

**The Peace of Mind and Body Project: Treatment Development of Yoga
for Anger Management in Incarcerated Adults (POMB)**

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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

The Peace of Mind and Body Project

RCT Version 3, 3/31/22

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **PURPOSE:** The study is about developing and evaluating two programs. These programs are designed to help inmates manage symptoms of anger and aggression.
- **PROCEDURES:** You will be asked to complete surveys and interviews; and, if you are eligible, you will be randomly assigned to one of two programs. One program is yoga classes and the other is health education classes. These classes are designed for inmates who have symptoms of anger and aggression. These classes will meet once per week over 10 weeks. You will also complete 3 follow-up assessments: half way through the program, at the end of the program, and 8 weeks after the program ends.
- **TIME INVOLVED:** The study will take 18 weeks to complete. During this time, you have up to 5 meetings with study staff to complete assessments. Each meeting will each take 30-60minutes. You will also participate in a 10-week study program (yoga or health education classes) with weekly, 60-75 minute classes. In total, this research study will take approximately 15 hours of your time over 18 weeks.
- **COMPENSATION:** You will receive \$20 for your time after completing each of the follow-up assessment meetings (up to 80 total). Your payment will be put into your commissary account at the Rhode Island Department of Corrections (RIDOC). If you are released, you will be paid in the form of a money order or gift card. You may also choose to have us mail your payment to a family member or significant other.
- **RISKS:** There are some risks associated with the study. You may feel uncomfortable answering sensitive personal questions. You will be able to skip any questions that bother you. There is a risk of loss of privacy. There are also risks associated with taking yoga classes. Since yoga involves physical exercise, physical injury is a possible risk. In rare cases, dizziness or fainting may occur. Several procedures are in place to minimize these risks, and are described in this consent form.
- **BENEFITS:** You may or may not benefit from this study. In the assessments, we will ask about mental health symptoms and give you emergency referrals if you need them. Your participation will provide information to help improve treatments for inmates who have difficulty managing anger.
- **ALTERNATIVES TO PARTICIPATION:** Your decision whether or not to participate in this study will not affect any current or future treatment while incarcerated or anywhere else. Your decision whether or not to participate in this study will not affect how long you are incarcerated or any privileges you get there.

1. Researcher(s):

Principal Investigators: Lauren Weinstock, PhD, Associate Professor of Psychiatry and Human Behavior, Brown University; 401-455-6304; Brown University, Box G-BH, Providence, RI 02912. Lisa Uebelacker, PhD, Professor of Psychiatry and Human Behavior, Brown University at Butler Hospital; 401-455-6381; Psychosocial Research, Butler Hospital, 345 Blackstone Blvd, Providence, RI 02906.

Co- Investigator: Geoffrey Tremont, PhD, Director, Neuropsychology, Rhode Island and Miriam Hospitals; 401-444-4500; 593 Eddy Street, Providence, RI 02903.

Project Coordinator: Hannah Graves, ScM, Project Coordinator, Brown University; 401-444-1953; Brown University, Box G-BH, Providence, RI 02912.

2. What is this study about?

The purpose of the study is to develop and evaluate two programs. These programs are designed to help people manage symptoms of anger and aggression while incarcerated. The study's two programs are health education and yoga.

You are being asked to be in this study because you are aged 18-70 years old, incarcerated, and you reported a history of anger and aggression.

3. What will I be asked to do?

If you decide to participate, here's what will happen:

- 1) First Assessment Meeting. A member of the study staff will ask you questions about anger and aggressive behaviors, mental health symptoms, and physical activity. This will take approximately 45 minutes to complete. We will use results from this meeting to decide if this study is a good match for you. If you do not meet the study's eligibility requirements, this will be your last meeting.
- 2) Randomization. This study will have 2 different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. One group will participate in yoga classes and one group will participate in health education classes.
- 3) Study Programs. Both programs are 10 week programs that meet one time per week for 80 minutes.
 - a. Yoga Classes. If you get matched to the yoga program, you will participate in 10 weeks of yoga classes. Each yoga class is led by a registered yoga teacher and will meet one time per week. Each class lasts for 60-75 minutes. Classes will include breathing, stretching, and strengthening exercises. Additionally, the teacher will give you suggestions for how you may choose to use yoga skills between classes. You will also be offered a book that you are welcome to use.
 - b. Health Education Classes. If you get matched to the health education program, you will participate in 10 weeks of classes. Each class lasts for 60-75 minutes. Each week will cover a different health topic. Classes will include group discussion, and/or audio/video clips. You may also be given readings to explore during your personal time.
- 4) Follow-up Assessment Meetings. There are up to 4 follow-up assessments. Each meeting will take approximately 30-60 minutes. The first follow-up takes place half way through your study program (5 weeks after your first assessment). The second follow-up is after your study

program classes end (10 weeks after your first assessment). The third follow-up is only for people assigned to the yoga program and is 1 month after your classes end (14 weeks after your first assessment). The final follow-up is 8 weeks after your classes end (18 weeks after your first assessment). If you are released from RIDOC before to completing the study, we will complete your assessments in the community. These assessments may take place over the phone, at our offices at Brown University, or in a facility where you are located (i.e. residential treatment facility).

Study Timeline:

Week	Activity	Payment
Week 1	First assessment; Randomization (yoga or health education assignment); Class 1	N/A
Week 2:	Class 2	N/A
Week 3	Class 3	N/A
Week 4	Class 4	N/A
Week 5	Class 5; 1st follow-up assessment	\$20 for completing the assessment
Week 6	Class 6	N/A
Week 7	Class 7	N/A
Week 8	Class 8	N/A
Week 9	Class 9	N/A
Week 10	Class 10 (final class); 2nd follow-up assessment	\$20 for completing the assessment
Week 11- 13	No study commitments	N/A
Week 14	Yoga participants: 3 rd follow-up assessment Health education participants: No study commitments	Yoga: \$20 for completing the assessment Health Education: N/A
Week 15-17	No study commitments	N/A
Week 18	Final follow-up assessment	\$20 for completing the assessment

Your participation in this study may last up to approximately 15 hours over 18 weeks.

- 5) Audio recording. During the study, we will audio record some of the assessments and all of the program classes. We do this so we can supervise our research staff and class teachers. All audio recorders are passcode protected and encrypted to protect your confidentiality.

Assessment audio recordings: You can ask us not to audio record an interview and still be in this study. You can also ask that a recording be deleted.

Study program recordings: Program classes (yoga or health education) are always recorded. This is a requirement to participant in the study. If you are not willing to be a part of an audio recorded program, you cannot be in this study.

- 6) Records review. We will ask you to sign a separate form that gives us permission to review your criminal justice records. This will allow us access to your discipline and incident reports at RIDOC. You can ask us not to do the records review and still participate in this study.

4. Will I be paid?

You will be paid \$20.00 for each of the follow-up assessments. This will add up to a total of \$80.00, if you complete all of the follow-up meetings. If you leave the study early, or if we have to take you out of the study, you will only be paid for the assessments you completed. Your payments will be deposited directly into your commissary account at RIDOC. If you are released from jail/prison, you will receive these payments in the form of a money order or gift card. You may also choose to have us mail your compensation to a family member or significant other.

5. What are the risks?

In this study we will be asking you about sensitive personal issues. Some of these questions may make you uncomfortable, or bring up unpleasant feelings and memories. You will be able to skip or not answer any questions that bother you. All the questions will be asked by research staff who are trained to deal sensitively with these issues. You will be referred to someone who can help you if you feel very uncomfortable. You may also become uncomfortable due to the length of the interview process. You may break any interview up into shorter periods over several sessions, if you choose. There is also some risk for loss of privacy. Privacy protections are described in section #7 below.

If you are part of the yoga program, another possible risk is physical injury as you will be engaging in physical exercise. 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 teachers 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.

If you find out you are pregnant during the study, please tell research staff, and do not participate in any yoga classes. Study yoga classes are not designed specifically for pregnant women.

Compensation in case of injury: Many kinds of research involve some risk of injury. Even though the investigators are careful to prevent any harm, you might develop medical problems from being in this study. If you do have problems, the researchers will give you information that may be of help to you in getting proper medical care, if you ask for it. Brown University does not pay for medical or other costs. Signing this form does not mean that you give up any liability rights for personal injury.

6. What are the benefits?

You may not directly benefit from this research study. We will ask about your mental health symptoms and give you emergency referrals if you need them. Your participation will provide information to help improve treatments for inmates who have difficulty managing anger. Participating in this study will not affect how long you are incarcerated or any privileges you get there. This study will also not affect your current or future treatments options.

7. How will my information be protected?

In order for us to schedule our interviews, the jail/prison staff will need to know who we plan to interview. The researchers will keep your other information confidential. The information we will collect is only for the study and will **NOT** be shared with the jail/prison, probation, or parole. We are committed to protecting your privacy.

You will not be identified in any reports that come from this study. Your information will only be labeled using a study ID number. Information about you will be protected in locked Brown University research offices and secure computers. Only research staff who need the information will have access to it.

In this study, we will audio record some of your assessments and all of your program classes. We will use digital, passcode protected, encrypted audio recorders to protect your privacy. Recordings will be transferred to Brown's secure computer server. Files will be deleted from the recorders after transfer. This information will be kept confidential.

The permission you give us to use your information will not expire. The study data may be kept permanently. While this study is going on, you will not be allowed to see this information about you. You may have this information when the study is over.

One possible risk is loss of privacy. Loss of privacy may occur because you will be participating in group classes. We will ask all study participants to keep information confidential. However, we cannot guarantee that they will do so.

We have received a Certificate of Confidentiality from the National Center for Complementary and Integrative Health. This will protect the researchers from being forced, even by court order or subpoena, to provide information about you. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below*.

The National Center for Complementary and Integrative Health, Brown University, The Miriam Hospital, or Butler Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. The Certificate cannot be used to resist a demand for this information. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Information we are required to share:

While you are incarcerated:

We are required to contact jail/prison staff if you tell us certain things.

These things include:

- escape plans
- that any inmate has had sexual contact with anyone while incarcerated
- that a child or elderly person is being abused or neglected
- If you are in danger of hurting yourself or someone else while in jail/prison, we will tell jail/prison staff and they will follow their regular safety procedures. This is the same as would normally happen in jail or prison.

We will also report inappropriate behavior toward study staff.

If any of these situations occur, we will notify a social worker, nurse, and/or the highest ranking person available (i.e. captain, lieutenant, correctional officer, etc.).

If you are released, we are required to report the following:

- If you are in serious or current danger of hurting yourself, we may need to tell others to help you stay safe.
- If you are in serious danger of hurting someone else, we may need to tell that person and/or the appropriate police departments.
- If we hear that someone has abused or neglected a child or elderly person, we have to let the appropriate agencies know.

Information you tell us that is not listed above will be kept confidential. It will not be told to prison staff, parole, probation, or anyone else. It will also be protected by the Certificate of Confidentiality. By signing this consent form, you agree to these conditions.

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 search this Web site at any time.

8. Are there any alternatives to this study?

During your participation in this research, you are free to receive any other treatments or services. There are many other forms of treatment available in jail/prison.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. Research information collected up to the time that you quit will remain part of the study data. A decision to quit the study will NOT affect your treatment, how long you are incarcerated, or any privileges you get there.

If you refuse to participate in or leave the study, your current or future relationship with Brown University, Butler Hospital, The Miriam Hospital, or the Rhode Department of Corrections will not be affected. Your participation in the study may be stopped by the researchers without your consent. If this happens, you have a right to know the reasons for the decision.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can contact Dr. Lauren Weinstock at Brown University at 401-455-6304 or by mail at Brown University, Box G-BH, Providence, RI 02912.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050, toll-free at 1-866-309-2095, by email at IRB@Brown.edu, or by mail at 350 Eddy Street, Brown University, Box 1986, Providence, RI 02912.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date

/

PRINTED NAME

Research Staff Signature and Date

/

PRINTED NAME