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

Signature Page

Lauren Weinstock, Ph.D., MPI

01/09/2023
Date

Lisa Uebelacker, Ph.D., MPI

01/09/2023
Date

CLINICAL INTERVENTION STUDY PROTOCOL

The Peace of Mind and Body Project: Treatment development of yoga for anger management in incarcerated adults

Principal Investigators:

Lauren Weinstock, Ph.D.
Associate Professor, Brown University

Lisa Uebelacker, Ph.D.
Professor, Brown University
Assistant Director of Psychosocial Research, Butler Hospital

Supported by:

The National Center for Complementary and Integrative Health, R34AT010172

Tool Revision History

Version Number: 1.9
Version Date: 12/15/2022
Summary of Revisions Made:

Version Number	Version Date	Summary of the Revision
1.1	6/10/19	Update recruitment procedures (location of announcements and individually approaching inmates to assess interest)
1.2	07/05/19	The following changes are in response to NCCIH's requested edits to our protocol: • Adding the length of time each participant will be in the study • Added information about randomization in section 3, study design • Added more information on minimum group size • Added in the number of interventionists, yoga teachers and health education teachers • Added details on percent adherence in section 5.4 • Added more information on randomization in section 6.2.5, blinding • Clarified primary and exploratory outcomes • Clarified where to find Table 4 in the hypothesis section • Corrected errors found in Table 3 • Added data collection completion rates as a feasibility outcome The following change is per the RIDOC's Medical Director's request to decrease the burden on their staff/facilities: • Changed the exclusion criterion from "any endorsed item on the Physical Activity Readiness Questionnaire (PAR-Q) combined with lack of medical clearance lack of medical clearance from prison healthcare staff to participate in the study interventions" to "any endorsed item on the Physical Activity Readiness Questionnaire (PAR-Q)."
1.3	10/18/19	Corrected a typographical error found in Table 3, Schedule of Evaluations, Phase 2.
1.4	12/20/19	The following changes have been made per our completion of Phase 1 of this pilot study, guided by focus groups and key informant interviews: • Removed restriction on sex of yoga and Health Education teachers. • Updated Health Education teacher qualifications. • Changed our inclusion criterion to include sentenced and unsentenced inmates serving 90 days or more

		• Updated our PAR-Q exclusion criterion to exclude item 6 (relating to hypertension medications) from the exclusion criterion. • Specified we will run classes in men's medium (n=20) and women's facilities (n=20). We will not run classes in men's minimum security facility. • Indicated that the length of classes will be 60-75 minutes. • Typographical errors
1.5	02/27/20	Per NCCIH request, we clarified wording that the populations being studied are Men's medium security prison and Women's combined minimum and medium security prisons.
1.6	03/31/22	Addition of qualitative interview for participants in the yoga intervention at 14 weeks post enrollment.
1.7	06/09/22	Updated RIDOC personnel per NCCIH request.
1.8	07/27/22	Increase the number of participants that could be enrolled in the pilot RCT in order to reach the study's randomization goal.
1.9	12/15/22	Increase the number of participants that could be enrolled in the pilot RCT in order to reach the study's randomization goal.

TABLE OF CONTENTS

Page

STUDY TEAM ROSTER

Lauren Weinstock, PhD.
Role: MPI
Associate Professor, Brown University
Address: Brown University, Box G-BH, Providence, RI 02912
Tel: 401-455-6304; Fax: 401-455-6235; Email: lauren_weinstock@brown.edu

Lisa Uebelacker, Ph.D.
Role: MPI
Professor, Brown University
Assistant Director of Psychosocial Research, Butler Hospital
Address: Butler Hospital, 345 Blackstone Blvd., Providence, RI, 02906
Tel: 401-455-6381; Fax: 401-455-6235; Email: luebelacker@butler.org

Leslie Brick, Ph.D.
Role: Study Statistician
Assistant Professor, Brown University
Address: Brown University, Box G-BH, Providence, RI 02912
Tel: 401-444-1958; Fax: 401-444-1911; Email: leslie_brick@brown.edu

Hannah Graves, Sc.M.
Role: Study Coordinator
Project Coordinator, Brown University
Address: Brown University, Box G-BH, Providence, RI 02912
Tel: 401-444-1953; Fax 401-444-1904; Email: hannah_graves@brown.edu

Jennifer Johnson, Ph.D.
Role: Co-Investigator
C. S. Mott Endowed Professor of Public Health, Professor of OBGYN, Professor of Psychiatry and Behavioral Medicine, Michigan State University
Address: 200 East 1st St, Flint, MI 48502
Tel: (810) 600-5669; Fax: 810-600-5609; Email: Jennifer.Johnson@hc.msu.edu

Tracie Shea, Ph.D.
Role: Co-Investigator
Professor, Brown University
Address: Veterans Affairs Medical center, 830 Chalkstone Avenue, Bldg 32, Providence, RI 02903
Tel: 401-273-7100 x6248; Fax: 401-457-3311; Email: m_shea@brown.edu

Geoffrey Tremont, Ph.D.
Role: Co-Investigator
Director, Neuropsychology, Rhode Island Hospital and The Miriam Hospital
Address: 593 Eddy Street, Providence, RI 02803
Tel: 401-444-4500; Fax: 401-444-6643; Email: gtremont@lifespan.org

PARTICIPATING STUDY SITES

Brown University: 164 Angell Street, Providence, RI 02912
Contact: Lauren Weinstock, Ph.D.

Butler Hospital: 345 Blackstone Boulevard, Providence, RI 02906
Contact: Lisa Uebelacker, Ph.D.

Lifespan: 593 Eddy Street, Providence, RI 02903
Contact: Geoffrey Tremont, Ph.D.

Michigan State University: 200 East 1st St, Flint, MI 48502
Contact: Jennifer Johnson, Ph.D.

Rhode Island Department of Corrections: 40 Howard Ave, Cranston, RI 02920
Contact: Erin Boyar

PRÉCIS

Study Title

The Peace of Mind and Body Project: Treatment development of yoga for anger management in incarcerated adults

Objectives

Our proposed project will have two phases. Specific Aims for each phase include:

1. Phase 1: To refine our current manualized hatha yoga intervention and health education intervention to target high levels of anger dysregulation in prisoners.
   a. To conduct focus groups with prisoners and criminal justice stakeholders (separately) to understand ways of increasing feasibility, acceptability, and efficacy of yoga for anger management as well as feasibility and acceptability of our control arm (health education);
   b. To solicit feedback from experts in correctional mental health, addiction, and yoga; and
   c. To modify our existing yoga treatment manual, health education manual, and instructor fidelity scales.

2. Phase 2: To conduct a pilot randomized clinical trial (n = 40) of hatha yoga vs. a health education group (attention control) for prisoners high in self-reported anger dysregulation. Participants will be enrolled in the active intervention for 10 weeks, and then be followed for 8 weeks.
   a. To assess feasibility and acceptability of both the yoga class and the health education control group. We will assess credibility of the assigned intervention and expectancy for improvement for both groups at baseline, program satisfaction following program participation, participant adherence, ability to hold group classes (with a certain number of participants), and instructor fidelity to the manuals. We will conduct structured interviews following program participation to further understand and develop strategies to improve acceptability and feasibility.
   b. To assess safety, we will track all adverse events in a structured fashion. We do not expect to see any serious adverse events definitely or probably related to study participation.
   c. To assess feasibility of research procedures, we have benchmarks for recruitment rate, retention for study assessments, and reliability of instructor fidelity measures.

If successful, this project will provide us with materials, experience, and pilot data needed for the next step in this research, namely, a fully powered randomized clinical trial with anger dysregulation as the primary outcome.

Design and Outcomes

In Phase 1, we will conduct focus groups with prisoners and representatives from important criminal justice stakeholder groups (separately). We will also conduct individual interviews with prison administrators as key informants.

In Phase 2, we will conduct a pilot randomized clinical trial (n = 40) of hatha yoga vs. a health education group (attention control) for prisoners high in self-reported anger dysregulation. Participants will be enrolled in the active intervention for 10 weeks, and then be followed for 8 weeks. We will assess feasibility and acceptability of both the yoga class and the health education control arm, safety, and feasibility of research procedures.

In both programs, participants be involved in the study for approximately 15 hours over 18 weeks.

Interventions and Duration

Yoga classes. The manualized hatha yoga program will begin with an initial individual session with a yoga teacher to increase motivation for class attendance and self-efficacy for yoga practice between classes. Subsequently, participants will be asked to attend one 60-75 minute class per week for 10 weeks.

Health education. The program consists of information about general health topics. Participants will be asked to attend one 60-75 minute class per week for 10 weeks. Each week will cover a different topic.

Sample Size and Population

Phase 1 of the proposed project will include up to 18 prisoners and 6 representatives from important criminal justice stakeholder groups in focus groups. Also in Phase 1, we will conduct interviews with 3 separate prison administrators as key informants. Because RIDOC administrators may have a supervisory role over other RIDOC stakeholders, we believe it may not be prudent to have them participate in focus groups with other staff. Thus, prison administrators will be interviewed individually and separately as key informants (which are not considered to be human subjects, per the Brown University IRB).

Phase 2 of the proposed project will include 40 prisoners in the pilot. All prisoners will be high in self-reported anger dysregulation. Participants will be prisoners aged 18 to 70. We will recruit 20 men and 20 women to participate.

1. STUDY OBJECTIVES

1.1 Primary Objective

The primary aim of this treatment development research is to develop and establish the feasibility, acceptability, and safety of a hatha yoga intervention for prisoners with anger dysregulation and aggression. Development of the yoga intervention (and the health education control condition) will be informed by our prior experiences conducting research on yoga for depression, bipolar disorder, and chronic pain in community settings and by our prior experiences evaluating behavioral interventions for mental health outcomes in the criminal justice context.

The Specific Aims of this treatment development research are:

1. Phase 1: To refine our current manualized hatha yoga intervention and health education intervention to target high levels of anger dysregulation in prisoners.
   a. To conduct focus groups with prisoners and criminal justice stakeholders (separately) to understand ways of increasing feasibility, acceptability, and efficacy of yoga for anger management as well as feasibility and acceptability of our control arm (health education);
   b. To solicit feedback from experts in correctional mental health, addiction, and yoga; and
   c. To modify our existing yoga treatment manual, health education manual, and instructor fidelity scales.

2. Phase 2: To conduct a pilot randomized clinical trial (n = 40) of hatha yoga vs. a health education group (attention control) for prisoners high in self-reported anger dysregulation. Participants will be enrolled in the active intervention for 10 weeks, and then be followed for 8 weeks.
   a. To assess feasibility and acceptability of both the yoga class and the health education control group. We will assess credibility of the assigned intervention and expectancy for improvement for both groups at baseline, program satisfaction following program participation, participant adherence, ability to hold group classes (with a certain number of participants), and instructor fidelity to the manuals. We will conduct structured interviews following program participation to further understand and develop strategies to improve acceptability and feasibility.
   b. To assess safety, we will track all adverse events in a structured fashion. We do not expect to see any serious adverse events definitely or probably related to study participation.
   c. To assess feasibility of research procedures, we have benchmarks for recruitment rate, retention for study assessments, and reliability of instructor fidelity measures.

We hypothesize that we will hit all benchmarks in table 4 on page 38. If successful, this project will provide us with materials, experience, and pilot data needed for the next step

in this research, namely, a fully powered randomized clinical trial with anger dysregulation as the primary outcome.

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Prisoner mental health is an area of high public health significance. The United States (US) has the highest rates of incarceration and criminal justice (CJ) involvement in the world.[1] Nearly 7 million people pass through the US CJ system each year, and 1.6 million people are housed in US prisons at any given time.[2] In addition to the well documented and significant racial, ethnic, and socioeconomic disparities encountered in the CJ system,[3] there is a disproportionately high mental health burden among those who are incarcerated. Indeed, the US CJ system has been described, by proxy, as the largest mental healthcare system in the United States.[4] Roughly 50% of prisoners report a history of one or more psychiatric diagnoses,[5] most commonly depressive and anxiety disorders, trauma-related disorders, psychotic-spectrum illnesses, and disorders of impulse control.[6] Prisoners also report a disproportionately high rate of lifetime substance use disorders, ranging in prevalence from 25-58%,[6–8] and as high as 74% among those with a history of psychiatric illness.[5] Following from this substantial psychiatric and substance use morbidity, and further complicated by the high medical burden also documented in this population,[9] prisoners are at significantly heightened risk for suicide and premature all-cause mortality, both in prison[10] and upon community re-entry.[11]

Of particular interest has been a focus on anger dysregulation. With significant transdiagnostic relevance, anger is a negative affective state of variable duration, ranging in intensity from "mild irritation or annoyance to intense fury and rage."[12] In addition to being an affective experience, anger involves cognition and physiological arousal. Anger is typically associated with negative cognitions surrounding a triggering event, particularly those focused on themes of perceived injustice and attributions of blame.[13] Anger is also typically marked by activation of the neuroendocrine system and autonomic arousal, consistent with a fight-or-flight response, with corresponding elevations in heart rate, muscle tension, skin flushing, and shortness of breath.[14] Anger is frequently – though not always – paired with **aggression**, marked by behaviors that aim to "warn, intimidate, control, or attack, or gain retribution,"[13] such as verbal or behavioral intimidation or punishment (i.e., in the form of interpersonal confrontation or violence) toward others.

Together, anger dysregulation and aggression are frequently encountered in the CJ setting, and in fact, may contribute to the very offenses that result in initial CJ involvement and incarceration.[15] While incarcerated, anger dysregulation may contribute to affective distress and exacerbation of underlying mental health problems. Overt aggression further increases risk of disciplinary action,[16,17] such as placement in restraints or prison seclusion,[18] and may delay parole or release decisions.[19] After prison release, anger dysregulation and aggression may precipitate clinical deterioration, and contribute to risk for reoffending and recidivism.[20,21]

2.2 Study Rationale

In the criminal justice (CJ) system in the US, there are high rates of mental health and substance use disorders. Although prisons must provide treatment, the CJ system is resource-poor and the presenting problems of prisoners are diverse. To maximize efficiency in the CJ context, recent efforts focus adjunctive interventions on symptoms that are most detrimental to prisoners, and that are shared across diverse conditions. Of particular interest has been anger dysregulation, as this is prevalent in CJ-involved populations, contributing not only to distress and exacerbation of other mental health problems, but also to risk of aggression. Overt aggression further increases risk for prison behavioral infractions or placement in restraints or seclusion, and may delay parole or release decisions.

There are many limitations to existing approaches to anger management in prison. We propose that hatha yoga could serve as a useful adjunctive treatment for anger within prisons. In addition to preliminary research showing that yoga programs may improve anger regulation, research has also demonstrated benefits of yoga for related symptoms of depression, anxiety, and trauma-related emotion reactivity and arousal. Yoga may be delivered in a relatively low-cost fashion. Finally, prisoners may view yoga as less stigmatizing than more traditional anger management interventions, particularly given its focus on physical body awareness/movement and on overall wellness.

Despite a recent proliferation of yoga programs for various problems in prisons, empirical research on this topic is minimal, with a small number of studies limited by significant methodological concerns. We propose to conduct *systematic* treatment development research that would prepare us to study whether yoga (vs. a health education control group) is an effective adjunctive treatment for prisoners with anger dysregulation.

3. STUDY DESIGN

In Phase 1, we will conduct 4 focus groups, composed of approximately 6 individuals each (N=24). To achieve this number, we will consent up to 72 individuals to achieve our enrollment goals. The first 3 focus groups will be compromised of 18 prisoners in each of the 3 RIDOC facilities where we plan to conduct the next phase of this research project (men's minimum, n=6; men's medium, n=6; women's combined minimum/medium n=6). The fourth focus group will consist of 6 representatives from important criminal justice stakeholder groups, including correctional officers, prison treatment staff, and justice-focused members of the public. To complement the focus groups, we will conduct separate interviews (n=3) of prison administrators as key informants. Enrollment period for this phase will last approximately 4 months.

In Phase 2, we will consent up to 175 prisoners in order to achieve our enrollment goal of 40 prisoners who meet study inclusion for randomization to conditions in the pilot RCT. Participants will be recruited from the Rhode Island Department of Corrections (RIDOC) in Cranston, RI. They will be randomized to either the yoga intervention or the health education group. The study research assistant will randomize participants in the prison using small opaque envelopes labeled with a number and the strata (for example, male medium 1, male medium 2, etc.). Depending on group assignment, participants will be invited to participate in 10 weekly sessions of yoga or the health education group, to be held in the facility where they reside. Group classes will be held in relevant spaces in the facilities at RIDOC (i.e. classrooms, chapels, library, etc.). The hatha yoga intervention will involve an initial individual session with a yoga teacher, designed to increase motivation for yoga class attendance and self-efficacy for adapted yoga practice between classes. Following the initial individual session, participants will be invited to attend one 60-75 minute yoga class for 10 weeks in the prison facility where they reside. Registered yoga teachers will deliver the intervention. The Health education control group will be a 10-week program that consists of weekly 60-75 minute group classes in the prison facility where the participants reside. In classes, instructors will provide information about general health topics through a variety of means such as slides, handouts, and/or audio and video clips. This class will be taught by instructors with experience working in correctional settings and post-baccalaureate experiences or certification in a relevant health care field. In addition to the baseline assessment, outcome assessments will occur at 5 weeks (mid-intervention), 10 weeks (post-intervention), 14 weeks (qualitative interview for yoga participants only), and at 8 week follow-up, for a total length of participation of each individual participant of 4.5 months. Enrollment period for this phase will last approximately 7 months.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion and Exclusion Criteria, Prisoners, Phase 1.

Participants must meet all of the relevant inclusion criteria to participate in the study. Inclusion/exclusion criteria for prisoners in Phase 1 will be similar to those proposed for the pilot RCT (see Phase 2):

Phase 1 (Focus Group) Inclusion Criteria – Prisoners

1. Sentenced prisoners who are incarcerated in the women's and men's minimum and medium security prison facilities at the RI Department of Corrections (RIDOC) in Cranston, RI.
2. Ages 18-70;
3. Clinically significant anger dysregulation, as evidenced by a score ≥ 86 on the Novaco Anger Scale (NAS);
4. Ability and willingness to provide informed consent; and
5. Willingness to be audio recorded in the focus group meeting.

Phase 1 (Focus Group) Exclusion Criteria – Prisoners

1. Presence of current manic or psychotic symptoms, or suicide risk (warranting referral to prison mental health clinical staff);
2. Any endorsed item on the Physical Activity Readiness Questionnaire (PAR-Q);
3. Current weekly yoga practice or current participation in mindfulness- based programming;
4. Pregnancy; and
5. Inability to understand English sufficiently well to understand the consent form or assessments when they are read aloud

4.2 Inclusion and Exclusion Criteria, Stakeholders, Phase 1.

Participants must meet all of the relevant inclusion criteria to participate in the study.

Phase 1 (Focus Group) Inclusion Criteria – Stakeholders

The fourth focus group will consist of 6 representatives from important criminal justice stakeholder groups, including correctional officers, prison treatment staff, and justice-focused members of the public.

1. 18 years or older;
2. Currently employed in one of the stakeholder settings described above
3. Able to speak English sufficiently well to participate in the interview
4. Willing to be audio recorded during the focus group meeting, and

5. Willing to consent to participate in the focus group.

Because prison administrators operate in a supervisory role over the stakeholder groups described above, we will conduct separate, individual interviews with up to 3 prison administrators, who will serve as key informants for purposes of conducting the proposed research. As content experts, it has been determined by the Brown University IRB that prison administrators as key informants are not considered to be human subjects participants for purposes of the proposed research.

Phase 1 (Focus Group) Exclusion Criteria – Stakeholders

None.

4.3 Inclusion and Exclusion Criteria, Prisoners, Phase 2.

Participants must meet all of the relevant inclusion criteria to participate in the study.

Phase 2 Inclusion Criteria – Prisoners

1. Age 18-70;
2. Clinically significant anger dysregulation, as evidenced by a score ≥ 86 on the Novaco Anger Scale (NAS);
3. Prisoner or jail detainee, with anticipated duration of remaining time incarcerated of 90 days or more, allowing for participation in the 10 week intervention;
4. Ability and willingness to provide informed consent; and
5. Willingness to be audio recorded in the intervention condition sessions (e.g., yoga or health education groups).

Phase 2 Exclusion Criteria – Prisoners

1. Presence of current manic or psychotic symptoms, or suicide risk (warranting referral to prison mental health clinical staff);
2. Any endorsed item on the Physical Activity Readiness Questionnaire (PAR-Q) except for item 6 (i.e., participants can be included even if they endorse item 6);
3. Current weekly yoga practice or current participation in mindfulness- based programming;
4. Pregnancy; and
5. Inability to understand English sufficiently well to understand the consent form or assessment instruments when read aloud.

4.4 Study Enrollment Procedures

4.4.1. Recruitment and Screening – Prisoner Participants.

Recruitment will follow procedures successfully used to recruit prisoners into our completed and ongoing trials at the study site over the past decade. Participants will be recruited from the women's combined minimum and medium security prison and the men's medium security prison facilities of the RIDOC in Cranston, RI (see letter of support). Recruitment will occur in one of four ways. First, with permission from prison treatment staff and security personnel, research staff will make announcements to inmates to briefly explain the study (i.e. in housing units, medical units, etc.). Research staff will either individually approach inmates to assess their level of interest in the study, or hand out "interest slips" of paper, on which participants can confidentially indicate interest or lack of interest in learning more about the study. We request that all prisoners complete the "interest slip," regardless of interest in participation, to ensure privacy of responses. Second, we will identify potentially eligible participants based on their time in prison and release dates from prison records and approach them privately. This information is already publicly available (http://www.doc.ri. Gov/inmate_search/search.php), but is often provided to us in list form by the Deputy or his/her assistant for greater ease in identifying individuals who are not anticipated to be released within 90 days. Third, with the assistance of behavioral health leadership at the RIDOC, with whom we have a long history of collaboration, we will provide an in-service to prison psychiatrists and mental health counselors, and distribute study brochures so that they may refer potentially eligible participants to the study. Brochures will contain study details and guidance regarding how a participant can confidentially request more information about the study. To further minimize risk of coercion, we will not solicit direct referrals from prison mental health or other staff. Fourth, we will post flyers in each recruitment facility indicating that interested prisoners should submit an "interest slip" to learn more about our study.

Participants who indicate potential interest in the study are approached privately in a confidential setting. To meet with an inmate at the RIDOC, research staff will notify RIDOC personnel of the name/prison ID of the inmate we wish to approach. We will emphasize that this initial meeting with the RA is completely voluntary, and that refusal to meet with a member of our study team for this initial meeting will have no impact (positive or negative) on their status in the prison. If the inmate agrees to meet with the RA, the research staff will meet with the inmate in as private of an area as possible (i.e. classroom, mod, chapel, library, attorney's room when not in use by attorneys, etc.). If the research staff meets with an inmate in a more public area (i.e. visiting room), they will move to an area as far away from others as possible and speak in hushed tones to avoid being overheard.

4.4.2. Recruitment and Screening – Stakeholder Participants.

For stakeholder participants: Our RIDOC partners have agreed to give us their directories and to let their staff know about the study and that we may be approaching them. Using the staff directory, we will individually and confidentially reach out to stakeholders internal to the RIDOC. We are using this strategy in our current IRB-approved

protocol for the Project CARE study, and have used this strategy successfully to enroll and interview stakeholders for Dr. Johnson's prison depression implementation treatment study (R01 MH095230). Community stakeholders will be recruited through the RI-based Center for Prisoner Health and Human Rights, of which Drs. Weinstock and Johnson are members. Prison counselors and staff who indicate potential interest in focus group participation will be approached privately.

Prison administrators as key informants: Because RIDOC administrators may have a supervisory role over other RIDOC stakeholders, we believe it may not be prudent to have them participate in focus groups with other staff. Thus, prison administrators will be interviewed individually and separately as key informants. As with the stakeholders, we will recruit administrators through the RIDOC staff directory, and will emphasize that that participation has no impact on their employment or affiliation with the RIDOC. All key informants will be reminded that there is no penalty if they choose to not participate in the key informant interview and that they may terminate the interview at any time.

4.4.3. Informed Consent Procedures – Prisoner Participants.

Research staff will carefully explain all aspects of the study to a potential participant, including its voluntary nature, risks and benefits, the schedule of visits, and the expected duration of participation, and will elicit and answer any questions the participant may have. Potential participants will also be informed that: (1) a decision to not participate in the research will have no impact on their status, access to treatment, or length of stay at the prison; (2) the study has a Certificate of Confidentiality; and (3) the study information will be kept confidential from prison staff, officers of the court, parole officers, or others in the criminal justice system. Study staff will also carefully review the limits to confidentiality, including the prison's mandatory reporting procedures for suicidal ideation and homicidal ideation (see below). We will ask participants if they would like us to read the consent forms aloud.

Participants who give their consent will sign a copy of the document and will be given a signed copy of the informed consent document. Informed consent procedures have been developed to comply with the Code of Federal Regulations 45 CFR 46.116, *General Requirements for Informed Consent* and 46.117 *Documentation of Informed Consent*, and are subject to oversight and approval of Brown University's Institutional Review Board and the Medical Research Advisory Group of the RIDOC. Freedom to refuse to participate or to discontinue participation at any time without penalty will be emphasized.

It is possible that some participants will be released from prison prior to study completion. For that reason, participants will be asked to provide written permission for us to try to locate them through significant others, their appointed parole/probation officer, and/or post-release treatment program, but will not be excluded if they are unwilling to do so. Participants will be able to refuse or revoke locator consent. Once a participant has agreed to participate in the research and signed the informed consent, s/he will undergo the baseline assessment phase.

4.4.4. Informed Consent Procedures – Stakeholder Participants.

Study staff will fully explain the study procedures, risks and benefits, and alternatives to participation. We will emphasize that participation has no impact on their employment or affiliation with the RIDOC. All participants will be reminded that there is no penalty for participants who choose to not participate or to withdraw from the study.

4.4.5. Enrollment and Randomization.

In Phase 1, for prisoners, if a participant is determined to be eligible following the baseline assessment, s/he will be enrolled. For stakeholders, enrollment occurs when they sign the informed consent form at the focus group meeting.

In Phase Two (pilot RCT), if a participant is determined to be eligible following the baseline assessment, s/he will be enrolled and randomized to either the yoga intervention or the health education group.

Recruitment will be rolling. If we ever have more than 10 people enrolled in a class, we will halt recruitment until there is room in both classes for new participants (maximum class size = 10).

4.4.6. Documentation of Reasons for Ineligibility.

All potential participants who are approached for the study (i.e., express interest in the study) will be tracked on paper and in REDCap along with the status of their participation. Potential participants will have a study record documenting which inclusion criteria were assessed and the outcome of that assessment. A study RA will complete an inclusion/exclusion form for each potential participant indicating their eligibility status. This form will be signed by the RA and the PC/MPI. The paper version of the study record is linked to the participant's name and other personal identifiers only by the study ID number. A separate form will be used to link the potential participant's name to ID. Both study data and identifiable data are entered into REDCap and paper copies are locked separately in file cabinets in locked offices at Brown University. REDCap has the ability to restrict identifiable data access to only necessary study personnel. Those without access to identifiable data, will only be able to see the participant's identification number and de-identified data in REDCap.

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Hatha yoga intervention. The yoga intervention will involve an initial individual session with a yoga teacher, designed to increase motivation for yoga class attendance and self-efficacy for adapted yoga practice (see below) between classes. Following the initial individual session, participants will be invited to attend one 60-75 minute yoga class for 10 weeks in the prison facility where they reside. Class length must be flexible as research staff do not control exactly when all participants will be able to arrive at the designated classroom. Registered yoga teachers will deliver the intervention. Potential risks include loss of privacy or breach of confidentiality, and mild physical injury.

Health education control group. To match for attention, the control condition will be a 10-week program that consists of weekly 60-75 minute group classes in the prison facility where the participants reside. In classes, instructors will provide information about general health topics through a variety of means such as slides, handouts, and/or audio and video clips. This class will be taught by instructors with experience working in correctional settings and post-baccalaureate experiences or certification in a relevant health care field. Potential risks include loss of privacy or breach of confidentiality.

5.2 Handling of Study Interventions

5.2.1. Hatha Yoga Intervention.

The yoga intervention will involve an initial individual session with a yoga teacher, designed to increase motivation for yoga class attendance and self-efficacy for adapted yoga practice (see below) between classes. Following the initial individual session, participants will be invited to attend one 60-75 minute yoga class for 10 weeks in the prison facility where they reside. Each class will consist of: breathing exercises, brief guided centering meditation, warm-ups, standing postures, floor postures, an inversion, relaxation, and between-class practice assignments. Classes will emphasize mindfulness, including noticing emotions, thoughts, and physical sensations related to anger, and moderate physical activity. Classes will include some teaching of a relevant yoga theme, such as nonviolence (ahimsa). We will plan themes with input from prisoners and other stakeholders prior to starting classes and rotate through themes. Themes may be introduced via a brief meditation at the beginning of class, and mentioned briefly through class. Between-class practice assignments will be tailored to the prison setting. With input from our stakeholders, we will design a series of brief yoga practices that prisoners can engage in either a) on a daily basis, such as when they wake up or before bed; and b) when they notice that they need to cope with angry or other difficult feelings. Practices may include breathing exercises, brief meditation, and simple poses. We will provide participants with written descriptions and diagrams to assist them with yoga practice. Because each participant will have an individual introduction session with a yoga teacher before beginning the classes, and because sessions are not cumulative, participants can

enter the group at any time (i.e., rolling enrollment). Minimum class size is 1, maximum is 10. We prefer to have a group of at least 4 participants for a group effect, with larger groups (i.e, 8-10) being more cost-effective, of 8-10, but recognize that there will be times that not all participants can attend; thus, we will run the classes as long as 1 participant attends.

Yoga teachers. The Yoga Alliance is a professional organization which sets standards for yoga teacher training. One can be a Registered Yoga Teacher (RYT) at the 200- or 500-hour level. Experienced Registered Yoga Teachers (E-RYT) at the 500-hour level have at least 4 years of experience and 2000 hours of teaching, and are qualified to train teachers and provide continuing education. All study yoga teachers will be RYTs. We will hire and train 2-4 yoga teachers. Male or female instructors will teach classes in both the RIDOC men's and women's facilities. Teachers will also have study-specific training on research methods, anger and emotion dysregulation, and adverse events with the PIs, and on the yoga manual with our local yoga expert consultant, Mr. Tom Gillette (E-RYT) and Co-I Dr. Tremont (RYT). Yoga instructor supervision will include the following: Dr. Tremont, with Mr. Gillette's assistance, will oversee delivery of yoga classes to ensure adherence to the manual and to maintain good quality of instruction. Once trained, teachers will meet twice monthly with Mr. Gillette and/or Dr. Tremont for supervision. If an instructor falls below 80% adherence in 3 consecutive classes, we will implement remediation measures, such as observing classes and providing direct instruction to the teacher. Continued non-adherence may be grounds for replacement.

Instructor adherence. We will develop an adherence measure in order to evaluate whether yoga teachers can reliably deliver the manualized program. This adherence measure will have two components: a) a checklist corresponding to the manual to ensure that instructors lead each major component of the class; and b) scales regarding the degree to which the instructor adheres to the style of the class outlined in the manual. (For example, does he/ she repeatedly direct participants to attend to physical sensation in their bodies?). Dr. Tremont and Dr. Uebelacker will train an RA to conduct adherence ratings on audio-recorded yoga classes, as video will not be allowed in the RIDOC. Once Dr. Tremont and the RA have achieved an acceptable degree of reliability ($r > .80$), the RA will conduct adherence ratings of 20% of classes. Dr. Tremont and Mr. Gillette will review ratings with teachers. Dr. Tremont and/or Dr. Uebelacker will rate classes on a monthly basis to test RA reliability against a "gold standard" in an ongoing fashion.

5.2.2. Health Education Control Group.

To match for attention, the control condition will be a 10-week program that consists of weekly 60-75 minute group classes. In classes, instructors will provide information about general health topics through a variety of means such as slides, handouts, and/or audio and video clips. There will be an emphasis on group discussion of relevant topics; instructors do not just lecture. The core rationale for this course is that good physical health is important for good mental health. In prior research, we have developed and successfully used a manual for teaching this class; the manual will be modified based on feedback from prisoners and prison staff in Phase 1 of this study. Sample class topics are: What to Eat; What Not to Eat; Protecting Your Heart; Physical Activity Guidelines; Diabetes; Cancer Prevention; and Getting a Good Night's Sleep. In

modifying the manual, we will pay attention to making sure that any health-related recommendations are feasible both within prison and for a person on a limited budget in the community. Instructors provide will information and encourage questions but avoid psychotherapeutic techniques or personalized goal-setting. Instructors will give participants readings to explore on their own. Because each week covers a different topic and sessions are not cumulative, participants can enter the group at any time (i.e., rolling enrollment), further providing equipoise with the yoga group. Minimum class size is 1, maximum is 10.

Health education instructors. This class will be taught by health education instructors who have experience working in correctional settings and post-baccalaureate experiences or certification in a relevant health care field. We will hire and train 2 health education instructors. Training procedures will be similar to those used for yoga teachers, with training from Drs. Weinstock and Uebelacker, and additional input from Co-I Dr. Johnson. To enhance equipoise, similar to the yoga arm, male or female instructors will teach HE classes in the participating RIDOC men's and women's facilities. Although it may be difficult to conceal the fact that this is a control group from instructors, we will encourage instructors to do their best work.

Instructor adherence. Health education instructor supervision, adherence, and adherence rating procedures will be the same as those used for the yoga instructors, with Dr. Uebelacker as the supervisor, and Dr. Uebelacker training the RA in adherence ratings and serving as the gold standard rater.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions.

Once a participant is enrolled in the study, participants will not be excluded for any concomitant intervention.

5.3.2 Required Interventions.

None.

5.3.3 Prohibited Interventions.

None.

5.4 Adherence Assessment

Yoga participant adherence. To be considered adherent, a participant must attend 6/10 classes. Our target is for 70% of all participants to complete 6/10 classes in the RCT.

Health education participant adherence. To be considered adherent, a participant must attend 6/10 classes. Our target is for 70% of all participants to complete 6/10 classes in the RCT.

6. STUDY PROCEDURES

6.1 Schedule of Evaluations

Table 1. Schedule of Evaluations, Phase 1, Prisoners.

Assessment	Baseline and Enrollment: (Day-30 to Day -1)	Focus Group Visit 1 (Day 0)
Inclusion/ Exclusion	**X**	
Informed consent form	**X**	
Demographics	**X**	
Novaco Anger Scale – Provocation Inventory	**X**	
MINI (screening)	**X**	
Physical Activity Readiness Questionnaire	**X**	
Payment		**$20**

Table 2. Schedule of Evaluations, Phase 1, Stakeholders.

Assessment	Baseline and Enrollment: (Day-30 to Day -1)	Baseline, Enrollment, Visit 1 (Day 0)
Inclusion/ Exclusion	**X**	
Informed consent form		**X**
Demographics		**X**
Payment		**$20**

Table 3, Schedule of Evaluations, Phase 2.

Assessment	Type of Assessment	Baseline1, Visit 1 (Day 0)	After initial class	After each class	Wk 5	Wk 10	Wk 14	Wk 18
Inclusion/ Exclusion	Interview, pre-randomize	**X**						
Informed Consent Form	Pre-randomize	**X**						
Enrollment/ Randomization	Interview	**X**						
CEQ	Self-report		**X**					
CSQ-8	Self-report					**X**		
Qualitative Interview	Interview					**X**	**X (yoga only)**	
Homework Questionnaire	Self-report			**X**				
Injuries due to yoga	Self-report			**X**				
SAFTEE- GI	Interview	**X**			**X**	**X**		**X**
Novaco Anger Scale-Provocation Inventory	Self-report	**X**			**X**	**X**		**X**
Aggression Questionnaire- Short Form	Self-report	**X**			**X**	**X**		**X**
Behavioral Infractions in Prison	Record Review	**X**			**X**	**X**		**X**
Patient Health Questionnaire-9	Self-report	**X**			**X**	**X**		**X**
PROMIS Anxiety	Self-report	**X**			**X**	**X**		**X**
SF-12 from RAND Medical Outcomes Study	Self-report	**X**			**X**	**X**		**X**
Anger Rumination Scale	Self-report	**X**			**X**	**X**		**X**
Experiences Questionnaire	Self-report	**X**			**X**	**X**		**X**
Stroop Color and Word Test	Task	**X**			**X**	**X**		**X**
MINI (screening)	Interview	**X**						

Assessment	Type of Assessment	Baseline1, Visit 1 (Day 0)	After initial class	After each class	Wk 5	Wk 10	Wk 14	Wk 18
Physical Activity Readiness Questionnaire	Self-report	**X**						
Life Events Checklist/PTSD Checklist	Self-report	**X**						
Treatment History Interview	Interview	**X**			**X**	**X**		**X**
International Physical Activity Questionnaire	Self-report	**X**			**X**	**X**		**X**
Payment					**$20**	**$20**	**$20**	**$20**

Abbreviations: timepoints: Wk5, Wk10, Wk18 = Week 5, Week 10, Week 18.

6.2 Description of Evaluations

Assessments will be administered by research assistants (RAs) trained in procedures to ensure confidentiality and proper management of research data.

6.2.1 Baseline Visit and Focus Group --Prisoners – Phase 1.

Consenting Procedure—Prisoners Phase 1

Written informed consent will be obtained at the baseline visit. Please see section 4.4 for more information about the consent procedures.

Screening—Prisoners Phase 1

Following informed consent, all participants will complete an initial demographics questionnaire. In phase 1, prisoner participants will also complete a baseline interview consisting of only those measures (see Table 1) that will be used to determine eligibility for participation in the focus groups. Study eligibility will be determined and documented on the prisoner focus group inclusion/exclusion sheet.

For purposes of assessment of certain inclusion/exclusion criteria, a brief diagnostic interview will be used to assess current mania, psychosis, or active suicide risk (warranting referral to prison mental health treatment staff).

List of measures used to assess inclusion/ exclusion criteria:

- Novaco Anger Scale – Provocation Inventory
- MINI (Screening)
- Physical Activity Readiness Questionnaire

Additional assessments—Prisoners Phase 1

There will be no additional assessment of participants in phase 1. We will conduct focus groups as described in section 6.2.3.

Payment—Prisoners Phase 1

Payment to prisoners for participation in the focus group is $20.

6.2.2 Screening and Focus Group -- Stakeholders – Phase 1

Screening – Stakeholders Phase 1

Stakeholders will be screened only for age, position at the RIDOC or other role in the criminal justice system (e.g., community advocate), and ability to speak English sufficiently well to participate in the focus groups. Screening will occur prior to the signing of consent in the focus groups. Study eligibility will be determined and documented on the stakeholder inclusion/exclusion sheet.

Consenting Procedure– Stakeholders Phase 1

Written informed consent will be obtained at the time of the focus group. Please see section 4.4 for more information about the consent procedures.

Additional assessments– Stakeholders Phase 1

There will be no additional assessment of participants in phase 1. We will conduct focus groups as described in section 6.2.3.

Payment—Stakeholders Phase 1

Payment to stakeholders for participation in the focus group is $20.

6.2.3 Focus Group Procedures and Study Material Revision

In Phase 1 of the study, participants who provide informed consent and are determined to be eligible for participation will be enrolled in one of 4 focus groups. Eligible prisoner participants will be invited to attend a single-session focus group. Focus groups will be recruited and convened one at a time, sequentially across the three RIDOC prison facilities where prisoners reside (i.e., men's minimum, men's medium, and women's minimum/ medium). The stakeholder focus group will be held at our Brown University offices on the Butler Hospital campus. We anticipate all focus groups will last between 60-75 minutes each.

Focus groups will be designed to solicit feedback re: 1) yoga classes; 2) health education classes; and 3) general study design. We will ask participants for feedback on each of these aspects of the study, with a particular focus on 1) tailoring that may be needed to make interventions more feasible or acceptable, safe, and efficacious for addressing anger management needs in this population, and 2) how to discuss and market the study to so that the procedures are accurately portrayed, and stigma and barriers to participation are minimized.

Focus group leaders. MPIs Weinstock and Uebelacker, and/or named study Co-Investigators will conduct focus groups and individual interview with key informants. As content experts and developers of the research interventions and protocols, and with prior experiences leading focus groups and analyzing qualitative data, study MPIs and Co-Is are well equipped and have the expertise to perform this study role.

Study Material Revision. Themes derived from focus group will then be shared with and discussed with the entire scientific team and staff at RIDOC. Following this comprehensive review of focus group data, Drs. Weinstock and Uebelacker will make initial modifications to the study materials, in an effort to maximize acceptability, feasibility, and safety of the study procedures and conditions. The revised materials will then be circulated to the scientific team, consultants, and other key informants for additional comment. This feedback will then be reviewed by Drs. Weinstock and Uebelacker, and integrated into the study materials in an iterative manner.

6.2.4 Baseline Visit -- Prisoners – Phase 2.

Consenting Procedure—Phase 2

Written informed consent will be obtained at the baseline visit. Please see section 4.4 for more information about the consent procedures.

Screening—Phase 2

Following informed consent, all participants will complete an initial demographics questionnaire. In phase 2, prisoner participants will also complete an interview consisting of those measures that will be used to determine eligibility for participation.

For purposes of assessment of certain inclusion/exclusion criteria, a brief diagnostic interview will be used to assess current mania, psychosis, or active suicide risk (warranting referral to prison mental health treatment staff). A brief questionnaire (PARQ) will be used to determine whether a participant can safely engage in a moderate level of physical activity. If the

participant endorses an item of this measure (except for item 6 which refers to hypertension medications, which are permissible in this study), they will be ruled ineligible.

List of measures used to assess inclusion/ exclusion criteria:

- Physical Activity Readiness Questionnaire
- Novaco Anger Scale – Provocation Inventory
- MINI (Screening)

Enrollment—Phase 2

If a participant meets all inclusion/ exclusion criteria, he/she will be enrolled in the study at this baseline visit. Study eligibility will be determined and documented on the RCT inclusion/exclusion sheet.

Baseline assessments—Phase 2

Remaining baseline assessments are detailed in Table 3.

Randomization—Phase 2

Randomization will occur at the baseline visit after all assessments are completed. Participants may begin study classes within one week of randomization.

6.2.5 Blinding – Phase 2.

The following individuals will be blinded during the course of the study: Dr. Lauren Weinstock, MPI; Dr. Leslie Brick, Statistician; Dr. Jennifer Johnson, Co-I; Dr. Tracie Shea, Co-I.

The following individuals will not be blinded during the course of the study: Dr. Lisa Uebelacker, MPI; Dr. Geoffrey Tremont, Co-I; Hannah Graves, Project Coordinator; study interventionists; study RA. Randomization will be conducted by the study RA and overseen by Hannah Graves, Project Coordinator (see section 9.2.2 for more information on randomization).

Dr. Uebelacker will be the non-blind PI and will primarily be responsible for supervision of the interventionists and ensuring therapist/ yoga instructor adherence. Dr. Weinstock will be the blind PI and will be primarily responsible for the supervision of the research assistants. Dr. Brick, the study statistician, will be blind to group assignment (and will have no contact with participants.) When there is a question about whether a participant meets inclusion criteria, Dr. Weinstock will make a decision about inclusion. Drs. Uebelacker, Ms. Graves, and study RAs will meet separately to discuss intervention-specific concerns (e.g., need to cancel class due to lack of participants).

To ensure that blindness will be maintained, there will be a separate data collection instrument in REDCap to enter randomization assignment. Only non-blind study personnel will have access to this section of REDCap. We will also have a separate section in REDCap for intervention specific data (e.g., dates of sessions attended, yoga homework) that only the non-blinded staff will have access to.

In reporting adverse events to the Safety Monitoring Committee, determination of "causal relationship" will be made by the non-blind PI only, as it may require knowledge of which intervention arm the participant is in. The standard Adverse Events Reporting Form of our IRB does not ask for intervention arm; thus risk of unblinding from AE reporting is minimal.

The non-blind PI will meet with yoga instructors and HE instructors for supervision. The instructor/ therapist adherence ratings will be conducted by the non-blind PI and RA.

We will keep a record of any instances of unblinding. This record will be used to improve procedures for a larger clinical trial. After all data are collected and the database is locked, the blind PI may be unblinded so as to contribute to data interpretation.

Participants cannot be blind to study intervention. However, we will present both interventions (Yoga or HE) with equipoise to all participants in written materials and orally.

6.2.6 Follow-up Visits – Phase 2.

For all follow-up assessments, research staff will make every effort to conduct the assessment within one week before or one week after the exact due date of the assessment. However, because all data can be analyzed with modern statistical methods regardless of whether it was collected inside that window, RAs will still collect data if possible even if it is later than that two-week window. We will record optimum date for the assessment as well as the actual date of the assessment.

Participants will complete a brief assessment after each class that they attend.

In addition, all participants will be assessed at: baseline, 5 weeks (mid-intervention), 10 weeks (post-intervention), 14 weeks (yoga group participants only), and at 8 week follow-up. In addition to demographics, we will assess acceptability of the intervention conditions, safety of the yoga condition, anger and aggression, secondary outcomes (depression and anxiety symptoms, general functioning), potential intervention mechanisms of action (anger rumination, decentering, impulsivity), and other descriptive characteristics (trauma history, treatment utilization, physical activity levels).

In the event that a participant is released back into the community before they complete all of their study assessments, we will complete them in the community. We will aim to complete all of these follow-up assessments by telephone. However, there may be some circumstances that might make it difficult for a participant to complete the follow-up assessment by telephone (e.g., limited phone minutes, enrollment in a residential treatment program). In such cases, we will complete the follow-up assessment in person in our offices at Brown University or in the facility where the participant is located (e.g., residential treatment facility, with facility approval). Additionally, if a participant is transferred to another facility at RIDOC, we will complete their assessments at the other facility (e.g., Men's Maximum Security) with RIDOC approval.

Please see table 3 for a list of all assessments to be completed at each visit.

6.2.7 Completion/Final Evaluation – Phase 2

Even if prisoners drop out of study treatment, we will attempt to collect data at all assessment points if prisoners agree to it.

6.3 Audiorecording

We will audio record all focus groups for purposes of transcription and assessment of data for qualitative analysis. This will be a requirement for participation in the focus groups. We will audio record assessment interviews in order to perform reliability checks. Participants may refuse audio recording of assessments but still participate in the study. We will audio record all classes (yoga and health education) for purposes of instructor supervision and to monitor instructor adherence to the intervention protocols. Because the interventions will be delivered in group format, and because it is imperative that we provide supervision and monitor adherence

of the instructors, participants may not refuse audio recording of classes in this study (e.g., if one participant refused audio recording of classes, we would not have these recordings for the group as a whole).

6.4. Material Inducements

In phase 1 (focus groups), we will compensate participants $20 for completion of the focus groups. For prisoner participants, this compensation will be in the form of money paid directly into their commissary account at the RIDOC. For stakeholder participants, this compensation will be in the form of a money order or gift card, paid to them directly upon completion of the focus group.

In phase 2 (pilot RCT), we will compensate participants $20 for each of the follow-up assessments (mid-intervention, post-intervention, 4 week follow-up (yoga participants only) and 8 week follow-up). In total, participants may receive up to $80 compensation. Similar to our procedures for prisoner participant compensation in phase 1, the compensation will be in the form of money paid directly into their commissary account at the RIDOC. If a participant is released from the RIDOC while still enrolled in the study, and completes any follow-up assessment in the community, this compensation will be provided in the form of a money order or gift card. Additionally, a participant may also choose to have us mail their compensation to a family member or significant other of their choosing.

7. SAFETY ASSESSMENTS

7.1. Human Subjects

For yoga, the only expected adverse event is:

- Physical injury (mild)

For group HE, there are no expected adverse events.

Drs. Weinstock and Uebelacker will be responsible for overseeing the safety of all participants. Drs. Tremont, Shea, and Johnson (who maintains a clinical license in RI) will be available to serve as clinical back-up for the MPIs, when required. Participant safety will monitored in two ways: (a) during the intake or ongoing assessments by the research staff, and (b) during intervention sessions. Research assessments will be conducted at study intake, 5 weeks (mid-intervention), 10 weeks (post-intervention), 14 weeks (yoga group participants only) and at 8 week follow-up. For those randomized to the yoga condition, yoga instructors will carefully monitor participants for any physical injury during each class. We will carefully monitor all participants for significant suicidal ideation (SI), homicidal ideation (HI), and for adverse events and serious adverse events at each time point.

There are five major sources of low to moderate risk associated with participation in the proposed study.

1. Potential coercion. It is possible that individuals may feel coerced into participating. This is a particularly important risk to minimize with incarcerated individuals. This is also an important risk to minimize with stakeholders (i.e., prison staff or other RIDOC employees).
2. Potential suicidal or homicidal ideation. Given that prisoner participants will have risk factors for suicide or homicide (e.g., a mental health diagnosis, incarceration), some participants may experience suicide ideation or behavior or homicidal ideation in the course of study participation.
3. Increased distress due to assessment procedures. It is possible that some participants will experience increased intrapersonal or interpersonal psychological distress as a result of participating in focus groups (prisoner and stakeholder participants), and yoga and health education groups. In the vast majority of cases, we believe that any increased distress experiences will be mild and transitory in nature.
4. Confidentiality and loss of privacy. The greatest potential risks to those participating in the research are legal or social, caused by the inadvertent loss of confidential information obtained during the data collection process. That is, a participant's identity may be inadvertently exposed or questionnaire material may be released or disclosed to unauthorized persons. In the case of such a breach, serious personal and social consequences could conceivably occur. However, such risks can be minimized by instituting the proper procedures to protect confidentiality and by having resources in place to provide counseling and referrals. We have extensive experience taking appropriate measures to safeguard confidential information in research with criminal justice populations. These measures are described below.
6. Potential physical injury **(phase 2 only)**. Because yoga is a physical activity, there is a small risk of physical injury for those participants who are in study yoga classes.

Protection Against Risks

All research materials collected or received by the Butler Hospital research team will be covered by HIPAA regulations according to hospital policy. Data and safety monitoring will take place to assure the safety of subjects (see below). All participants will be reminded that their participation is voluntary and that they can withdraw at any time without penalty. Additionally, the risks described above will be minimized by the following procedures:

1. We will minimize the risk of potential coercion by following standard procedures for obtaining informed consent. Prior to enrolling prisoner participants in the research, we will fully explain the study procedures, risks, benefits, and alternatives to participants, emphasizing that participation has no impact on the other services they receive at the prison, the terms or length of their confinement, or any other community services that they receive post-release. Also, participants who do not consent or who withdraw will receive appropriate referrals (e.g., for mental health treatment), if needed. For stakeholder participants, we will also fully explain the study procedures, risks and benefits, and alternatives to participation. We will emphasize that participation has no impact on their employment or affiliation with the RIDOC. All participants will be reminded that there is no penalty for participants who choose to not participate or to withdraw from the study.

2. We will minimize the risk of potential suicidal or homicidal ideation by instituting the proper procedures for protecting the safety of participants and others, which we have applied extensively in our prior and ongoing research at the RIDOC. During incarceration, Per RIDOC policy, their standards for mandatory reporting of suicide risk (i.e., breaking confidentiality to report suicide risk) specify that we are required to report anyone who has had suicidal ideation within the past 24 hours (as determined through query and follow-up for an endorsement of any score > 0 on item 9 of the PHQ-9 or reporting of any current desire to hurt oneself to any member of the research staff). We will follow this RIDOC policy, per their requirements for researchers conducting human subjects research with any of their facilities. If the participant reports this level of SI within the past 2 weeks, but not in the 24 hours prior to the assessment, the RA will notify one of the PIs (both of who are licensed psychologists) or their covering licensed clinician who will make a clinical determination if further referral or action is needed, and a voluntary referral will be offered. Participants meeting the prison's SI mandatory reporting criteria (or those who elect the voluntary referral) will be referred to a prison mental health clinician for evaluation, who will follow prison procedures. When confidentiality must be broken due to a RIDOC mandatory report, the research staff member will report the information to a social worker, a nurse, and/or the highest ranking person available (i.e. Captain, Lieutenant, Correctional Officer, etc.). We will prioritize reporting to a medical staff member first, but will report to the highest ranking person available if a medical staff member is unavailable at the time of the report. Standard prison procedures include: (1) checking with the prison's behavioral health department to see if the person has already been flagged as having SI; (2) having a licensed mental health clinician check in with the person and do a suicide risk evaluation; and/or (3) if needed, putting the person on psychiatric observation within the prison. If the prison mental health professional determines that someone's risk has gone down, that person will leave psychiatric observation and return to the general population. All of these procedures are set and executed by the prison, which follows its own ethical and legal requirements. We will clearly describe this in our consent form. Homicidal risk will be defined by reporting any desire to hurt another person, including any member of the study staff. Standard mandatory reporting procedures (e.g., contact prison mental health staff), per RIDOC policy, will be followed.

Given study inclusion criteria, we think it unlikely that anyone will be released into the community while participating in the study. However, we do have procedures in place for people post-release. During the post-release period, definitions of suicide risk, and homicide risk will be the same those described above; however, we will rely upon our standard study procedures (vs. RIDOC mandatory/ voluntary reporting criteria) to facilitate clinician referral and safety assessment, as needed. If any study staff member identifies an individual who reports any suicidal or homicidal ideation in the course of standard assessment procedures, the staff member will immediately contact Dr. Weinstock or Dr. Uebelacker (or the licensed covering clinician). The covering clinician will evaluate the participant over the telephone or in person. First, they will conduct a suicide and homicide risk assessment to determine whether it is necessary to take immediate action to prevent the participant from causing harm to self or others. If needed, actions that the covering clinician may take include escorting the person to the emergency Patient Assessment Service (PAS) at Butler Hospital (if the person is in our offices), having a family member transport the person to Butler Hospital or another hospital, or sending an ambulance so that the individual may be evaluated for inpatient psychiatric hospitalization.

A participant who has undergone a suicide or homicide risk assessment may continue to participate in the study unless the study PIs, in concert with the participant's healthcare providers, deem study participation to increase risk for this particular participant.

3. We will minimize the risk of distress by informing all participants that they do not have to answer questions that they find too distressing and will be reminded that they can discontinue participation at any time. Focus groups will be led by a licensed clinician (Drs. Weinstock, Uebelacker, and/or one of the study Co-Is) to help facilitate the stabilization and referral process if participants who decompensate during study procedures. In the pilot RCT, clinical backup will be provided during all assessments and intervention sessions by a licensed clinician to help facilitate the stabilization and referral process for participants who decompensate during study procedures. The need for additional services will also be monitored during each clinical (assessment or intervention) contact. Participants will be formally assessed at 4 time points (baseline, 5 weeks, 10 weeks, 18 weeks). Incarcerated participants who manifest significant psychiatric symptomatology (i.e., psychosis or mania per the MINI Neuropsychiatric Interview) will be referred to appropriate clinical prison staff for evaluation, per RIDOC policy, following the same procedures for participants who report significant homicidal ideation or suicide risk (as described above). For any assessments in the community (in the rare event that a participant is released from prison prior to study completion), a licensed clinician (the MPIs or their covering clinician) will be available at all times to provide clinical coverage. Research staff will notify the licensed clinician if there are any safety concerns

4. We will minimize potential risks due to loss of confidentiality of research data by instituting the proper procedures to protect confidentiality and by having resources in place to provide counseling and referrals. We have extensive experience taking appropriate measures to safeguard confidential information in research with criminal justice populations. We will minimize potential risks due to loss of confidentiality of research data by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All participants will be informed about the limits of confidentiality concerning suicidal intent, homicidal intent, suspected child abuse, suspected elder abuse, and other prison-required mandatory reporting issues (i.e., sexual contact within the prison, weapons in the prison, prison escape plans). All information will be treated as confidential material and will be available only to research staff. All information will be kept in locked file cabinets at Brown University. Computer data files will be kept on Brown's secure research servers and Care New England's REDCap system, will be available only to authorized personnel, and no names or obvious identifying information will be stored in data files. No participant will be identified in any report

of the project. To further protect participants, there will be a Federal Certificate of Confidentiality for this project, which is now automatically awarded by NIH when a proposal is funded. Potential subjects will be informed that a Certificate of Confidentiality has been obtained for this project and that this certificate will protect the investigators from being forced to release any research data in which participants can be identified, even under court order or subpoena, although this protection is not absolute. Potential participants will be informed of the situations during the informed consent process (and as documented in the informed consent document) in which they may not be protected under the Certificate of Confidentiality. No information about participants will be released without their permission or where required by law.

Audio recording is necessary to: a) obtain and transcribe focus group data and b) conduct supervision and adherence ratings for interventionists. Audio recording of assessments is also important, but not mandatory, for measurement of assessment reliability (i.e., because only a random selection of recordings will be used for this purpose, it is not necessary that every participant or every session be recorded).

As in our past 10 years of prison research, audio recording is accomplished through the use of credit-card size digital audio recorders, which have password-protection and encryption capabilities thereby protecting their contents during transport between the RIDOC and our research offices. These digital recordings are regularly transferred to Brown's secure computer server (designed to hold and protect digital audio and video recordings for clinical trials) via USB connection and secure file transfer to Brown's secure audio server, and the recorders are wiped. This is the same procedure that has been used in our completed and ongoing intervention studies with prisoners and jail detainees at the recruitment site. Participants will be asked to give informed written consent to audio recording at the time of intervention study entry. To assure the confidentiality and protection of participants with respect to audio taping, the following steps will be taken: a) each recording will be labeled with the following: focus groups- focus group number, the interviewer's name, and the focus group date; group classes- the type of class, the interventionist's name, and the date; assessments- the participant's ID number, the interviewer's name, and the date of the assessment; b) all recordings will be stored on a secured computer server designed to hold and protect research data; and c) access to the audio recordings will be limited to only those research staff who need access to the recordings to perform their duties.

Although group discussion will be kept to a minimum in the yoga class, a participant's confidential statements during any of the study group sessions (e.g., focus group, yoga class, health education group) may be disclosed by another member of their corresponding group. To minimize risk, we will remind all participants that: a) any group discussion should be kept confidential; and b) because we cannot guarantee confidentiality due to the group nature of the discussion, all participants should be careful about disclosing anything that they want kept private. Finally, we will ask all participants not to disclose the names of prisoners in their group to others outside the group.

5. We will minimize potential risk for physical injury by: a) requiring all participants in yoga classes to be medically appropriate for moderate physical activity; and b) requiring all instructors to be registered yoga teachers with experience in directing people in how to achieve yoga postures without physical injury. Class content will be designed to accommodate the needs of yoga-naïve students who are not currently physically active. By presenting modifications of all postures, and by using props (e.g., chairs, blankets), the risk for injury will be minimized. Injuries due to yoga will be monitored at frequent intervals during this part of the study and patients will be followed for a sufficient period of time (2 months) after completing yoga classes to ensure stabilization of injuries.

Benefits of the proposed research to the subjects and others.

The potential risks associated with participation in this study appear to be mild to moderate. Although there is a risk for distress, the procedures proposed for monitoring distress should ensure that participants who require a higher level of care receive it. Participants assigned to yoga may benefit from improved anger regulation and associated behaviors. The study provides additional screening, assessment, and referral to emergency services, as needed, for all study participants, and in no way restricts or limits the treatment individuals would have received had they not participated in the study. Moreover, participants are helping other incarcerated individuals with high levels of anger dysregulation by providing information that will improve treatments for this population. Thus, the potential benefits outweigh the potential risks of the study.

Importance of knowledge to be gained.

To our knowledge, this current R34 proposal represents the first attempt to *systematically* develop and pilot a yoga intervention for anger dysregulation in incarcerated individuals. This pilot study will lay the groundwork for a larger, stage II clinical trial (R01) to evaluate the effectiveness of yoga for anger management, and for improvement in associated behaviors, other mental health symptoms, and functioning in prison. The risks involved in the study are minimal compared to the need for treatments for this population.

Risk-Benefit Ratio.

We believe that most serious risks (e.g., loss of confidentiality, major psychological distress due to study participation, or serious physical injury due to yoga participation) to subjects are very unlikely. We have attempted to minimize these risks (described above). While some risks may be more likely to occur (e.g., minor, transient psychological distress), these risks are much less serious. The risk of ineffective treatment is a serious risk, but one which: 1) is minimized through safeguards described above; 2) is common to any treatment as usual for emotional disturbance in the prison or community setting. Therefore, the potential benefits of the proposed study seem to outweigh the potential risks of this study for the individual participants.

7.2 Specification of Safety Parameters

Safety issues will be minimal in Phase 1 given that participation involves only a single focus group, no yoga classes, and no formal assessment of suicidality. However, should an issue arise (e.g., a voluntary report of suicide ideation), staff would manage it in the same way that they would manage it in Phase 2.

Please see Table 4 for a summary of safety issues, how they are assessed, when they are assessed, and relevant staff actions.

Table 4. Assessment and Management of Safety Issues, Summary, Phase 2

Safety Issue	How assessed	When Assessed in Phase 2	Relevant Research Staff Actions
Suicide or homicidal ideation	PHQ-9 Participant report to research staff	BL, wk5, wk10, wk18 Any point	Immediate clinical assessment as described in DSMP
Injuries due to yoga	Structured self-report	Weekly during first 10 weeks	Follow until resolution; may result in changes to yoga instructor manual
Other AEs	SAFTEE Participant report to research staff	BL, wk5, wk10, wk18 Any point	If related to study participation, follow resolution; potential changes to procedures particularly if AE is also unexpected

7.3 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

See Table 3.

7.4 Adverse Events and Serious Adverse Events

An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these regardless of relationship to participation in the study.

Unanticipated problems. The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Serious adverse events (SAEs). A serious adverse event (SAE) is one that meets one or more o the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred; includes a suicide attempt or drug overdose)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Unanticipated problems will be recorded in the data collection system throughout the study. Study staff will record all reportable events with start dates occurring any time after informed consent is obtained until 8 weeks (i.e., follow-up assessment after the last day of class participation). Each time participants attend classes, we will inquire about injuries due to study participation. At midpoint, endpoint, and at week 8 follow-up, study staff will administer the SAFTEE in order to inquire about the occurrence of AE/SAEs during the previous 8-10 weeks. SAEs related study participation will be followed for outcome information until resolution or stabilization.

Characteristics of an adverse event will include: a) relationship to study intervention, b) expectedness of SAEs, and c) event severity.

Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

Relatedness of SAEs

The Study PI and Independent Monitoring Committee will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention. The risk information to assess expectedness can be obtained from preclinical studies, the investigator's brochure, published medical literature, the protocol, or the informed consent document.

Expected AEs for this study include:

- Any event that may be reasonably anticipated to occur as a result of the study procedure (i.e., mild aches or pains following a yoga class)

Severity of Event

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

7.5 Reporting Procedures

Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB, SMC, and NCCIH within 7 days of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB, SMC, and NCCIH within 14 days of the investigator becoming aware of the problem.

All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

Adverse event reporting

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Data Safety and Monitoring Board (DSMB), IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer and DSMB within 3 days of the investigator becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the SMC, IRB, and other oversight organizations in accordance with their requirements, and will be reported to NCCIH on an annual basis.
- All other AEs documented during the course of the trial will be reported to NCCIH on an annual basis by way of inclusion in the annual report and in the annual AE summary which will be provided to NCCIH and to the DSMB. The DSMB Report will state that all AEs have been reviewed.

7.6 Follow-up for Adverse Events

Any SAEs related study participation will be followed for outcome information until resolution or stabilization. Follow-up reports will be submitted to the IRB, SMC, or NCCIH as required in each specific instance.

7.7 Safety Monitoring

The NCCIH requires that all Human Subjects research studies undergo independent monitoring, and NCCIH Program Officials will provide specific guidelines to the PI for the study.

8. INTERVENTION DISCONTINUATION

Prisoners will be discontinued from an intervention in the following circumstances:

- If the prisoner or prison staff does not believe it is in the best interest of the prisoner to continue. As soon as an MPI is informed of this, study staff will speak with the participant about discontinuation, if possible.
- If a prisoner chooses to discontinue attendance.
- If one of the MPIs, in consultation with the relevant instructor, finds the prisoner to be so disruptive to the rest of the class that he/she has a repeated and substantive negative impact on the other participants.
- If a prisoner is released from prison unexpectedly.
- If a prisoner exhibits inappropriate behavior towards study staff.

Participants will continue with subsequent assessments if they are willing to do so. Assessment schedule and assessments used will not change.

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

For this pilot treatment development trial, assessment of feasibility, acceptability, and safety of the intervention and research procedures is the primary goal. Nonetheless, pilot data can be used to demonstrate whether the effects of treatment look promising across a set of outcome variables, to begin to examine the distribution of outcome variables to inform future analytic strategies, and to suggest, in concert with results from larger scale clinical trials in related fields, the range of effect sizes that would be reasonable to expect in a future trial.

Because this is a treatment development study, we have chosen our sample sizes as being sufficient to assess feasibility and acceptability. This study is not powered to assess differences between treatments.

9.1.1. Summary of Aims, Endpoints, and Data Analytic Strategy.

Table 5 summarizes each aim, the target endpoint, and the data analysis strategy, where applicable.

Table 5. Summary of Aims, endpoints, and analyses.		
Aim/ Objective	Endpoint	Analyses
Phase 1 – Focus Groups		
To conduct focus groups with prisoners and criminal justice stakeholder groups (separately) to understand ways of increasing feasibility, acceptability, and efficacy of yoga for anger management as well as feasibility and acceptability of our control arm (health education);	Conduct 4 focus groups, composed of approximately 6 individuals each.	Qualitative analysis – see description below.
To solicit feedback from experts in correctional mental health, addiction, and yoga	Feedback received from experts in relevant areas	Qualitative analysis– see description below.
To modify our existing yoga treatment manual, health education manual, and instructor fidelity scales.	Draft of yoga manual, health education manual, and instructor fidelity scales	N/A
Phase 2 – Pilot RCT		
To conduct a pilot RCT of hatha yoga vs. health education	40 prisoners enrolled & follow up assessments completed	N/A
To assess feasibility and acceptability of both the yoga class and the health education control group. ** This is primary.**	See Table 6 for a complete list	Descriptive statistics (see Table 6) and qualitative data analysis
To assess safety, we will track all adverse events in a structured fashion.	See Table 6 for a complete list	Descriptive statistics (see Table 6)
To assess feasibility of research procedures,	See Table 6 for a complete list	Descriptive statistics (see Table 6)
To assess within-group changes on outcomes. The primary clinical target (and primary outcome for a subsequent efficacy trial) will be anger dysregulation assessed by the NAS at post-intervention (wk10). Secondary targets (and secondary outcomes for a subsequent efficacy trial) include Aggression (AQ-SF); behavioral infractions, depression (PHQ-9), anxiety (PROMIS Anxiety), and functional impairment (SF-12). We will assess these changes from pre-intervention to post-intervention (wk10), and pre-intervention to follow-up (wk18). ** This is exploratory.**	Endpoint = post-intervention (wk10); follow-up (wk18)	Within-subjects t-tests (e.g., from pre-intervention to post-intervention/wk10, and pre-intervention to wk18). We will conduct analyses separately by treatment group. We will calculate effect sizes (Cohen's d) from pre- to post- treatment/wk10, with corresponding confidence intervals.
Assess within-group changes on anger rumination, decentering, and impulsivity. ** This is exploratory.**	Endpoint = post-intervention (wk10).	Within-subjects t-tests (e.g., from pre-intervention to wk10). We will conduct analyses separately by treatment group.

9.1.2. Description of Assessment Instruments.

All interview and self-report assessment measures were chosen because they have strong psychometric properties for measurement of constructs of interest to the study, and have been used in other NIH-funded clinical trials and prospective studies. With signed releases of information (ROIs) obtained at the baseline assessment, we will supplement interview and self-report data with criminal justice records review to assess for rates of behavioral infractions in prison.

***Acceptability and Feasibility*.** Intervention credibility and patient expectations for intervention success at baseline will be measured with the Credibility Expectancy Questionnaire (CEQ)[23]; this is administered after their initial class. The Client Satisfaction Questionnaire (CSQ-8)[24] will be used post-treatment to assess satisfaction with treatment. We will also use qualitative responses to a detailed post-treatment interview to gain participants' feedback about intervention components and research procedures. Finally, it is critical that the amount of yoga practice at home be measured as accurately as possible. Participants will complete a yoga homework questionnaire on a weekly basis. The tool will yield three indices of home practice: frequency of extended home practice, minutes of extended home practice, and frequency of micro home practice.

***Participant safety*.** After each homework questionnaire, we will ask participants in the yoga arm only whether they experienced any injuries as a result of yoga practice. At each follow-up, we will administer the Systematic Assessment of Treatment-Emergent Events – General Inquiry (SAFTEE)[25] to all participants. This allows us to systematically assess number of adverse events, severity, and resulting impairment. Finally, any time a participant reports an adverse event to any staff member, a research assistant will talk with the participant to ascertain information for recording of the adverse event. For adverse events ascertained by any of these three possible methods, the research assistant gets information on what happened, start and stop dates, severity, functional impact, interactions with healthcare professionals, perceived cause, and possible relation to study participation. For more information and details on coding of AEs, please see DSMP.

Anger and aggression. We will use the two-part Novaco Anger Scale and Provocation Inventory (NAS-PI)[26,27] to measure anger. The first part of the measure, the Novaco Anger Scale (NAS) will be used to measure the primary outcome of anger dysregulation. The NAS is a 48-item scale that yields a total score reflecting the likelihood and severity of experiencing anger reactions across cognitive, arousal, and behavioral, domains of anger. Each of these domains has a corresponding subscale that can be evaluated separately. The Novaco Provocation Inventory (PI), contains 25 items that assess anger reactivity to a variety of provocations (e.g., annoyances, disrespect, frustration, perceived injustice). This will be a secondary outcome. The NAS-PI is among the most widely used measures of anger,,[28] and has demonstrated strong reliability and validity (including concurrent validity with other measures of anger,[29–32]) across many different samples,[33–35] including incarcerated[30–32,36] and other CJ-involved[36–38] individuals. To measure aggression, we will use the Aggression Questionnaire-Short Form (AQ-SF).[39,40] The AQ-SF is a widely used scale that measures self-reported physical and verbal aggression. It has been validated for use across range of populations,[40,41] including those who are CJ-involved.[42,43] Finally, we will assess frequency of behavioral infractions in prison, and receipt of disciplinary action through review of local criminal justice records, as well as through self-report.

Other Secondary Outcomes. The Patient Health Questionnaire (PHQ-9)[44] will be used to assess depression via self-report. The PHQ-9 has established reliability and validity. We will use the self-report PROMIS anxiety[45] 8-item scale (short form 8A) to assess , anxiety severity. Functional impairment will be assessed via the SF-12,[46] a brief, widely used self-report measure

of physical and mental health functioning.

Potential Mechanisms of Action. The Anger Rumination Scale (ARS)[47,48] is a 19-item self-report questionnaire that measures the tendency to focus and perseverate on angry affect and past anger experiences. Unlike the cognitive subscale of the NAS, this scale measures a cognitive process, rather than the content of cognitions, per se. We will use the Experiences Questionnaire (EQ)[49,50] to assess decentering. Decentering is a process of distancing from and observing cognitive content, without judgment or reactivity.[51] The EQ consists of 20 items and two subscales: decentering and rumination. Finally, the Stroop Color Word Test[52–54] will be administered as a task-based measure of disinhibition and impulsivity.

Other Measures. Subjects will be asked for demographic information and, number of prior arrests and incarcerations, and length of time spent incarcerated. **For purposes of determining inclusion/ exclusion criteria**, the mood and psychosis modules of the brief MINI Neuropsychiatric Interview[55] will be used to assess for current mania, psychosis, or active suicide risk (see section 4.7.1). The Physical Activity Readiness Questionnaire[56] (PAR-Q) will be used to determine whether a participant is able to safely engage in a moderate level of physical activity. As noted in section 4.7.1, if someone answers "yes" to any of the 7 items on the scale they will be ruled ineligible for the study. **For descriptive purposes**, the Life Events Checklist/PTSD Checklist[57,58] (LEC/PCL) will be used to assess for lifetime history of trauma exposure and severity of PTSD symptoms. The Treatment History Interview[59] (THI) will be used to assess mental health treatment (i.e., pharmacotherapy, psychotherapy, group therapy, 12-step participation) received over the course of study participation. Finally, we will use the International Physical Activity Questionnaire[22] (IPAQ), a self-report measure of physical activity. We have adapted this scale to measure amount of yoga practice engaged in during the follow-up time period, as well as other physical activity. The Qualitative Interview - Intersectional Stigma (for yoga participants only) will be conducted to assess intersectional stigma or multilevel resiliency in the context of incarceration among people participating in a yoga program.

9.2 Sample Size and Randomization

9.2.1. Sample Size.

This project consists of three phases: In Phase 1, we will conduct focus groups with up to 18 prisoners and 6 prison stakeholders. In Phase 2, we will consent up to 175 prisoners in order to achieve our enrollment goal of 40 prisoners who meet study inclusion for randomization to conditions in the pilot RCT. We will assess feasibility, acceptability, and safety of the interventions and research design, and examine key outcomes within relevant confidence intervals. This phase of the study is not designed to be adequately powered to assess efficacy; rather, it is focused on feasibility, acceptability, and safety.

9.2.2. Treatment Assignment Procedures.

Participants in Phase 2 will undergo randomization. Randomization will be conducted using a blocked stratified randomization scheme. We will stratify patients based on gender and facility (i.e., men's medium security [n= 20], and women's combined minimum and medium security [n=20]). Randomization sequences will be generated by computer. Because we cannot bring computers into the prison, we will have someone not associated with the study conceal the group assignments within small opaque envelopes labeled with a number and the strata (for example, male medium 1, male medium 2, etc.). Research assistants will then take the envelopes to the prison, and open them when randomization occurs.

9.3 Definition of Populations

All data analysis will use the intent to treat population and use all available data. There is no per protocol analysis planned.

9.4 Interim Analyses and Stopping Rules

9.4.1 Interim analysis.

There is no interim data analysis plan.

Data analysis of Phase 1 qualitative data will occur during and immediately after data collection in Phase 1.

Data analysis of Phase 2 data will occur after enrolling 10, 20, and 40 participants (for feasibility and acceptability outcomes).

9.4.2 Halting Rules.

If there are any SAEs judged related to the study intervention, we will halt the study intervention until an ad hoc safety review is convened with the DSMB, MPIs, site PI, and other relevant study staff. The safety review will determine whether the study should continue per protocol, proceed with enhanced monitoring, be further investigated, be discontinued, or be modified and then proceed. Subsequent review of serious, unexpected, and related AEs by the DSMB, IRB, the sponsor(s), or relevant local regulatory authorities may also result in suspension of further study interventions. The study sponsor(s) retain the authority to suspend additional enrollment and study interventions/ administration of study product for the entire study, as applicable.

9.5 Outcomes

9.5.1 Primary Outcome.

The primary outcomes are acceptability, feasibility, and safety.

Target treatment development outcomes. We monitor treatment development outcomes (see Table 6) throughout the trial. Target outcomes were chosen on face validity, clinical experience, and, when available, relevant clinical literature. At 3 time points throughout the RCT (i.e., after enrolling 10, 20, and 40 participants), the scientific team will convene to discuss how our actual procedural outcomes compare to the target outcomes. Discrepancies will result in: 1) investigation (using qualitative or other data) of the reason for the failure to meet this outcome; and 2) discussion amongst the research team. Depending on the nature of the discrepancy, we may modify recruitment procedures, assessment procedures, instructions to participants, instructor training procedures, or other aspects of the trial. Ultimately, failure to meet these outcomes could result in a decision not to write a grant proposal for a large-scale RCT; in other cases, it may inform the design of a subsequent RCT.

Primary data analyses will be focused on feasibility and acceptability (see Table 6) using intent-to-treat population. Study measures and endpoints will continue to be collected for all enrolled participants if they are willing, even in the event of premature discontinuation of the study intervention.

Table 2. Target Outcomes	
Description (Assessment method)	Target
Feasibility and Acceptability-- Hatha yoga, Health education	
Acceptability (qualitative interview)	Most feedback positive; few substantive negative comments. Negative comments used to enhance procedures.
Credibility at baseline (CEQ)	Average > 50 (i.e., midpoint score between low and high credibility) on subscale
Expectancy at baseline (CEQ)	Average > 50 (i.e., midpoint score) on subscale
Program satisfaction (CSQ-8)	Average total score > 24
Home practice (homework questionnaire)	70% of yoga participants engage in practice at least 2 times per week for 6/10 weeks.
Class attendance	70% of all participants complete 6/10 classes in the RCT
Instructor adherence (Adherence measures)	Yoga instructors and HE instructors achieve at least 80% adherence on a random subset of classes taught
Class size	70% of classes have 4 or more participants.
Safety	
Adverse events (SAFTEE; injuries due to yoga)	No serious adverse events or injuries that are possibly, probably, or definitely related to study participation.
Feasibility and Acceptability—Research Procedures	
Recruitment rate	Average of 6 enrolled per month
Retention rate	80% complete week 10 assessment; 70% complete wk. 18 assessment
Completion of items on assessment instruments	At least 90% of items are completed on each assessment instrument (so each will be valid).

9.5.2 Secondary/ Exploratory Outcomes.

In Phase 2, we will also examine change in key variables over time. This is an exploratory analysis.

Specifically, we will look at change over time the in the following variables. The primary outcome in a subsequent efficacy study is in **bold and underlined**. Secondary outcomes are in standard text. *Potential mechanisms are in italics.*

- **NAS-Provocation Inventory from BL to wk10**; BL to wk18.
- Aggression Questionnaire – Short Form, BL to wk10; BL to wk18.
- Number of behavioral infractions in Prison, BL to wk10; BL to wk18
- PHQ-9, BL to wk10; BL to wk18
- PROMIS Anxiety, BL to wk10; BL to wk18
- SF-12 physical health composite score, BL to wk10; BL to wk18
- SF-12 mental health composite score, BL to wk10; BL to wk18
- *Anger rumination scale, BL to wk10; BL to wk18*
- *Experiences Questionnaire, BL to wk10; BL to wk18*

- *Stroop Color and Word Test, BL to wk10; BL to wk18*

9.6 Data Analyses

Qualitative Data Analysis. We will identify themes through team-level review of transcripts and group discussions.

Quantitative Data Analysis. In the past, researchers have used pilot data to estimate an effect size for future power calculations. Kraemer et al.[60] emphasized the limitations of this practice due to the likelihood of large standard errors surrounding effect size estimates, and the concern that ultimately, large-scale RCTs should be powered to detect between-group differences considered to be *minimally clinically significant.*

Using data from the pilot RCT, we will examine differences in means and SDs (or frequencies) of key variables (e.g.,NAS total score, NAS subscale scores, secondary outcomes, and possible mechanisms) across time points using repeated-measures ANOVA. We will use effect size estimates to characterize differences between groups at each timepoint and will calculate associated 95% confidence intervals of these estimates in order to understand the precision, or lack thereof, of our estimates. We recognize that, due to the likely size of these CIs, these analyses may not permit definitive conclusions.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Participants will answer self-report data on standardized paper forms. Data will be entered in REDCap and double checked for accuracy. For the RCT (Phase 2), there will be a separate data collection instrument in REDCap to enter randomization assignment (yoga or health education). Additionally, we will have section of REDCap for intervention specific data (e.g., dates of sessions attended, yoga homework). Only non-blinded study personnel will have access to this section of REDCap. Blind personnel will be restricted.

Data and audio recordings will be identified with a participant ID number and identifying information will not be attached to paper data forms. All data (identifiable and non-identifiable) will be entered and tracked in REDCap. REDCap has the ability to restrict identifiable data access to only necessary study personnel. Those without access to identifiable data, will only be able to see the participant's identification number and de-identified data in REDCap. Care New England's instance of REDCap has been deemed HIPAA compliant by CNE Information Technology.

All paper records will be kept in a locked file cabinet. Any identifying information will be stored in a separate locked file cabinet from non-identifiable data at our offices at Brown University. All audio recorders are password-protected and encrypted for purposes of safe transport between the RIDOC facilities and Brown University offices. Digital recordings will be regularly transferred to Brown's secure computer server (designed to hold and protect digital audio and video recordings for clinical trials) via USB connection and secure file transfer to Brown's secure audio server, and the recorders are wiped.

10.2 Data Management

All Data will be collected using standardized paper forms or (if collected by telephone) will be directly entered into the Care New England REDCap database. Data from paper forms will be entered into REDCap and double checked for accuracy. Data entered directly into REDCap (if collected by telephone) will be reviewed by the Project Coordinator for completion and discrepancies. Any discrepancies will be resolved by the Project Coordinator in consultation with the MPIs as needed.

Care New England's REDCap is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails, and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium and was initiated at Vanderbilt University. Network transmissions (data entry, survey submission, web browsing, etc.) in REDCap are protected via Secure Sockets Layer (SSL) encryption. Access to REDCap can be restricted at different levels (e.g., research assistant, PI, and Co-Investigators). Exported data from REDCap will be stored on a secure password-protected server at Brown University.

Please see also "Data Handling and Record Keeping" in the DSMP.

10.3 Quality Assurance

10.3.1 Training

All research personnel will have formal training in research with human subjects (e.g., CITI training, GCP training). Drs. Weinstock and Uebelacker will provide training to and supervise the research assistants. RAs will have a bachelor's or master's degree, and will receive training in the informed consent process and their ethical responsibilities when conducting research, with a particular focus on the ethics involved with research with prisoner populations. All interviewers will receive specific training in the assessment instruments to be administered and in all study-related safety protocols. With assistance from the PIs, study Co-I Dr. Tremont and study consultant Mr. Gillette will supervise yoga instructors. Drs. Weinstock and Uebelacker will supervise the health education instructors, with additional assistance from Co-I Dr. Johnson.

10.3.2 Quality Control Committee

Drs. Uebelacker and Weinstock will be responsible for quality control of this study. They review recruitment and retention reports, and AE reports, on weekly basis.

10.3.3 Metrics

None of the outcome data include interview-administered questionnaires, so there are no relevant inter-rater reliability requirements.

10.3.4 Protocol Deviations

During weekly study meetings, protocol deviations will be discussed with the MPIs, including plans for corrective action. Protocol deviations will be logged on the protocol deviation tracking sheet and filed in the regulatory binder.

10.3.5 Monitoring

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Specific instructions for each step of the data management process, from acquisition to storage, will be included in a manual of procedures (MOP).

Data quality will be monitored by random inspection of the completed forms by one of the research assistants and any problems detected will be discussed with the PI. Standard data checking procedures will include checking forms for missing data, double entry with discrepancy resolution, daily back-up copies of computer files, and examination of key variables for skewness, variability, missing data, and outliers. Data and materials will be collected specifically for the proposed project.

Data collection and accurate documentation are the responsibility of the study staff under the supervision of MPIs. All source documents must be reviewed by the study team to ensure that they are accurate and complete.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent documents and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study. The consent form should be separate from the protocol document.

11.2 Informed Consent Forms

A signed consent form will be obtained from each participant. The consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant and this fact will be documented in the participant's record.

11.3 Participant Confidentiality

Data will be collected using standardized paper forms or (if collected by telephone) will be directly entered into the Care New England REDCap database, and will only be identified with the study's ID of the participant. Identifiable data will be restricted to only necessary study personnel (both paper forms and in REDCap). Collected forms will be transported to Dr. Weinstock's data entry center hosted by Brown University.

The computer systems used for data entry and analysis are protected by passwords and secure logon and data communications procedures to minimize the potential for disclosure of research information either inadvertently or as a result of external attack. Within each computer system, only those users authorized to access the data for a given study are able to do so. Research records are stored in areas that are locked when staff is not present.

All research data will be entered into Care New England's REDCap. Please see section 10.2 Data Management for more information. .

All paper forms will be referenced to a participant ID number and will be kept in locked file cabinets. The participant's ID number can be connected to the participant's name only through a single master file, accessible only to research staff. Consent forms and other documentation with personal identifiers will be kept in a separate file from other data. We will use encrypted, password-protected audio recorders and a locked transport box for transportation of paper files from RIDOC to Brown University offices at Butler Hospital.

Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NCCIH, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NCCIH, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

11.5 Inclusion of Special Classes, Women and Minorities, and Children

Special classes. Because the purpose of this study is to develop and evaluate the feasibility and acceptability of yoga and the health education control condition for prisoners with anger dysregulation, it is necessary to sample a prison population. Prisoners are an understudied population with complex treatment needs; hence the urgency for more research attending to the emotional and behavioral needs of this population. Because the target population is constituted

by sentenced prisoners, the Prisoner Checklist for research has been included as an appendix to this application. Incarcerated children 18-21 will be eligible.

Inclusion of Women and Minorities. Because the purpose of this application is to develop and pilot a Hatha yoga intervention for prisoners with anger dysregulation, the study population will consist of sentenced male and female inmates.

Extant data from prisoners at participating facilities in Rhode Island have been used to estimate the racial and ethnic distribution of the prisoner participants in the focus groups (n=18) and in the pilot randomized trial (n=40) phases of the proposed research. For females, the overall racial distribution will be approximately 66% White, 17% African American, 2% Asian, 4% American Indian or Alaska Native, and 11% other. The overall ethnic distribution for women will be approximately 17% Hispanic or Latina and 83% Non-Hispanic or Latina. For males, the overall racial distribution will be 48% White, 28% African American, 2% Asian, 4% American Indian or Alaska Native, and 18% other. The overall ethnic distribution for men will be approximately 24% Hispanic or Latino and 76% Non-Hispanic or Latino.

If the minority distribution of our participants falls below the targeted minority distribution (i.e., if halfway through the study, the proportions of African Americans or Hispanics recruited are less than two thirds of the proportion of that minority distribution for the RIDOC), then we will conduct additional outreach to the group that fell below their targeted enrollment numbers. We will also attempt to obtain feedback on why individuals for that group may refuse to participate in the study. Based on the feedback, we will take corrective action. All subjects will be asked to identify their race and ethnicity separately, by self-report, at the time of study entry, when demographic information is collected. We plan to conduct analysis to determine whether minority status is associated with any of the treatment utilization or clinical outcome data collected as part of this investigation. The Targeted/Planned Enrollment Table displays the expected racial and ethnic distribution of participants for this study.

Inclusion of Children. Individuals aged 18-21 who meet our inclusion criteria will be included in this study. Individuals younger than 18 will not be included. Stakeholder focus group participants will be employees of the RIDOC, and therefore over the age of 18. However, children 18-21 will be included. This study will not include anyone under 18 years of age (the age of emancipation in Rhode Island) because individuals younger than age 18 are supervised by the RI Juvenile Corrections Division (not the RIDOC) and because adolescent developmental issues would confound outcomes of interest to the study and because incarcerated individuals. Additional instruments and study methods would also be required to assess the unique mental health needs of a younger population. Thus, the current research is not applicable to children under the age of 18.

Because children ages 18-21 are of legal age, they will be treated as adults and will be able to consent and agree to participate in the study themselves. Our consent procedures are conducted face-to-face, with trained interviewers guiding eligible subjects step-by-step; materials are written at a Grade 7 level and the interviewers ensure that each element is understood. In addition, consent forms will be read aloud.

12. COMMITTEES

An external local SMC will be assembled to evaluate the data and safety to participants enrolled in the study. We will recruit 3 non-Brown-affiliated board members who have experience in clinical trials and/or yoga research and/or anger dysregulation research and/or research with criminal justice samples as well as the ethical issues involved with a randomized

control study. No member of the SMC will have co-published with the MPIs within the past three years, and they will not collaborate with the MPIs on any other studies.

RIDOC. We have a letter of support from the RI Department of Corrections (RIDOC) for this project. We have submitted this protocol to the RIDOC Medical Research Advisory Group (MRAG) for their review and approval prior to beginning any human subjects research at their site. We have contacts at RIDOC from years of conducting research in their facilities. This includes our point person, the Associate Director for Planning and Research, as well as contacts in each facility, including Deputies and the Programs Coordinator.

OHRP. In addition, the Brown University IRB submitted this protocol to the US Office of Human Research Protections (OHRP) and received their certification of this research protocol.

13. PUBLICATION OF RESEARCH FINDINGS

Drs. Weinstock and Uebelacker will be responsible for oversight and approval of any publications or presentations that arise from this research.

As is required, we will also provide draft materials (to include presentations, publications) based on this research to the attention of the Associate Director of Planning and Research at RIDOC, prior to dissemination. The purpose of the review is to allow the opportunity to ensure that the Department specific data is being accurately interpreted, not to edit the content of the work.

14. REFERENCES

1. Collier L. Incarceration nation. *APA Monit Psychol*. 2014;45:56.

2. Kaeble DK, Glaze LE. *Correctional Populations in the United States, 2015*.; 2016.

3. Binswanger IA, Redmond N, Steiner JF, Hicks LS. Health disparities and the criminal justice system: An agenda for further research and action. *J Urban Heal*. 2012;89:98-107.

4. Lopez G. How America's criminal justice system became the country's mental health system. *Vox*. 2016. https://www.vox.com/2016/3/1/11134908/criminal-justice-mental-health.

5. James D, Glaze LE. *Mental Health Problems of Prison Inmates. Special Report of the Justice Statistics*. Washington, DC: US Department of Justice, Office of Justice Programs, Bureau of Justice Statistics; 2006.

6. Al-Rousan T, Rubenstein L, Sieleni B, Deol H, Wallace RB. Inside the nation's largest mental health institution: a prevalence study in a state prison system. *BMC Public Health*. 2017;17:342.

7. Bronson J, Stroop J, Zimmer S, Berzofsky M. *Drug Use, Dependence, and Abuse among State Prisoners and Jail Inmates, 2007-2009*. Washington, DC; 2017.

8. Fazel S, Bains P, Doll H. Substance abuse and dependence in prisoners: A systematic review. *Addiction*. 2006;101:181-191.

9. Wilper AP, Woolhandler S, Boyd JW, et al. The health and health care of US prisoners: results of a nationwide survey. *Am J Public Heal*. 2009;99:666-672.

10. Noonan M. *Mortality in State Prisons, 2000-2014 - Statistical Tables*. Washington, DC; 2016.

11. Fazel S, Baillargeon J. The health of prisoners. *Lancet*. 2011;377:956-965.

12. Spielberger CD, Reheiser EC. Assessment of emotions: Anxiety, anger, depression, and curiosity. *Appl Psychol Heal Well-Being*. 2009;1:271-302.

13. Kassinove H, Tafrate RC. Anger-related disorders: Basic issues, models, and diagnostic considerations. In: Feinder EL, ed. *Anger Related Disorders: A Practitioner's Guide to Comparative Treatments*. Vol New York: Springer; 2006:1-27.

14. Herrero N, Gadea M, Rodríguez-Alarcón G, Espert R, Salvador A. What happens when we get angry? Hormonal, cardiovascular and asymmetrical brain responses. *Horm Behav*. 2010;57:276-283.

15. Novaco RW. Reducing anger-related offending: What works. In: *What Works in Offender Rehabilitation: An Evidence-Based Approach to Assessment and Treatment*. 2013:211-236.

16. Gonçalves LC, Gonçalves RA, Martins C, Dirkzwager AJE. Predicting Infractions and health care utilization in prison: A meta-analysis. *Crim Justice Behav*. 2014;41:921-942.

17. Houser KA, Welsh W. Examining the association between co-occurring disorders and seriousness of misconduct by female prison inmates. *Crim Justice Behav*. 2014;41:650-666.

18. Metzner JL, Fellner J. Solitary confinement and mental illness in U.S. prisons: A challenge for medical ethics. *J Am Acad Psychiatry Law*. 2010;38:104-108.

19. Porporino FJ, Motiuk LL. The prison careers of mentally disordered offenders. *Int J Law Psychiatry*. 1995;18:29-44.

20. Farzan-Kashani J, Murphy CM. Anger problems predict long-term criminal recidivism in partner violent men. *J Interpers Violence*. 2017;32:3541-3555.

21. Kroner DG, Loza W. Evidence for the efficacy of self-report in predicting nonviolent and violent criminal recidivism. *J Interpers Violence*. 2001;16:168-177.

22. Craig CL, Marshall AL, Sjöström M, et al. International Physical Activity Questionnaire (IPAQ): 12-country reliability and validity. *Med Sci Sport Exerc*. 2003;35:1381-1395.

23. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry*. 2000;31:73-86.

24. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. *Eval Progr Plann*. 1982;5:233-237.

25. Rabkin JG, Markowitz JS, Ocepek-Welikson K, Wager SS. General versus systematic inquiry about emergent clinical events with SAFTEE: implications for clinical research. *J Clin Psychopharmacol*. 1992;12:3-10.

26. Novaco RW. *The Novaco Anger Scale and Provocation Inventory (NAS-PI)*. Los Angeles: Western Psychological Services; 2003.

27. Novaco RW. Anger as a risk factor for violence among the mentally disordered. In: *Violence and Mental Disorder: Developments in Risk Assessment*; 1994:21-59.

28. Eckhardt C, Norlander B, Deffenbacher J. The assessment of anger and hostility: A critical review. *Aggress Violent Behav*. 2004;9:17-43.

29. Williams TY, Boyd JC, Cascardi MA, Poythress N. Factor structure and convergent validity of the Aggression Questionnaire in an offender population. *Psychol Assess*. 1996;8:398-403.

30. Suter JM, Byrne MK, Byrne S, Howells K, Day A. Anger in prisoners: Women are different from men. *Pers Individ Dif*. 2002;32:1087-1100.

31. Mills JF, Kroner DG, Forth AE. Novaco anger scale: Reliability and validity within an adult criminal sample. *Assessment*. 1998;5:237-248.

32. Baker MT, Van Hasselt VB, Sellers AH. Validation of the Novaco Anger Scale in an incarcerated offender population. *Crim Justice Behav*. 2008;35:741-754.

33. Jones JP, Thomas-Peter BA, Trout A. Normative data for the Novaco Anger Scale from a non-

clinical sample and implications for clinical use. *Br J Clin Psychol*. 1999;38:417-424.

34. Novaco RW, Chemtob CM. Anger and combat-related posttraumatic stress disorder. *J Trauma Stress*. 2002;15:123-132.

35. Chemtob CM, Novaco RW, Hamada RS, Gross DM. Cognitive-behavioral treatment for severe anger in posttraumatic stress disorder. *J Consult Clin Psychol*. 1997;65:184-189.

36. Moeller SB, Novaco RW, Heinola-Nielsen V, Hougaard H. Validation of the Novaco Anger Scale–Provocation Inventory with nonclinical, clinical, and offender samples. *Assessment*. 2016;23:624-636.

37. Novaco RW, Taylor JL. Anger and assaultiveness of male forensic patients with developmental disabilities: Links to volatile parents. *Aggress Behav*. 2008;34:380-393.

38. Novaco RW, Taylor JL. Assessment of anger and aggression in male offenders with developmental disabilities. *Psychol Assess*. 2004;16:42-50.

39. Buss AH, Perry M. The Aggression Questionnaire. *J Pers Soc Psychol*. 1992;63:452-459.

40. Bryant FB, Smith BD. Refining the architecture of aggression: A measurement model for the Buss-Perry Aggression Questionnaire. *J Res Pers*. 2001;35:138-167.

41. Webster GD, Dewall CN, Pond RS, et al. The brief aggression questionnaire: Psychometric and behavioral evidence for an efficient measure of trait aggression. *Aggress Behav*. 2014;40:120-139.

42. Wolff N, Morgan RD, Shi J, Huening J, Fisher WH. Thinking styles and emotional states of male and female prison inmates by mental disorder status. *Psychiatr Serv*. 2011;62:1485-1493.

43. Diamond PM, Magaletta PR. The Short-Form Buss-Perry Aggression Questionnaire (BPAQ-SF): A validation study with federal offenders. *Assessment*. 2006;13:227-240.

44. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16:606-613.

45. Schalet BD, Pilkonis PA, Yu L, et al. Clinical validity of PROMIS Depression, Anxiety, and Anger across diverse clinical samples. *J Clin Epidemiol*. 2016;73:119-127.

46. Burdine JN, Felix MRJ, Abel AL, Wiltraut CJ, Musselman YJ. The SF-12 as a population health measure: An exploratory examination of potential for application. *Health Serv Res*. 2000;35:885-904.

47. Sukhodolsky DG, Golub A, Cromwell EN. Development and validation of the anger rumination scale. *Pers Individ Dif*. 2001;31:689-700.

48. Anestis MD, Anestis JC, Selby EA, Joiner TE. Anger rumination across forms of aggression. *Pers Individ Dif*. 2009;46:192-196.

49. McCracken LM, Gutieŕrez-Martínez O, Smyth C. "Decentering" reflects psychological flexibility in people with chronic pain and correlates with their quality of functioning. *Heal Psychol*.

2013;32:820-823.

50. Fresco DM, Moore MT, van Dulmen MHM, et al. Initial psychometric properties of the Experiences Questionnaire: Validation of a self-report measure of decentering. *Behav Ther*. 2007;38:234-246.

51. Bernstein A, Hadash Y, Lichtash Y, Tanay G, Shepherd K, Fresco DM. Decentering and related constructs: A critical review and metacognitive processes model. *Perspect Psychol Sci*. 2015;10:599-617.

52. Strauss GP, Allen DN, Jorgensen ML, Cramer SL. Test-retest reliability of standard and emotional Stroop tasks: An investigation of color-word and picture-word versions. *Assessment*. 2005;12:330-337.

53. Golden CJ. Stroop Color and Word Test: A manual for clinical and experimental uses. *Chicago: Stoelting*. 1978:1-46.

54. Sharma L, Markon KE, Clark LA. Toward a theory of distinct types of "impulsive" behaviors: A meta-analysis of self-report and behavioral measures. *Psychol Bull*. 2014;140:374-408.

55. Sheehan D V., Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *Journal of Clinical Psychiatry*. 1998;59:22-33.

56. Thomas S, Reading J, Shephard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). *Can J Sport Sci*. 1992;17:338-345.

57. Gray MJ, Litz BT, Hsu JL, Lombardo TW. Psychometric properties of the life events checklist. *Assessment*. 2004;11:330-341.

58. McDonald SD, Calhoun PS. The diagnostic accuracy of the PTSD Checklist: A critical review. *Clin Psychol Rev*. 2010;30:976-987.

59. Linehan MM, Heard HL. *Treatment History Interview-4 (THI-4)*. Seattle,WA: University of Washington; 1996.

60. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry*. 2006;63:484-489

15. SUPPLEMENTS/APPENDICES

None.

National Center for Complementary and Integrative Health

Data and Safety Monitoring Plan (DSMP)

Treatment Development of Yoga for Anger Management in Incarcerated adults

Name of Sponsor:	National Center for Complementary and Integrative Health
Grant Number:	
Version Date:	December 20, 2019
Version Number:	1.2

1 STUDY OVERVIEW

1.1 Purpose of Study

The overall goal of this project is to conduct treatment development research that would prepare us to study whether hatha yoga (vs. a health education control group) might be an effective adjunctive treatment to target anger dysregulation in people in prison. We will conduct focus groups (n = 24) to gain feedback from men and women in prison, and from prison administrators. We will then conduct a pilot randomized controlled trial (n = 40) of hatha yoga vs. health education for anger dysregulation. In total, the sample will be 58 incarcerated individuals and 6 prison administrators, ages 18-70 years, who meet the study's inclusion criteria and sign the consent form. The sample will be recruited from the women's and men's medium security prison facilities at the RI Department of Corrections (RIDOC) in Cranston, RI.

1.2 Adherence Statement

The Data Safety Monitoring Plan (DSMP) outlined below will adhere to the protocol approved by the Brown University IRB.

2 PROTOCOL AMENDMENTS

All protocol amendments, other than minor administrative changes as defined by the NCCIH Guidance on Changes in Clinical Studies in Active Awards will be submitted in a prospective manner to NCCIH except when necessary to protect the safety, rights, or welfare of subjects. Prior to submission to NCCIH the proposed changes will be reviewed and approved by the Independent Monitor(s). IRB-approval will not be sought until after NCCIH approval of the protocol amendment has been obtained.

3 MULTI-SITE STUDIES

Not applicable.

4 CONFIDENTIALITY

4.1 Protection of Subject Privacy

Subject confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples in addition to any study information relating to subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study subjects. The clinical study site will permit access to such records.

4.2 Confidentiality During Adverse Event (AE) Reporting

AE reports and annual summaries will not include subject or group-identifiable material. Each report will only include the identification code.

5 EXPECTED RISKS

Expected risks to the subject are as follows:

Potential coercion. It is possible that individuals may feel coerced into participating. This is an especially important risk to minimize with incarcerated individuals. We will minimize the risk of potential coercion by following standard procedures for obtaining informed consent (see section 9). We will begin this process during the intake where we will clarify the nature of the study and possible alternatives upfront. Prior to enrolling participants in the research, we will fully explain the study procedures, risks, benefits, and alternatives to participants, emphasizing that participation has no impact on the other services they receive at the prison, the terms or length of their confinement, or any other community services that they receive post-release. Also, participants who do not consent or who withdraw will receive appropriate referrals (e.g., for mental health treatment), if needed. All participants will be reminded that there is no penalty for participants who choose to not participate or to withdraw from the study. All reimbursements for participating will be commensurate with participants' time required for participating in the research.

Physical injury. Because yoga is a physical activity, there is a small risk of physical injury for those participants who are in study yoga classes. The risk of physical injury will be minimized by: a) requiring all participants in yoga classes to be medically appropriate for moderate physical activity; and b) requiring all instructors to be registered yoga teachers with experience in directing people in how to achieve yoga postures without physical injury. Class content will be designed to accommodate the needs of yoga-naïve students who are not currently physically active. By presenting modifications of all postures, and by using props (e.g., folding chairs, blocks, and blankets), the risk for injury will be minimized. Injuries due to yoga will be monitored at frequent intervals during this part of the study and patients will be followed for a sufficient period of time (2 months) after completing yoga classes to ensure stabilization of injuries.

Suicide or homicide ideation. Given that participants will have risk factors for suicide or homicide (e.g., a mental health diagnosis, incarceration), some participants may experience suicide ideation or behavior in the course of study participation. During incarceration the RIDOC standards for mandatory reporting of suicide risk specify that we are required to report anyone who has had suicidal ideation within the past 24 hours (as determined by participant reporting of any current desire to hurt oneself to any member of the research staff). If the participant reports this level of SI within the past 2 weeks, but not in the 24 hours prior to the assessment, a voluntary referral will be offered. Participants meeting the prison's SI mandatory reporting criteria (or those who elect the voluntary referral) will be referred to a prison mental health clinician for evaluation, who will follow prison procedures. Standard prison procedures include:

(1) checking in the prison's electronic medical record to see if the person has already been flagged as having SI; (2) having a licensed mental health clinician check in with the person and do a suicide risk evaluation; and/or (3) if needed, putting the person on psychiatric observation within the prison. If the prison mental health professional determines that someone's risk has gone down, that person will leave psychiatric observation and return to the general population. All of these procedures are set and executed by the prison, which follows its own ethical and legal requirements. We will clearly describe this in our consent form. Homicidal risk will be defined by reporting any desire to hurt another person, including any member of the study staff. Standard mandatory reporting procedures (e.g., contact prison mental health staff) will be followed.

Given study inclusion criteria, we think it unlikely that anyone will be released into the community while participating in the study. However, we do have procedures in place for people post-release. During the post-release period, definitions of suicide risk, and homicide risk will be the same those described above; however, we will rely upon our standard study procedures (vs. RIDOC mandatory/voluntary reporting criteria) to facilitate clinician referral and safety assessment, as needed. If any study staff member identifies an individual with significant clinical deterioration or who report any suicidal or homicidal ideation in the course of standard assessment procedures, the staff member will immediately contact Dr. Weinstock or Dr. Uebelacker (or the licensed covering clinician). The covering clinician will evaluate the participant over the telephone or in person. First, they will conduct a suicide and homicide risk assessment to determine whether it is necessary to take immediate action to prevent the participant from causing harm to self or others. If needed, actions that the covering clinician may take include escorting the person to the emergency Patient Assessment Service (PAS) at Butler Hospital (if the person is in our offices), having a family member transport the person to Butler Hospital or another hospital, or sending an ambulance so that the individual may be evaluated for inpatient psychiatric hospitalization.

A participant who has undergone a suicide or homicide risk assessment may continue to participate in the study unless the study PIs, in concert with the participant's healthcare providers, deem study participation to increase risk for this particular participant. Participants who are hospitalized due to concerns about suicidality will be discontinued from the study.

Distress due to assessment or intervention procedures. It is possible that some participants will experience increased intrapersonal or interpersonal psychological distress as a result of participating in assessment or intervention. In the vast majority of cases, we believe that any increased distress experiences will be mild and transitory in nature. We will minimize the risk of distress by informing all participants that they do not have to answer questions that they find too distressing and will be reminded that they can discontinue participation at any time. Moreover, clinical backup will be provided during all assessments and intervention sessions by a licensed clinician to help facilitate the stabilization and referral process for participants who decompensate during study procedures. The need for additional services will also be monitored during each clinical (assessment or intervention) contact. Participants will be formally assessed at 4 time points (baseline, 5 weeks, 10 weeks, 18 weeks). Incarcerated participants who manifest significant psychiatric symptomatology (i.e., psychosis or mania per the MINI Neuropsychiatric Interview) will be referred to appropriate clinical prison staff for evaluation, per RIDOC policy. As noted above, we will follow these same procedures for participants who report significant homicidal ideation or suicide risk. For assessments in the community, a licensed clinician (the MPIs or their covering clinician) will be available at all times to provide clinical coverage. Research staff will notify the licensed clinician if there are any safety concerns

Confidentiality and loss of privacy. The greatest potential risks to those participating in the research are legal or social, caused by the inadvertent loss of confidential information obtained during the data collection process. That is, a participant's identity may be inadvertently exposed or questionnaire material may be released or disclosed to unauthorized persons. In the case of such a breach, serious personal and social consequences could conceivably occur. However, such risks can be minimized by instituting the proper procedures to protect confidentiality and by having resources in place to provide counseling and referrals. We have extensive experience taking appropriate measures to safeguard confidential information in research with criminal justice populations. We will minimize potential risks due to loss of confidentiality of research data by having all information collected and handled by research staff, including study interventionists, trained to deal appropriately with sensitive clinical issues. All participants will be informed about the limits of confidentiality concerning suicidal intent, homicidal intent, suspected child abuse, suspected elder abuse, and other prison-required mandatory reporting issues (i.e., sexual contact within the prison, weapons in the prison, prison escape plans). All information will be treated as confidential material and will be available only to research staff. All information will be kept in locked file cabinets at Brown University. Computer data files will be kept on Brown's secure research servers, will be available only to authorized personnel, and no names or obvious identifying information will be stored in data files. No participant will be identified in any report of the project. Written consent will be obtained to contact other persons for the purpose of locating the participant for follow-up and participants can refuse or revoke such requests. Participants will update their contact information and contact person (in the unanticipated event of a reduced sentence and release prior to study completion) at each assessment point to ensure that this information remains appropriate. To further protect participants, there will be a **Federal Certificate of Confidentiality** for this project, which is now automatically awarded by NIH when a proposal is funded. Potential subjects will be informed that a Certificate of Confidentiality has been obtained for this project and that this certificate will protect the investigators from being forced to release any research data in which participants can be identified, even under court order or subpoena, although this protection is not absolute. Potential participants will be informed of the situations during the informed consent process (and as documented in the informed consent document) in which they may not be protected under the Certificate of Confidentiality. No information about participants will be released without their permission or where required by law.

Audio recording is necessary to rate reliability of the interview assessments and also study interventionists' fidelity to the treatment. As in our past 10 years of prison research, audio recording is accomplished through the use of credit-card size digital audio recorders, which have password-protection *and* encryption capabilities thereby protecting their contents during transport between the RIDOC and our research offices. These digital recordings are regularly transferred to Brown's secure computer server (designed to hold and protect digital audio and video recordings for clinical trials) via USB connection and secure file transfer to Brown's secure audio server, and the recorders are wiped. This is the same procedure that has been used in our completed and ongoing intervention studies with prisoners and jail detainees at the recruitment site. Participants will be asked to give informed written consent to audio recording at the time of intervention study entry. To assure the confidentiality and protection of participants with respect to audio taping, the following steps will be taken: a) each recording will be labeled with the participant's study identification number, the intervention provider's/interviewer's name, and the session/interview date; b) all recordings will be stored on a secured computer server designed to hold and protect research data; and c) access to the audio recordings will be limited to only those research staff who need access to the recordings to perform their duties.

Finally, a participant's confidential statements during a focus group or a treatment group may be repeated by another member of the group. To minimize risk, we will remind all participants that: a) group discussion should be kept confidential; and b) because we cannot guarantee confidentiality due to the group nature of the discussion, all participants should be careful about disclosing anything that they want kept private. Finally, we will ask all participants not to disclose the names of prisoners in their focus group or treatment group to others outside the group.

3 ADVERSE EVENT/ UNANTICIPATED PROBLEMS

3.1 Definitions

3.1.1 Adverse Event (AE)

An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these regardless of relationship to participation in the study.

3.1.2 Unanticipated Problems (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

3.1.3 Serious Adverse Event (SAE)

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred; includes a suicide attempt or drug overdose)

- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

3.2 Time Period and Frequency for Event Assessment and Follow-Up

Unanticipated problems will be recorded in the data collection system throughout the study.

Study staff will record all reportable events with start dates occurring any time after informed consent is obtained until 8 weeks (i.e., follow-up assessment after the last day of class participation). Each time participants attend classes, we will inquire about injuries due to study participation. At midpoint, endpoint, and at week 8 follow-up, study staff will administer the SAFTEE in order to inquire about the occurrence of AE/SAEs during the previous 8-10 weeks. SAEs related study participation will be followed for outcome information until resolution or stabilization.

3.3 Characteristics of an Adverse Event

3.3.1 Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

3.3.2 Expectedness of SAEs

The Study PI and Independent Monitoring Committee will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention. The risk information to assess expectedness can be

obtained from preclinical studies, the investigator's brochure, published medical literature, the protocol, or the informed consent document.

Expected AEs for this study include:

- Any event that may be reasonably anticipated to occur as a result of the study procedure (i.e., mild aches or pains following a yoga class)

3.3.3 Severity of Event

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

3.4 Reporting Procedures

3.4.1 Reporting for Multi-Center Trials

Not applicable.

3.4.2 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB, SMC, and NCCIH within 7 days of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB, SMC, and NCCIH within 14 days of the investigator becoming aware of the problem.

All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

3.4.3 Adverse Event Reporting of Non-IND Studies

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the Safety Monitoring Committee (SMC), IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer and SMC within 3 days of the investigator becoming aware of the event. Other serious and unexpected AEs related to the intervention will be reported within 7 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the SMC, IRB, and other oversight organizations in accordance with their requirements, and will be reported to NCCIH on an annual basis.
- All other AEs documented during the course of the trial will be reported to NCCIH on an annual basis by way of inclusion in the annual report and in the annual AE summary which will be provided to NCCIH and to the SMC. The SMC Report will state that all AEs have been reviewed.

3.4.4 Adverse Event Reporting for IND Studies

Not applicable.

3.4.5 Events of Special Interest (if applicable)

None.

3.4.6 Reporting of Pregnancy

Because prenatal yoga is considered safe and is recommended for pregnant women, and the yoga intervention that we intend to provide will not be strenuous, we have no reason to believe that it will be harmful to pregnant women. However, if a woman becomes pregnant during the course of the study, we will ask her to stop participating in the yoga intervention. With her permission, we will continue assessments with her on the usual assessment schedule.

3.5 Halting Rules

If there are any SAEs judged related to the study intervention, we will halt the study intervention until an ad hoc safety review is convened with the SMC, MPIs, site PI, and other relevant study staff. The safety review will determine whether the study should continue per protocol, proceed with enhanced monitoring, be further investigated, be discontinued, or be modified and then proceed.

Subsequent review of serious, unexpected, and related AEs by the SMC, IRB, the sponsor(s), or relevant local regulatory authorities may also result in suspension of further study interventions. The study sponsor(s) retain the authority to suspend additional enrollment and study interventions/administration of study product for the entire study, as applicable.

7 QUALITY CONTROL AND QUALITY ASSURANCE

7.1 Subject Accrual and Compliance

7.1.1 Measurement and Reporting of Subject Accrual

Review of the rate of subject accrual and compliance with inclusion/exclusion criteria will occur at least monthly during the recruitment phase to ensure that a sufficient number of participants is being enrolled, in keeping with proposed recruitment projections, and that they meet eligibility criteria as outlined in the grant proposal. We will submit accrual reports to NCCIH as required.

7.1.2 Measurement and Reporting of Participant Adherence to Treatment Protocol

Data on adherence to the treatment protocol will be collected weekly by research staff and reviewed at least monthly by the MPIs. Adherence of participants will be evaluated by rates of class attendance (adherence to intervention) and rates of follow-up assessment completion (adherence to assessments). There is very limited preliminary data on the adherence rate of this population to weekly yoga classes; one of the aims of this study is to assess that adherence rate. During the study, the MPIs and study staff will continually discuss ways to enhance adherence.

7.2 Justification of Sample Size

This project consists of two phases: Phase 1 – Focus Groups (N=24), and Phase 2– Feasibility and Pilot Testing (n=40). In phase 1, we will conduct 4 focus groups with a total of 24 participants. This should provide sufficient feedback to modify our current yoga manual specifically for anger dysregulation in prison. In Phase 2, we will conduct a pilot RCT (n = 40), in which participants will be assigned to either weekly hatha yoga or health education classes for 10 weeks (on a 1:1 basis). We will assess feasibility, acceptability, and safety of the interventions and research design, and examine key outcomes (anger dysregulation, aggression) within relevant confidence intervals. This phase of the study is not designed to be

adequately powered to assess efficacy; rather, it is focused on feasibility, acceptability, and safety.

7.3 Stopping Rules

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

7.4 Designation of a Monitoring Committee

An external local Safety Monitoring Committee (SMC) will be assembled to evaluate the data and safety to participants enrolled in the study. We will recruit 3 non-Brown-affiliated board members who have experience in clinical trials and/or yoga research and/or anger dysregulation research and/or research with criminal justice samples as well as the ethical issues involved with a randomized control study. No member of the Committee will have co-published with the MPIs within the past three years, and they will not collaborate with the MPIs on any other studies.

7.5 Safety Review Plan

MPIs will review study progress and safety at least monthly and typically on a weekly basis. Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the SMC twice per year (see description of content in section 7.4).

After review by the SMC, reports will be forwarded to the IRB and NCCIH. The IRB and other applicable recipients will review progress of this study on an annual basis.

7.6 Study Report Outline for the SMC (Interim or Annual Reports)

The study team will generate Study Reports twice per year. Reports will include:

- Interim CONSORT document (number screened, number consented, reasons not eligible, status of all participants enrolled in the study, number completed the study vs. withdrawn)
- Actual vs. expected enrollment numbers
- Gender, age, race, and ethnicity of enrolled participants; whether all participants met inclusion/ exclusion criteria
- Reasons for any study withdrawals
- List and description of deaths, unanticipated problems, and SAEs
- Summary table of AEs
- Analysis of whether AE rates are inconsistent with pre-study expectations.
- List of protocol deviations, if any
- Ongoing quality assurance and quality control procedures and findings.

- Whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study

No PHI will be included in this report.

7.7 Submission of On-Site Monitoring/Audit and Inspection Reports

The IRB, IMC, and NCCIH Program Officials will receive copies of all study monitoring/audit or inspection reports within 14 days of PI receipt. For example, the NCCIH (Westat) monitoring report will be submitted to the IRB and SMC (NCCIH does not require copies of Westat monitoring reports).

7.8 Table A

Data type	*Frequency of review*	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	*Monthly or more often*	MPIs
	Semi-annually	SMC
	Annually	IRB, NCCIH
Status of all enrolled subjects, as of date of reporting	*Monthly or more often*	MPIs
	Semi-annually	SMC
	Annually	IRB, NCCIH
Data entry quality control checks on 20% of charts	*Monthly*	QA Reviewer, MPIs
Adherence data regarding study visits and intervention	*Monthly or more often*	MPIs
	Semi-annually	SMC
	Annually	IRB, NCCIH
AEs and rates	*Monthly or more often*	MPIs
	Semi-annually	SMC
	Annually	IRB, NCCIH
SAEs (unexpected and related)	*Per occurrence*	MPIs, SMC, NCCIH
SAEs (expected or unrelated)	*Per Occurrence*	MPIs
	Semi-annually	SMC
	Annually	NIH/NCCIH
Unanticipated Problems	*Monthly*	MPIs
	Per Policy	SMC, IRB, NCCIH

8 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study subjects, including accurate case report forms (CRFs), and source documentation.

Specific instructions for each step of the data management process, from acquisition to storage, will be included in a manual of procedures (MOP).

Data will be collected using standardized paper forms or (if collected by telephone) will be directly entered into the REDCap database, and will only be identified with the study's ID of the participant. The codes that link the name of the participant and the study ID will be kept confidential in a separate database on a secure server. Collected forms will be transported to Dr. Weinstock's data entry center hosted by Brown University. Data quality will be monitored by random inspection of the completed forms by one of the research assistants and any problems detected will be discussed with the PI. Standard data checking procedures will include checking forms for missing data, double entry with discrepancy resolution, daily back-up copies of computer files, and examination of key variables for skewness, variability, missing data, and outliers. Data and materials will be collected specifically for the proposed project.

The computer systems used for data entry and analysis are protected by passwords and secure logon and data communications procedures to minimize the potential for disclosure of research information either inadvertently or as a result of external attack. Within each computer system, only those users authorized to access the data for a given study are able to do so. Research records are stored in areas that are locked when staff is not present.

8.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of MPIs. All source documents must be reviewed by the study team to ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the MPIs or designee.

8.2 Database Protection

All research data (with the exception of HIPAA-defined personal identifiers) will be entered into REDCap. REDCap is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails, and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium and was initiated at Vanderbilt University. Network transmissions (data entry, survey submission, web browsing, etc.) in REDCap are protected via Secure Sockets Layer (SSL) encryption. Access to REDCap can be restricted at different levels (e.g., research assistant, PI, and Co-Investigators). Exported data from REDCap will be stored on a secure password-protected server at Brown University.

8.3 Source Document Protection

All paper CRFs will be referenced to a participant ID number and will be kept in locked file cabinets. The participant's ID number can be connected to the participant's name only through a single master file, accessible only to senior research staff. Consent forms and other documentation with personal identifiers will be kept in a separate file from other data. We will use encrypted, password-protected audio recorders and a locked transport box for transportation of paper files from RIDOC to Brown University offices at Butler Hospital.

See also 8.2. Database protection.

8.4 Schedule and Content of Reports

Report Type	Frequency of Review	Reviewer
Recruitment, enrollment, adherence and retention	Monthly or more often	MPIs, research staff
SMC Report	Twice per year (with additional per-event reports as detailed above)	SMC
IRB Annual review	Once per year (with additional per-event reports as detailed above	IRB

There is no interim data analysis plan.

Data analysis of Phase 1 qualitative data will occur during and immediately after data collection in Phase 1.

Data analysis of Phase 2 data will occur after 10, 20, and 40 participants have completed Phase 2. There are no masked data.

9 INFORMED CONSENT

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Informed consent procedures have been developed to comply with the Code of Federal Regulations 45 CFR 46.116, *General Requirements for Informed Consent* and 46.117, *Documentation of Informed Consent,* and contain all required elements. Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their families, if applicable. Freedom to refuse to participate or to discontinue participation at any time without penalty will be emphasized. A consent form describing in detail the study procedures and risks will be given to the subject. Consent forms will be IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will

sign the informed consent document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them: (1) that a decision not to participate in the research will have no impact on their status or expected length of stay at the prison; (2) that the quality of their clinical care in the prison will not be adversely affected if they decline to participate in this study; (3) the study has a NIH Certificate of Confidentiality; (4) the confidentiality of study information from jail staff, officers of the court, parole officers or others in the criminal justice system; and (5) and limits of confidentiality, including the jail's mandatory reporting procedures for suicide ideation (see Section 4.2).

We have utilized these procedures for informed consent in our current and completed research at the RIDOC for over 12 years. As a function of the strong history of research partnership between the RIDOC and our research group, in addition to RIDOC partnerships with other local investigators and institutions conducting human subjects research, RIDOC staff are familiar with and have fully cooperated with the procedures and policies to minimize coercion and protect participant confidentiality, as described above.

The consent process will be documented in the research record.

10 REPORTING CHANGES IN STUDY STATUS

During the funding of this study, any action by an IRB, the SMC, or one of the study investigators that results in a temporary or permanent suspension of the study will be reported to the NCCIH Program Official within 3 business days of notification.