DOCUMENT:

INFORMED CONSENT AND ASSENT

OFFICIAL STUDY TITLE:

TREATMENTS FOR IMPROVING MOOD IN DEPRESSED TEENS

(TEEN THRIVE-2)

R34AT009886

NCT NUMBER:

NCT03831347

DOCUMENT DATE:

(04/17/2019)

ASSENT FOR PARTICIPATION IN A RESEARCH PROJECT

BUTLER HOSPITAL AND BROWN UNIVERSITY

Treatments for Improving Mood in Depressed Teens—Open Trial

Research Project Summary

A research study is a way to learn more about people. We are doing a research study to understand how yoga may help teens with depression. 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 3 months. After starting the study, the amount of time that you spend on study treatments may amount to 3 hours per week (including time at home) for the 12 weeks. 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 come to an initial meeting with study staff. 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 him or her know that you would like to participate in this study. We will ask your parent to sign releases of information to contact both providers.

2. **Treatment during the study.** 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 go to an individual session with a yoga teacher, and then to one 45-minute yoga class each week for 12 weeks. The yoga program will occur in a room at Butler Hospital, and there will be up to 12 students in the class. The yoga teacher will also give you guidance on how to practice yoga at home, and ask you to try it. The teacher will give you your own yoga mat for home practice.

   Please treat any information you learn about other members of the yoga class as confidential information. Do not discuss information about other participants outside of the yoga classes.

3. **Weekly questionnaire.** Every week during the 12 weeks, we will ask you to complete a brief questionnaire that asks about home yoga practice.

4. **Monthly interviews and questionnaires.** Approximately 1 month after you start the study, we will call you at home or meet with you before a class 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. This interview and questionnaires will take no more than one 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 you attended.

5. **Audiorecording.** 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 use an audio-recorder. You or your parent may refuse audio-recording of interviews at any time and still participate in the study.

Text and Email 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, e-mail, or text message.

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? Text 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. Below, we discuss the kinds of messages you should and should not send by text.

Risks related to texts. Researchers will only use texts to schedule and provide reminders for research-related appointments, or to provide a link to our secure data-collection system, called REDCap. We will not send text messages to a group of recipients. If you share your phone or messages with others, they might be able to see that you are in this study. Please use a password on your phone to keep your information private.

How do emails with researchers work? Email from the study will be sent through REDCap. REDCap encodes the message so it cannot be read by someone that is not supposed to see it. You will get a message in your email from a research email address. Researchers will not check the study email address on a regular basis.

Risks related to emails. There is always a risk that the message could be read by someone else or sent to the wrong email address. Only the research team will have access to your email address and messages. We will only communicate by email to send you the information listed above. We will not send email messages that contain urgent information or private health information. We will not send messages that tell you to get medical care.

Using the REDCap secure e-mail system will help reduce the chance that others will see private information about the study. If you share a home computer with other family members and you do not want them to know that you are participating in this study, you should provide an e-mail address that only you can access. Your school (or employer, if relevant) will have access to any e-mail communications sent or received on a school or work computer. Additionally, when using any public computer you should be careful to protect your username and password, and make sure to log-out before getting up from the computer.

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 401-455-6381.

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.

In the yoga classes, it is possible that you may experience an injury such as a muscle strain. In order to reduce this risk of injury, we ask that you follow the yoga teacher's instructions and let him/ her 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 you completed during the course of the study. The total amount you may receive in this study is $100. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2 (by phone)	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30

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 the yoga class 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 researcher any questions you have about participating. If you decide you want to be in this study, please sign your name on the following page.

ASSENT FOR PARTICIPATION IN A RESEARCH PROJECT – SIGNATURE PAGE

I, _____ have read this form and this research study has been explained to me. I have decided that I want to be in this research study. My signature also indicates that I have received a copy of this form.

_____
[Print Name]

X_____ _____
[Sign your name above] [date]

X_____ _____
[Signature of Principal Investigator] [telephone]

or

X_____ _____
[Signature of Person Obtaining Assent] [telephone]

If you have further questions about this project or about research-related injuries, please contact Lisa Uebelacker, Ph.D. at (401) 455-6381 or Shirley Yen, PhD, at (401) 444-1915. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at (401) 455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

ADDITIONAL ASSENTS

Please place your initials next to each statement to which you agree.

	Initial here
I agree to have my interviews audiotaped. This will be used for research and training purposes only. I can change my mind at any time and this audiotape (and any copies) will be destroyed.	
I agree to allow researchers to send me texts, as described in this assent form.	
I agree to allow researchers to send me emails, as described in this assent form.	

_____

[Print Child Name]

X_____ _____

[Self] [date]

X_____ _____

[Witness] [date]

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—Open Trial

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 3 months. If eligible, you will receive 12 weeks of yoga classes. The amount of time that you spend on study treatments may amount to 3 hours per week (including time at home) during this 3-month period. Throughout the 3 months, there will also be monthly assessments which will last no more than 1 hour each time. You 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 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 come to an initial meeting with study staff. 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 updated 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 him or her know that you would like to participate in this study. We will ask you to sign releases of information to contact both providers. We must be able to contact these providers in order for you to participate in the study.

2. **Treatments during the study.** 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 go to an individual session with a yoga teacher, and then to one 45-minute yoga class each week for 12 weeks. The yoga program will occur in a room at Butler Hospital, and there will be up to 12 students in the class. The yoga teacher will also give you guidance on how to practice yoga at home, and ask you to try it. The teacher will give you your own yoga mat for home practice.

Please treat any information you learn about other members of the yoga class as confidential information. Do not discuss information about other participants outside of the yoga classes.

3. **Weekly questionnaire.** Every week during the first 12 weeks, we will ask you to complete a brief questionnaire that asks about home yoga practice.

4. **Monthly interviews and questionnaires.** Approximately 1 month after you start the study, we will call you at home or meet with you before a class to ask you about your mood, your thoughts about yourself, your ability to get things done at home, work/ school, and your level of exercise. You will also complete questionnaires on a computer in our offices or at home (using our internet data collection system called REDCap; please see more information below). 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 yoga classes.

5. **Audiorecording.** 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 use an audio-recorder. 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.

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

Text and Email Communications with Study Staff

You will be asked about your preferences for how research staff contact you. This may include telephone, mail, e-mail, or text message.

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? Text 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 there are only certain things you should communicate via text message.

Risks related to text communication. Your participation in this research may be considered health information that should be kept confidential. There are risks associated with sending messages related to health information via text. We will only communicate by text to schedule and provide reminders for

research-related appointments, or to provide a link to our secure data-collection system, REDCap. We will not send text messages to a group of recipients. If you share your mobile phone or messages with others, you risk losing privacy surrounding your health information and loss of privacy surrounding participation in this study. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study.

How do email communications with study researchers work? Email from the study will be sent through a CareNewEngland (CNE) secure e-mail "portal" system through REDCap that encrypts the message (encodes the message so it cannot be read by someone that is not supposed to see it). You will receive a notification in your regular email inbox from a research email address. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

Risks related to email communication. There are risks associated with communications by email. There is always a risk that the message could be intercepted or sent to the wrong email address. However, only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. We will not send email messages that contain urgent information or protected health information. We will not send messages that direct you to get medical care.

Using the REDCap secure e-mail system will help reduce the chance that you will experience loss of confidentiality when using e-mail. If you share a home computer with other family members and do not want them to know that you are participating in this study, you should provide an e-mail address that only you can access. Your school or employer, if relevant, will have access to any e-mail communications sent or received on a school or work computer. Additionally, when using any public computer you should be careful to protect your username and password, and make sure to log-out before getting up from the computer.

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 401-455-6381.

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, 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, by entering responses on an iPad web browser, 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 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 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.

As you will be taking yoga classes, which involves physical exercise, another possible risk is physical injury. In rare cases, dizziness or fainting may occur. We will take several steps to decrease this risk. First, all classes will be modified for each person's individual needs and abilities. Second, all instructors are registered yoga teachers. Third, 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 yoga classes 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 you complete during the course of the study. The total amount you may receive in this study is $100. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2 (by phone)	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30

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 currently or in the future will not be affected in any way if you decide not to participate in this research study.

Financial Disclosure

Not applicable.

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 or biospecimens 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 the yoga class 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 him/her 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. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Authorization: I have read this form and decided that _____

(name)

will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

_____

Signature

_____

Relationship (self, parent, guardian)

_____

Date

_____ _____

Signature of Principal Investigator OR Telephone

_____ _____

Signature of Person Obtaining Consent Telephone

If you have further questions about this project or about research-related injuries, please contact Lisa Uebelacker, Ph.D. at (401) 455-6381 or Shirley Yen, PhD, at (401) 444-1915. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at (401) 455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

ADDITIONAL CONSENTS

Please place your initials next to each statement to which you agree.

	Initial here
I agree to have my assessment(s) audiotaped. This will be used for research and training purposes only. I can withdraw my permission at any time and this audiotape (and any copies) will be destroyed.	
I agree to allow researchers to contact me by text, as described in this consent form.	
I agree to allow researchers to contact me by email, as described in this consent form.	

_____

[Print Name]

X_____ _____

[Self] [date]

X_____ _____

[Witness] [date]

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

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DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—Open Trial

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 he/she has indicated that he/she experiences sad or depressed mood. Participation in the study will last 3 months. If eligible, your child will receive 12 weeks of yoga classes. The amount of time that your child spends on study treatments may amount to 3 hours per week (including time at home) during this 3-month period. Throughout the 3 months, there will also be monthly assessments which will last no more than 1 hour 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 of participation, and possible different ways to help your child get the care he/she needs. 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 come to an initial meeting with study staff. During this meeting, we will ask your child questions about her/his mood, substance use, unusual experiences that he/she might have, eating habits, and other treatments for depression. We will also ask your child to complete questionnaires about his/her thoughts about him/her self, his/her ability to get things done at home and school, and his/her 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 his/her primary care provider agrees, your child will be able to be in the study. (If you have updated 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 him or her know that your child would like to participate in this study. We will ask you to sign releases of information to contact both providers. We must be able to contact these providers in order for your child to participate in the study.

   Treatments during the study. 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 go to an individual session with a yoga teacher, and then to one 45-minute yoga class each week for 12 weeks. The yoga program will occur in a room at Butler Hospital, and there will be up to 12 students in the class. The yoga teacher will also give your child guidance on how to practice yoga at home, and ask your child to try it. The teacher will give your child his/her own yoga mat for home practice.

We ask that participants treat any information they learn about other members of the yoga class as confidential information.

2. **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.

3. **Monthly interviews and questionnaires.** Approximately 1 month after your child starts the study, we will call your child at home or meet with your child before a class to ask your child about his/her mood, his/her thoughts about him/her self, his/her ability to get things done at home and school, and his/her level of exercise. Your child will also complete questionnaires on a computer in our offices or at home (using our internet data collection system called REDCap; please see more information below). 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 his/her opinion of the yoga classes.

4. **Audiorecording.** 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 your child shares with us. We will tell your child whenever we plan to use an audio-recorder. You 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 audiorecording assessments at the end of this consent form.

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

Text and Email Communications with Study Staff

You and your child will be asked about your preferences for how research staff contact you. This may include telephone, mail, e-mail, or text message.

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? Text 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 there are only certain things he/she should communicate via text message.

Risks related to text communication. Your child's participation in this research may be considered health information that should be kept confidential. There are risks associated with sending messages related to health information via text. We will only communicate by text to schedule and provide reminders for research-related appointments, or to provide a link to our secure data-collection system, REDCap. We will not send text messages to a group of recipients. If your child shares his/her mobile phone or messages with others, he/she risks losing privacy surrounding his/her health information and loss of privacy surrounding participation in this study. Your child should make sure to protect his/her phone with a password if he/she sends or receives text messages during participation in this study.

How do email communications with study researchers work? Email from the study will be sent through a CareNewEngland (CNE) secure e-mail "portal" system through REDCap that encrypts the message (encodes the message so it cannot be read by someone that is not supposed to see it). Your child will receive a notification in his/her regular email inbox from a research email address. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

Risks related to email communication. There are risks associated with communications by email. There is always a risk that the message could be intercepted or sent to the wrong email address. However, only the research team will have access to your child's email communications. We will only communicate by email to send your child the information listed above. We will not send email messages that contain urgent information or protected health information. We will not send messages that direct your child to get medical care.

Using the REDCap secure e-mail system will help reduce the chance that your child will experience loss of confidentiality when using e-mail. If your child shares a home computer with other family members and does not want them to know that he/she is participating in this study, your child should provide an e-mail address that only he/she can access. Your child's school (or employer, if relevant) will have access to any e-mail communications sent or received on a school or work computer. Additionally, when using any public computer your child should be careful to protect her/his username and password, and make sure to log-out before getting up from the computer.

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, he/she 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 401-455-6381.

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 him/ her self, 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 he/she has suicidal or homicidal thoughts or plans, or is 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, by entering responses on an iPad web browser, 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.

As your child will be taking yoga classes, which involves physical exercise, another possible risk is physical injury. In rare cases, dizziness or fainting may occur. We will take several steps to decrease this risk. First, all classes will be modified for each person's individual needs and abilities. Second, all instructors are registered yoga teachers. Third, if your child has a medical problem or injury when practicing yoga, we will help you 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 she becomes pregnant during the study. We will ask her not to participate in yoga classes if she becomes pregnant, although we may continue study assessments. If your child does not wish for us to share information about her 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 yoga classes 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 he/she completes during the course of the study. The total amount your child may receive in this study is $100. Your child will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2 (by phone)	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30

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 he/ she may not participate in this research study.

Financial Disclosure

Not applicable.

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 or biospecimens 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.

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 the yoga class 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 him/her 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 him/her self 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 his/her 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 his/her 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. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want your child to take part.

Authorization: I have read this form and decided that _____

(name of child)

will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

_____

Signature

_____

Relationship (self, parent, guardian)

_____

Date

_____ _____

Signature of Principal Investigator OR Telephone

_____ _____

Signature of Person Obtaining Consent Telephone

If you have further questions about this project or about research-related injuries, please contact Lisa Uebelacker, Ph.D. at (401) 455-6381 or Shirley Yen, PhD, at (401) 444-1915. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at (401) 455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

ADDITIONAL CONSENTS

Please place your initials next to each statement to which you agree.

	Initial here
I agree to have my child's assessment(s) audiotaped. This will be used for research and training purposes only. I can withdraw my permission at any time and this audiotape (and any copies) will be destroyed.	
I agree to allow researchers to contact my child by text, as described in this consent form.	
I agree to allow researchers to contact my child by email, as described in this consent form.	

_____

[Print Child Name]

X_____ _____

[Parent/ Guardian Signature] [date]

X_____ _____

[Witness] [date]

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Butler Hospital and Brown Medical School

Treatments for Improving Mood in Depressed Teens—Open Trial

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 he/she experiences sad or depressed mood. Participation in the study will last 3 months. If eligible, your child will receive 12 weeks of yoga classes. The amount of time that you spend on this study will be approximately 1 hour per month completing study assessments. 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 he/she needs. 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 come to an initial meeting with study staff. During this meeting, we will ask you questions about your child's mood, substance use, unusual experiences that he/she might have, eating habits, and other treatments for depression. We will also ask you to complete questionnaires about your child's thoughts about him/her self, his/her ability to get things done at home and school, and his/her level of exercise. This meeting will take 2-3 hours.

   We will use results from this meeting, as well as medical documentation from your child's primary care provider, 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 his/her primary care provider agrees, your child will be able to be in the study. (If you have updated 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 him or her know that your child would like to participate in this study. We will ask you to sign releases of information to contact both providers. We must be able to contact these providers in order for your child to participate in the study.

2. **Monthly interviews and questionnaires.** Approximately 1 month after your child starts the study, we will call you at home or meet with you before a class to ask you about your child's mood, his/her thoughts about him/her self, his/her ability to get things done at home and school, and his/her level of exercise. You will also complete questionnaires on a computer in our offices or at home (using our internet data collection system called REDCap; please see more information below). 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 yoga classes.

3. **Audiorecording.** 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 use an audio-recorder. 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.

Text and Email Communications with Study Staff

You and your child will be asked about your preferences for how research staff contact you. This may include telephone, mail, e-mail, or text message.

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? Text 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 there are only certain things you should communicate via text message.

Risks related to text communication. Your participation in this research may be considered health information that should be kept confidential. There are risks associated with sending messages related to health information via text. We will only communicate by text to schedule and provide reminders for research-related appointments, or to provide a link to our secure data-collection system, REDCap. We will not send text messages to a group of recipients. If you share your mobile phone or messages with others, you risk losing privacy surrounding you or your child's health information and loss of privacy surrounding participation in this study. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study.

How do email communications with study researchers work? Email from the study will be sent through a CareNewEngland (CNE) secure e-mail "portal" system through REDCap that encrypts the message (encodes the message so it cannot be read by someone that is not supposed to see it). You will receive a notification in your regular email inbox from a research email address. The study email address will not be monitored for return messages. Emails may NOT be received by researchers on a regular basis.

Risks related to email communication. There are risks associated with communications by email. There is always a risk that the message could be intercepted or sent to the wrong email

address. However, only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. We will not send email messages that contain urgent information or protected health information. We will not send messages that direct your child to get medical care.

Using the REDCap secure e-mail system will help reduce the chance that you will experience loss of confidentiality when using e-mail. If you share a home computer with other family members and do not want them to know that your child is participating in this study, you should provide an e-mail address that only you can access. Your employer, if relevant, will have access to any e-mail communications sent or received on a work computer. Additionally, when using any public computer you should be careful to protect your username and password, and make sure to log-out before getting up from the computer.

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. These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-455-6381.

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 teen, 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, by entering responses on an iPad web browser, 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 he/she completes during the course of the study. The total amount you may receive in this study is $100. You will be paid the following amounts at the following time points:

Timepoint	Amount
Baseline – visit 1	$30
Baseline – visit 2 (by phone)	$0
End of month 1	$20
End of month 2	$20
End of month 3	$30

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 currently or in the future will not be affected in any way if you decide not to participate in this research study.

Financial Disclosure

Not applicable.

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 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 or biospecimens 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 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 him/her 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
- Other healthcare and public safety professionals, if we are concerned that you or your child is at risk of hurting him/her self 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 you 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 his/her 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. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Authorization: I have read this form and decided that _____

(name)

will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

_____

Signature

_____

Relationship (self, parent, guardian)

_____

Date

_____ _____

Signature of Principal Investigator OR Telephone

_____ _____

Signature of Person Obtaining Consent Telephone

If you have further questions about this project or about research-related injuries, please contact Lisa Uebelacker, Ph.D. at (401) 455-6381 or Shirley Yen, PhD, at (401) 444-1915. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at (401) 455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro

ADDITIONAL CONSENTS

Please place your initials next to each statement to which you agree.

	Initial here
I agree to have my assessment(s) audiotaped. This will be used for research and training purposes only. I can withdraw my permission at any time and this audiotape (and any copies) will be destroyed.	
I agree to allow researchers to contact me by text, as described in this consent form.	
I agree to allow researchers to contact me by email, as described in this consent form.	

_____

[Print Child Name]

X_____ _____

[Parent/ Guardian Signature] [date]

X_____ _____

[Witness] [date]

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2020

IRBNET ID# 1187076

BUTLER IRB REFERENCE# 1802-001

BY (ADMINISTRATOR): CCordeiro