. Your child will also complete questionnaires on our secure data collection system, called REDCap. This interview and questionnaires will take about 30 minutes. We will ask your child to complete these interviews and questionnaires 2 months and 3 months after starting the study as well. At 3 months, we will also ask your child to answer a series of questions about their opinion of the group they attended. We will also ask your child to complete similar interviews and questionnaires, via videoconference and REDCap, again 3 months after classes end.

6. **Audio Recording.** During the study, we will audio record interviews and classes. We do this to make sure that study staff are following study procedures in the correct way, and also to make sure that we have correctly recorded information that your child shares with us. We will tell your child whenever we plan to audio record. Your or your child may refuse audio recording of interviews at any time and still participate in the study. We will ask for you to indicate whether you give permission for audio recording assessments at the end of this consent form.

   Please note that all yoga and CBT classes will be audio recorded; by signing this consent form you give us permission to do this.

Communications with Study Staff

You and your child will be asked about your preferences for research staff contacting you. This may include telephone, email, or text message. In order for your child to participate, we will need to be able to send links to videoconferences and online questionnaires to your child.

How do telephone communications with researchers work? When research staff contacts your child via phone for appointment reminders, they will be as discrete as possible. If they contact your child by phone, they will not discuss the reason for the phone call with anyone other than you or your child.

How do text communications with researchers work? Texts from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages constantly, but it will be checked periodically during regular office hours. Your child can respond to messages from researchers by sending them text messages, but they should not send private health information.

How do email communications with study researchers work? Emails from the study staff will be sent from a Care New England (carene.org) email address or from our REDCap system for secure data collection. Emails from the study staff will include links to a) a REDCap questionnaire; or b) our videoconference portal. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

How do videoconferences with study researchers work? The purpose of the videoconferences is to a) conduct study assessments; or b) conduct online yoga or group CBT meetings. In order to connect our electronic devices for a videoconference meeting, we will need to send an email message to your child. This message will contain instructions and a weblink to navigate the connection to the videoconference system. We will use a HIPAA-compliant videoconferencing system. For the confidentiality of others participating in the video conference as well as your child's own confidentiality, your child MUST attend the conference in a private space in your home, where there are no other people.

You and your child must agree to the following rules of group confidentiality in the telehealth setting:

- The session leader will monitor the session to make sure that the only people connected to the session are the designated group participants.
- All members of the group must agree to keep the group discussion confidential. Your child must agree to protect the group confidentiality, by not revealing the names of other members of the group, nor what is said and done in the group. Your child must agree to be in a private space in your home for the meeting. If your child violates this confidentiality, they will be removed from the group.
- Your child may not record any part of the group. The consequence for recording would be removal from the group for violating confidentiality, as well as possible legal consequences. We do this because we want to protect everybody's privacy.

Risks related to text and email communication, and videoconferencing. Your child's participation in this research may be considered health information that should be kept confidential.

There are risks associated with communications by text and email, and videoconferences. There is always a risk that a text or email message could be intercepted or sent to the wrong phone number or email address. If someone else were to intercept or read email or text messages sent between our

staff, you, or your child, or overhear the videoconference meeting with our researchers, they might be able to know about your child's participation in this research study. This, in turn, might reveal some of your child's private health information, such as medical or psychiatric symptoms. If you or your child choose to send emails with private health information to us, they could be intercepted or sent to the wrong address, with the resulting loss of confidentiality.

In addition, CBT and yoga classes are group meetings that include other participants who are enrolled in the study. Although we ask all participants to watch the videoconference privately, and maintain any information discussed in the meeting as confidential, we cannot guarantee that they will do so. It is possible that a group member could record the group without permission to do so.

Steps we take to reduce risk of loss of privacy. We will communicate by text or email to a) schedule and provide reminders for research-related appointments; b) send links to videoconferences; or c) to provide links to our secure data collection system, REDCap. We will not send messages to a group of recipients. Only the research team will have access to your child's email or text communications, and only the research team will be part of the videoconferences. We will not send email or text messages that contain urgent information or protected health information. We will not send messages that direct your child to get medical care. Medical issues should be discussed with the research team over the phone rather than by email or text.

We use a study-specific, password-protected cell phone for texting. Emails will be brief and be used for links that your child needs. They will be sent via REDCap or a carene.org email account. Data collected on REDCap is stored in a secure fashion. Our videoconference system is HIPAA compliant and all meetings will be monitored to ensure only desired participants are present.

Email addresses and any other information that personally identifies you or your child will be removed from the final research database when the study is over.

Steps you and your child can take to reduce risk of loss or privacy. Your child should make sure to protect their phone with a password if they send or receive text messages during participation in this study. If you or your child share a home computer with other family members and you do not want them to know your child is participating in this study, make sure to provide an email address that only your child can access. Keep in mind that an employer or school may have access to any email communications sent or received on a work or school computer, or through email accounts that are set up through software owned by a company or institution. Additionally, when using any public computer or a smartphone that might be found or used by others, your child should be sure to protect their username and password, and make sure to logout before moving away from the computer screen.

Contacting research staff by text or email. It is possible that a message your child sends via text or email will go unnoticed or will not be read by the research team for days or weeks. Therefore, they should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, questions about medications, concerns about effects of study procedures, etc.) should NOT be communicated by text or email. These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-430-5258.

Consent. At the end of this consent form, we will ask whether you consent for us to contact your child via text and/or email as described above.

Risks and Inconveniences

Because we will be asking your child questions about themselves, one possible risk is breach of confidentiality. We will treat your child's information as a confidential medical record at Butler Hospital. Information about your child will be handled by research staff involved in this study (at Butler Hospital or Brown University) who are trained in the protection of research participants and take steps to ensure confidentiality. If your child tells us that they have suicidal or homicidal thoughts or plans or are engaged in another behavior that may cause serious health problems, we will tell you and also take steps to keep your child safe. If your child tells us about abuse or neglect of children or elderly persons, we must report that to authorities.

As some of the information that we collect may be done using REDCap, our secure web application for managing online surveys and databases, there is the potential for loss of privacy/confidentiality. The REDCap database will need to include an email address and/or cell phone number in order to send your child the survey. As with other methods, any information that your child provides to us will only be available to study staff. All data captured in REDCap will be stored and hosted by a secure institutional server; no project data is ever transmitted by REDCap to other institutions or organizations. REDCap has been designed to be compliant with guidelines to minimize loss of privacy surrounding protected health information.

It is possible that your child may find some things we ask about to be upsetting and uncomfortable. We will do our best to make sure that your child is as comfortable as possible with any questions that we ask. Your child may refuse to answer any questions.

If your child is taking yoga classes, which involves physical exercise, another possible risk is physical injury. In rare cases, dizziness or fainting may occur. This is true particularly because the yoga teacher is not in the room with the participants and so is unlikely to see any subtle signs of distress. We will take several steps to decrease this risk. First, yoga teachers will have a 1:1 meeting with each participant prior to them starting group classes in order to understand and address any physical concerns participants may have and provide advice about how to manage them. Second, during class, yoga teachers will suggest modifications for each person's individual needs and abilities. Third, yoga teachers will only use postures and practices that have been successfully used in in-person yoga classes with people in this age range. Fourth, all instructors are registered yoga teachers. Finally, if your child has a medical problem or injury when practicing yoga, we will help them to get medical treatment if needed.

Parents of Female Participants Please Note: Although prenatal yoga can be beneficial for women who are pregnant, we do not recommend participation in a regular yoga class during pregnancy. We will ask you and your child to let us know if they become pregnant during the study. We will ask them not to participate in yoga classes if they become pregnant, although we may continue study assessments. If your child does not wish for us to share information about their pregnancy with you, we will not share that information. We will provide appropriate referrals to you or your child if needed.

There is no guarantee that participating in any of these programs will help your child to feel less depressed.

Benefits

1. It is possible that your child will experience less depression while they are in this study.
2. We will talk with your child approximately every 4 weeks to see how depressed your child is feeling. If, at any point, study staff determine that your child's condition is worsening significantly such that

your child may need additional treatment, we will contact your child's other medical providers immediately. We will work with you and with your child's provider to ensure that your child gets appropriate care.

Economic Considerations

If your child is eligible for this study, your child will be paid for completing interviews and questionnaires and other assessments, regardless of how many classes they complete during the course of the study. The total amount your child may receive in this study is $140. Your child will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30
End of month 6	$40

The study interventions and all of the tests and procedures that will be done only for this research will be paid for by the study funds.

Alternative Treatments/Alternative to Participation

Alternatives to participation in this study include getting standard treatment for your child's depression outside of this research program. Alternative community treatments for your child's depression include antidepressant medications or psychotherapy. Both CBT and yoga are available in non-research settings.

As an alternative to participating, you may choose not to allow your child to participate in these research procedures and receive care for depression elsewhere. Any care your child receives at Butler Hospital currently or in the future will not be affected in any way if you decide they may not participate in this research study.

Financial Disclosure

None.

Voluntary Participation

You are free to decide whether or not your child will participate in this study, and you are free to withdraw your child from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your or your child's current or future interactions with Butler Hospital, Care New England, or Brown University. Your child's participation in the study may be terminated by the researchers without regard to your consent; in that case, you and your child are entitled to an explanation of the circumstances leading to that decision.

Confidentiality

Personal identifiers will be removed from any identifiable private information about your child in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or a legally authorized representative).

General information about this study has been or will be submitted to the federal clinical trial registry databank, which can be accessed on the Internet at www.ClinicalTrials.gov.

Your child will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information your child provides to us will be maintained in accordance with state and federal laws. If your child tells us something that makes us believe that you or others have been or may be physically harmed, we will report that information to the appropriate agencies if required by law**.** In Rhode Island, we are required to report child abuse and neglect and elder abuse to state authorities.

To keep your child's information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your child's name or address) separately from study data (such as questionnaires that your child completes).

Clinically relevant research results will be disclosed to you or your child only if they are needed for your child's health care.

This research is covered by a **Certificate of Confidentiality**. Unless you give special written permission, the researchers and Butler Hospital cannot give out any information about your child that could potentially identify your child or be used as evidence in a legal case (including any federal, state, or local civil, criminal, administrative, or legislative case).

The only situations where researchers would share your child's information with others are:

(1) when a specific law (federal, state, or local) requires that potentially harmful things be reported to the authorities (such as reporting child abuse, elder abuse or spread of communicable diseases);
(2) when you have given permission (consent) for the information to be shared in order to help your child's medical treatment; or
(3) when your child's information will be used for other scientific research, as allowed by federal regulations protecting research subjects.

We ask all participants to treat any information they learn about other members of their yoga class or CBT group as confidential. However, we cannot guarantee that all participants will do so.

Authorization for Use/disclosure of Health Information that Identifies Your Child for a Research Study

If you sign this document, you give permission to Butler Hospital and the researchers at Brown University and Butler Hospital conducting this study to use your child's health information (information that identifies your child), for the purpose of conducting the research study described above.

The information you provide us and your child's health information related to this study may be shared with and used by individuals outside of Butler Hospital, including:

- Staff for this research project who are Brown University employees
- Yoga instructors and CBT providers who work on this research project
- Your child's primary care provider. We will ask you to sign a "Release of Information" form giving us permission to reach out to that provider. Your child's primary care provider will let us know if it is safe for your child to begin an exercise program. We may also contact them during the study to discuss any changes in your child's health status that may impact your child's ability to engage in exercise.
- Specialty mental health care providers for whom you provide written authorization for release of health information. If there is a change to your child's mental health status (e.g., your child becomes more depressed and may need more treatment), we will communicate with you and your child's mental health provider about this.
- Other healthcare and public safety professionals, if we are concerned that your child is at risk of hurting themselves or others.
- The Safety Monitoring Committee for this study. This committee is composed of 3-5 professionals who are responsible for ensuring that the research we conduct is done safely and properly. Typically, they do not have access to confidential patient information; however, it is possible that this committee would need to audit our research records.

The health information that we may use or share with others for research purposes includes any information that your child gives us as part of their study participation, and results of any assessments that we do as part of the study.

Your child's health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions. The U.S. Food and Drug Administration (FDA) may inspect all study records to ensure that the study is being conducted in accordance with FDA regulations.

Butler Hospital is required by law to protect your child's health information. Individuals outside of Butler that receive health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we cannot guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, your child may not participate in or receive research-related treatment in this study.
- Butler Hospital may not withhold treatment or refuse to treat your child based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your child's health information for this research study, you must contact one of the Principal Investigators, Shirley Yen or Lisa Uebelacker, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, researchers may still use the health information about your child that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to the personal health information about your child collected as part of this research study until the study is completed. At the conclusion of the research and at your request, you will have access to this personal health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy

Practices provided to you by Butler Hospital.

- Your child's health information will be provided to you or to your child's physician if it is necessary for their care.
- If all information that does or can identify your child is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members during your scheduled videoconference meeting. You should take as much time as you need to make your decision.

THIS FORM IS VALID UNTIL

DATE: January 31, 2022

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

Acknowledgements for REDCAP

All of my questions about this study have been answered to my satisfaction. (YES/ NO)

[*answer must be yes to continue*]

I give consent for my child to participate in this study. (YES/NO)

[*answer must be yes to continue*]

I agree to have my child's assessment(s) audio recorded. This will be used for research and training purposes only. (YES/NO)

I acknowledge risks related to the use of email associated with my child's participation, and I agree to allow researchers to contact my child via email, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]

Please indicate the email address researchers should use to contact your child:

Please re-enter the email address:

I acknowledge risks related to use of text associated with my child's participation, and I agree to allow researchers to contact my child via text, as described in the consent form. (YES/NO)

Please indicate the cell phone number researchers should use to contact your child:

Please re-enter the cell phone number:

I acknowledge risks related to use of videoconference associated with my child's participation, and I agree to allow my child to participate in research videoconferences, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—RCT

Sponsorship

This study is being paid for by a grant from the National Center for Complementary and Integrative Health.

Research Project Summary

You are being invited to participate in this study because your child has indicated that they experience sad or depressed mood. Participation in the study will last 6 months. During the first three months, your child will be randomized to one of two groups: 12 weeks of weekly video-based group cognitive-behavioral therapy for depression, or 12 weeks of video-based yoga classes. The amount of time that you will spend on this study will be one hour per month completing study assessments for the first 3 months, and then 1 hour on assessments 3 months after your child's participation in study classes ends. You and your child will be paid for study participation. The major risk of participation for you is loss of confidentiality. Study staff will take steps to reduce this risk.

You should know about the risks and benefits of this study to make a wise decision about whether to be a part of it. This consent form gives you information about the study. A member of the research team will also discuss this information with you. This discussion will cover why and how we are doing this study, any possible risks and benefits of participation, and possible different ways to help your child get the care they need. Once you understand what the study is about, we will ask you if you wish to be in the study. If so, we will ask you to sign this consent form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

Description of Procedures

1. **Initial Interview.** First, you and your child will have an initial meeting with study staff via secure videoconference. During this meeting, we will ask you questions about your child's mood, substance use, unusual experiences that they might have, eating habits, and other treatments for depression. We will also ask you to complete questionnaires about your child's thoughts about themselves, their ability to get things done at home and school, and their level of exercise. This meeting will take 2-3 hours.

   We will use results from this meeting to determine whether the study is a good match for your child. If so, we will contact your child's primary care provider in order to find out whether it is medically safe for your child to be in a yoga class. If their primary care provider agrees, your child will be able to be in the study. (If you have up-to-date documentation that your child may participate in physical education classes, this is an acceptable substitute for medical clearance that is specific to this study). If your child has an outside mental health provider, we will also let them know that your child would like to participate in this study. We will ask you to sign releases of information to contact these providers. We must be able to contact these providers in order for your child to participate in the study. We will send these releases to you and ask that you return them to us via email, fax, or mail.

2. **Random Assignment.** If your child is eligible for the study, your child will be randomly assigned to 1 of 2 treatment groups. Your child will have a 1/2 chance of being assigned to take yoga classes, and a 1/2 chance of being assigned to group cognitive-behavioral therapy. The words "random assignment" means that we will use a method similar to flipping a coin to find out which group your child will be in. Treatment groups will last 3 months.

3. **Monthly interviews and questionnaires.** Approximately 1 month after your child starts the study, we will meet with you via videoconference to ask you about your child's mood, their thoughts about themselves, their ability to get things done at home and school, and their level of exercise. You will also complete questionnaires on our secure data collection system called REDCap. This interview and questionnaires will take no more than 1 hour. We will ask you to complete these interviews and questionnaires 2 months and 3 months after starting the study as well. At 3 months, we will also ask you to answer a series of questions about your opinion of the group your child attended. We will ask you to complete similar interviews and questionnaires, via videoconference and REDCap, again 3 months after classes end.

4. **Audio Recording.** During the study, we will audio record all interviews and classes. We do this to make sure that study staff are following study procedures in the correct way and also to make sure that we have correctly recorded information that you share with us. We will tell you whenever we plan to audio record. You may refuse audio recording of interviews at any time and still participate in the study. We will ask for you to indicate whether you give permission for audiorecording assessments at the end of this consent form.

Communications with Study Staff

You and your child will be asked about your preferences for research staff contacting you. This may include telephone, email, or text message. In order for you and your child to participate, we will need to be able to send links to videoconferences and online questionnaires to you and your child.

How do telephone communications with researchers work? When research staff contacts you via phone for appointment reminders, they will be as discrete as possible. If they contact you by phone, they will not discuss the reason for the phone call with anyone other than you or your child.

How do text communications with researchers work? Texts from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages constantly, but it will be checked periodically during regular office hours. You can respond to messages from researchers by sending them text messages, but you should not send private health information.

How do email communications with study researchers work? Emails from the study staff will be sent from a Care New England (carene.org) email address or from our REDCap system for secure data collection. Emails from the study staff will include links to a) a REDCap questionnaire; or b) our videoconference portal. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

How do videoconferences with study researchers work? The purpose of the videoconferences is to conduct study assessments. In order to connect our electronic devices for a videoconference meeting, we will need to send an email message to you. This message will contain instructions and a weblink to navigate the connection to the videoconference system. We will use a HIPAA-compliant

videoconferencing system. For the confidentiality of you and your child, you MUST attend the conference in a private space in your home, where there are no other people.

Risks related to text and email communication, and videoconferencing. You and your child's participation in this research may be considered health information that should be kept confidential.

There are risks associated with communications by text and email, and videoconferences. There is always a risk that a text or email message could be intercepted or sent to the wrong phone number or email address. If someone else were to intercept or read email or text messages sent between our staff, you, or your child, or overhear the videoconference meeting with our researchers, they might be able to know about you and your child's participation in this research study. This, in turn, might reveal some of you or your child's private health information, such as medical or psychiatric symptoms. If you or your child choose to send emails with private health information to us, they could be intercepted or sent to the wrong address, with the resulting loss of confidentiality.

Steps we take to reduce risk of loss of privacy. We will communicate by text or email to a) schedule and provide reminders for research-related appointments; b) send links to videoconferences; or c) to provide links to our secure data collection system, REDCap. We will not send messages to a group of recipients. Only the research team will have access to you and your child's email or text communications, and only the research team will be part of the videoconferences. We will not send email or text messages that contain urgent information or protected health information. We will not send messages that direct you or your child to get medical care. Medical issues should be discussed with the research team over the phone rather than by email or text.

We use a study-specific, password-protected cell phone for texting. Emails will be brief and be used for links that your child needs. They will be sent via REDCap or a carene.org email account. Data collected on REDCap is stored in a secure fashion. Our videoconference system is HIPAA compliant and all meetings will be monitored to ensure only desired participants are present.

Email addresses and any other information that personally identifies you or your child will be removed from the final research database when the study is over.

Steps you can take to reduce risk of loss or privacy. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study. If you share a home computer with other family members and you do not want them to know you and your child are participating in this study, make sure to provide an email address that only you can access. Keep in mind that an employer or school may have access to any email communications sent or received on a work or school computer, or through email accounts that are set up through software owned by a company or institution. Additionally, when using any public computer or a smartphone that might be found or used by others, you should be sure to protect your username and password, and make sure to logout before moving away from the computer screen.

Contacting research staff by text or email. It is possible that a message you send via text or email will go unnoticed or will not be read by the research team for days or weeks. Therefore, you should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, questions about medications, concerns about effects of study procedures, etc.) should NOT be communicated by text/email. These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-430-5258.

Consent. At the end of this consent form, we will ask whether you consent for us to contact you via text and/or email as described above.

Risks and Inconveniences

Because we will be asking you questions about you and your child, one possible risk is breach of confidentiality. We will treat your information as a confidential medical record at Butler Hospital. Information about you or your child will be handled by research staff involved in this study (at Butler Hospital or Brown University) who are trained in the protection of research participants and take steps to ensure confidentiality. However, if you tell us that you have suicidal or homicidal thoughts or plans, we are obligated to take steps to keep you safe. If you tell us about abuse or neglect of children or elderly persons, we must report that to authorities.

As some of the information that we collect may be done using REDCap, our secure web application for managing online surveys and databases, there is the potential for loss of privacy/confidentiality. The REDCap database will need to include an email address and/or cell phone number in order to send you the survey. As with other methods, any information that you provide to us will only be available to study staff. All data captured in REDCap will be stored and hosted by a secure institutional server; no project data is ever transmitted by REDCap to other institutions or organizations. REDCap has been designed to be compliant with guidelines to minimize loss of privacy surrounding protected health information.

It is possible that you may find some things we ask about to be upsetting and uncomfortable. We will do our best to make sure that you are as comfortable as possible with any questions that we ask. You may refuse to answer any questions.

Benefits

There are no direct benefits to you. It is possible that your child will experience less depression while you are in this study. We will also monitor your child's depression symptoms every four weeks and help you and your child get appropriate medical treatment if it seems that your child's condition is worsening significantly.

Economic Considerations

If your child is eligible for this study, you and your child will be paid for completing interviews and questionnaires and other assessments, regardless of how many classes or groups they complete during the course of the study. The total amount you may receive in this study is $140. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30
End of month 6	$40

The study interventions and all of the tests and procedures that will be done only for this research will be paid for by the study funds.

Alternative Treatments/Alternative to Participation

You will not be provided with any treatment for yourself.

Alternatives to participation in this study include getting standard treatment for depression outside of this research program. Alternative community treatments for your child's depression include antidepressant medications or psychotherapy. Both CBT and yoga are available in non-research settings.

As an alternative to participating, you may choose not to participate in these research procedures and receive care for your child's depression elsewhere. Any care you or your child receives at Butler Hospital will not be affected in any way if you decide not to participate in this research study.

Financial Disclosure

None.

Voluntary Participation

You are free to decide whether you will participate in this study, and you are free to withdraw from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your or your child's current or future interactions with Butler Hospital, Care New England, or Brown University. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

We value your participation in this research as well as your child's participation. Your participation may give us additional insight into how yoga or CBT may work for your child. However, you may choose to allow your child to participate in this study (by signing a separate consent form for your child) but refuse to participate yourself. If you do not want to participate, do not sign this consent form.

Confidentiality

Personal identifiers will be removed from any identifiable private information about you or your child in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or your legally authorized representative).

General information about this study has been or will be submitted to the federal clinical trial registry databank, which can be accessed on the Internet at www.ClinicalTrials.gov.

You or your child will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information you provide to us will be maintained in accordance with state and federal laws. If you tell us something that makes us believe that you or others have been or may be physically harmed, we will report that information to the appropriate agencies if required by law**.** In Rhode Island, we are required to report child abuse and neglect and elder abuse to state authorities.

To keep your and your child's information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your name or address) separately from study data (such as questionnaires that you complete).

Clinically relevant research results will be disclosed to you only if they are needed for your child's health care.

This research is covered by a **Certificate of Confidentiality**. Unless you give special written permission, the researchers and Butler Hospital cannot give out any information about you or your child that could potentially identify you or your child or be used as evidence in a legal case (including any federal, state, or local civil, criminal, administrative, or legislative case).

The only situations where researchers would share you or your child's information with others are:

(1) when a specific law (federal, state, or local) requires that potentially harmful things be reported to the authorities (such as reporting child abuse, elder abuse or spread of communicable diseases);
(2) when you have given permission (consent) for the information to be shared in order to help your child's medical treatment; or
(3) when your child's information will be used for other scientific research, as allowed by federal regulations protecting research subjects.

Authorization for Use/disclosure of Health Information that Identifies You or Your Child for a Research Study

If you sign this document, you give permission to Butler Hospital and the researchers at Brown University and Butler Hospital conducting this study to use your and/or your child's health information (information that identifies you or your child), for the purpose of conducting the research study described above.

The information you provide us and your child's health information related to this study may be shared with and used by individuals outside of Butler Hospital, including:

- Staff for this research project who are Brown University employees
- Yoga instructors and CBT providers who work on this research project
- Your child's primary care provider. We will ask you to sign a "Release of Information" form giving us permission to reach out to that provider. Your child's primary care provider will let us know if it is safe for your child to begin an exercise program. We may also contact them during the study to discuss any changes in your child's health status that may impact your child's ability to engage in exercise.
- Specialty mental health care providers for whom you provide written authorization for release of health information. If there is a change to your child's mental health status (e.g., your child becomes more depressed and may need more treatment), we will communicate with you and your child's mental health provider about this.
- Other healthcare and public safety professionals, if we are concerned that you or your child is at risk of hurting yourself/themselves or others.
- The Safety Monitoring Committee for this study. This committee is composed of 3-5 professionals who are responsible for ensuring that the research we conduct is done safely and properly. Typically, they do not have access to confidential patient information; however, it is possible that this committee would need to audit our research records.

The health information that we may use or share with others for research purposes includes any information that you give us as part of your study participation, and results of any assessments that we do as part of the study.

You and your child's health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions. The U.S. Food and Drug Administration (FDA) may inspect all study records to ensure that the study is being conducted in accordance with FDA regulations.

Butler Hospital is required by law to protect you and your child's health information. Individuals outside of Butler that receive health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we cannot guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in this study.
- Butler Hospital may not withhold treatment or refuse to treat you or your child based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your or your child's health information for this research study, you must contact one of the Principal Investigators, Shirley Yen or Lisa Uebelacker, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, researchers may still use the health information about you or your child that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to the personal health information about you and your child collected as part of this research study until the study is completed. At the conclusion of the research and at your request, you will have access to this personal health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital.
- Your child's health information will be provided to you or to your child's physician if it is necessary for their care.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members during your scheduled videoconference meeting. You should take as much time as you need to make your decision.

THIS FORM IS VALID UNTIL

DATE: January 31, 2022

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

Acknowledgements for REDCAP

All of my questions about this study have been answered to my satisfaction. (YES/ NO)

[*answer must be yes to continue*]

I give my consent to participate in this study. (YES/NO)

[*answer must be yes to continue*]

I agree to have my assessment(s) audio recorded. This will be used for research and training purposes only. (YES/NO)

I acknowledge risks related to the use of email associated with my participation, and I agree to allow researchers to contact me via email, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]

Please indicate the email address researchers should use to contact you:

Please re-enter the email address:

I acknowledge risks related to use of text associated with my participation, and I agree to allow researchers to contact me via text, as described in the consent form. (YES/NO)

Please indicate the cell phone number researchers should use to contact you:

Please re-enter the cell phone number:

I acknowledge risks related to use of videoconference associated with my participation, and I agree to participate in research videoconferences, as described in the consent form. (YES/NO)

[*answer must be yes to continue*]