

**Treatments for Improving Mood in Women Survivors of Interpersonal Violence: A
Community-Engaged Study-1.2**

NCT06657950

Informed Consent Form

Date Last Updated: January 30, 2025

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Treatments for Improving Mood in Women—Screening Consent

Sponsorship

This study is being paid for by the National Center for Complementary and Integrative Health (NCCIH).

Introduction to Screening Consent Procedure

This consent refers to a screening procedure that must take place in order to determine eligibility for the research study. The screening procedure includes completion of an interview and questionnaires related to your mental health history, experiences of interpersonal violence, and physical activity.

This consent form will give you the information you will need to understand why this screening is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences, or discomforts you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends, and doctor. We also encourage you to ask questions now and at any time. If you decide to participate you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.

Description of Procedures

The purpose of the screening interview and questionnaires will be to determine your eligibility for being in the research study. If you decide that you would like to proceed, you will be asked questions about your mood, substance use, whether you see or hear things that are unusual and distressing for you, eating habits, experiences of interpersonal violence, and physical activity.

If you agree to take part in this screening procedure, you will be asked to take part in an interview and complete questionnaires. This interview will ask you questions related to your prior and current mental health status, as well as experiences of interpersonal violence. If you meet the final screening criteria and are determined qualified to participate in the study, you will then be administered the full informed consent for the study, which will describe why the research is being conducted, what you can expect from the process, other treatment options, and your rights as a research participant.

The screening procedure will take place here in the lab at Butler Hospital, via videoconference, or a safe, private place of your choosing, including your own home. If you agree to participate, immediately after completion of this form, the screening procedure will take between 1 and 2 hours.

We will use results from this meeting to determine whether the study is a good match for you. If you are not determined eligible to participate in the study, you will not be contacted in the future unless you sign a separate consent form indicating your interest in being contacted for other research studies.

Depending on your responses, we may request to contact your medical care provider (with your written permission) 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). 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 both providers. We must be able to contact these providers in order for you to participate in the study.

What are the Risks or Inconveniences of the Study?

We believe there are no known physical or social risks associated with these screening procedures. However, as a result of answering questions related to your current and past mental health, or experiences of interpersonal violence, you may experience some distress or emotional discomfort. 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.

A possible inconvenience may be the time it takes to complete this screening procedure.

Audio Recordings

We may audiorecord the interview with you 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 when we plan to use the 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 the assessment at the end of this consent form.

Benefits

You may not directly benefit from this screening procedure; however, we hope that for participants that are qualified to participate in the study, participation may be associated with lower distress. We also hope the study will help us to understand the development of treatments to improve mood in women with a history of interpersonal violence.

Economic Considerations

There are no costs and you will not be paid to participate in this screening procedure.

Alternative Treatments/Alternatives to Participation

There are no alternatives to participation for this screening procedure. However, alternatives to participation in the study for those who screen eligible involves getting treatment for distress outside of the research program.

Financial Disclosure

None

Voluntary Participation

You are free to decide if you want to take part in this screening procedure. You are also free to stop the screening procedure at any time. If you decide you do not want to be a part of this screening procedure, that will not have any impact on your care at Butler Hospital or Care New England.

Sharing Results of this Research with Participants

Clinically relevant results of this research, including results about you as an individual, may not be shared with you.

Confidentiality

As some of the information that we collect may be stored using REDCap, our secure web application for managing online surveys and databases, by entering responses on a web-browser, there is the potential for loss of privacy/ confidentiality. 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.

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. This includes a current report of experiencing interpersonal violence if you are 60 years of age or older.

To keep your information safe, we will store all information in REDCap, locked file cabinets that only research staff can open, and/or on password protected secure Care New England 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).

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can visit this Web site any time.

This research is covered by a **Certificate of Confidentiality**. Unless you give special permission in writing, 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.

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 participants.

Audio Recordings. Interview recordings will occur through the use of credit-card size digital audio recorders, which have password-protection and encryption capabilities thereby protecting their contents in the event of transport between the study site and our research offices. All digital recordings will be regularly transferred via USB and/or secure file transfer to Care New England's secure computer servers. After transferring the files, the file will be deleted from its original location (that is, the audio recorder). Recordings will be destroyed within six years of study completion.

Authorization for use/disclosure of your Identifying Health Information to Conduct this Study

If you sign this document, you give permission to the study research team at Butler Hospital to use your health information, including identifying information, for the purpose of doing the research study explained above.

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

- Yoga teachers who work on this project.
- The Safety Monitoring Committee for this study. This committee is made up of 3-5 professionals who help make sure that the research is done safely and properly. Typically they do not have access to private patient information; however, it is possible that they would need to look at our research records.
- The study monitor assigned by NCCIH. A person who is not part of the study may come to look at all study records to make sure we are following the rules of the study. This study

monitor will have access to your study record but is required to follow the same rules of confidentiality as the research team.

- Other healthcare and public safety professionals, if we are concerned you are a risk of hurting yourself or others.

The health information that study staff may use or share with others for this research includes any information that you give us as part of your participation in this screening procedure.

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, or for understanding public health problems. The FDA may inspect all study records to ensure that the study is being conducted according to FDA rules.

Butler Hospital is required by law to protect your health information. Individuals outside of Butler that receive your 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 proceed to the screening procedure. The screening procedure is required to determine eligibility to take part 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 the Principal Investigator, Tosca Braun, PhD, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, Butler researchers may still use or share health information about you that they already have, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to your personal health information related to this research until the study is over. At the end of the research and at your request, you will have access to your health information that Butler Hospital keeps, according to the Notice of Privacy Practices provided to you by Butler Hospital. The record includes medical information or billing records used by doctors or other health care providers at Butler Hospital.
- Your health information will be provided to you or to your physician or clinical care providers if it is necessary for your medical care.
- If all information that identifies you is removed from your health information, the remaining de-identified information will no longer be covered by this authorization and may be used or disclosed.

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

Questions

Taking part in this screening procedure is entirely voluntary. We urge you to discuss any questions about this screening procedure 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:

By signing this consent form, you indicate that you are voluntarily choosing to take part in this screening procedure to determine eligibility for a research study. You understand what this study is about and your questions have been answered. You will be given a copy of this document for your records and a copy will be kept with the study records. If you have any questions about the study, now or after you sign this form, you can contact the study team.

Printed Name of Participant

Signature of Participant

Date

Signature of Principal Investigator
~or~

Date

Signature of Person Obtaining Consent

Date

Telephone Number of Principal Investigator or Person Obtaining Consent _____

If you have further questions about this project or about research-related injuries, please contact Tosca Braun, Ph.D. [REDACTED]. 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: February 28, 2026 IRBNET ID# 1871144 BUTLER IRB REFERENCE# 2203-003 BY (ADMINISTRATOR): <i>C. Cordaro</i>
--

ADDITIONAL CONSENTS

Please place your initials next to each statement to indicate whether or not you agree.

	Agree	Do Not Agree
I agree to have my assessment(s) audiorecorded. No video or image will be recorded. This will be done for research and training purposes only. I can withdraw my permission at any time and the recording of my assessments (and any copies) will be destroyed.		

[Print Name]

X _____

[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: February 28, 2026 IRBNET ID# 1871144 BUTLER IRB REFERENCE# 2203-003 BY (ADMINISTRATOR): <i>C. Cordino</i>
--