

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

NCT06657950

Study Protocol and Statistical Analysis Plan

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Clinical Intervention Study Protocol

TREATMENTS FOR IMPROVING MOOD IN WOMEN: OPEN PILOT TRIAL, PHASE 1.2

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Butler Hospital IRB

STUDY OBJECTIVES

Study Title

Open Pilot Trial of the Integrative Yoga and Mindful Self-Compassion Program for Women Survivors of Violence

Specific Aim

The specific aim of this open pilot trial is to refine a complementary medicine intervention (Integrative Yoga and Mindful Self-Compassion program) and assess its feasibility, acceptability, and safety in women with a history of interpersonal violence victimization.

BACKGROUND AND STUDY RATIONALE

A staggering 30-50% of U.S. women have experienced interpersonal violence (physical or sexual violence) within their lifetime, including Non-Hispanic Black/African American (AA; 44%), Hispanic (34%), and Non-Hispanic White women (37%).¹ Violence drives “downstream” poor behavioral^{2–6} and physical health^{7–11}, with lifetime medical costs for IV-related care reaching \$2.1 trillion in 2014 – \$103,167 per female victim¹². Psychological distress is elevated among survivors due to prevalent stigma^{13–15}, chronic stress^{16–18}, and psychiatric disorders^{2–6,19} – driving poor health long after abuse has ended. Further, stigma and associated sequelae (e.g., shame, internalized stigma, emotion regulation)^{20–22} can magnify distress^{23–26} and adverse health effects^{27–29}. These sequelae of interpersonal violence may be alleviated through targeted intervention^{30–34}. Yet transdiagnostic approaches to reduce survivor distress *and* stigma sequelae can be rare, including those designed as responsive across racial and ethnic groups that together account for a significant portion of violence victimization prevalence in the U.S. Recent calls have thus been issued to develop responsive, trauma-informed approaches to help address the public health burden of violence and its sequelae across women, including those with intersecting characteristics of vulnerability^{15,35}.

The present study is an open pilot trial of a complementary medicine intervention integrating Trauma-Informed Yoga (TIY) with adapted Mindful Self-Compassion (MSC) training, developed using community-engaged research. The goal of the Integrated TIY and MSC (I-YMSC) intervention is to improve stigma sequelae and reduce distress in victims of violence. Self-compassion is recommended for trauma survivors by mindfulness and trauma experts^{36–38} as it targets stigma-related problems (affect dysregulation, shame)^{39–45} and may improve distress in the long-term^{46–48}. Yet, MSC can also temporarily increase short-term distress (“backdraft”)^{49,50}. TIY reduces short-term distress^{51–53} and promotes physiological-autonomic regulation^{54–60}. We hypothesize TIY will offset and integrate temporary distress in MSC, allowing persistence for optimal therapeutic effects. The PI’s program evaluation data suggests adapting MSC to address stigma sequelae and integrating this approach with TIY is warranted and has potential to ameliorate distress experienced by victims of interpersonal violence. Following on formative intervention development work with survivors, the specific aim of this open pilot trial is to refine the adapted I-YMSC intervention and assess its feasibility, acceptability, and safety.

METHOD

Brief Description of Participants

Women with a history of interpersonal violence (N=15, ≥ 18 and ≤ 65 years old) in Rhode Island and Massachusetts will be enrolled. Efforts will be made to recruit and counterbalance participants across three racial and ethnic groups (Black/African American, Hispanic, and Non-Hispanic White) as these groups together account for a significant portion of experienced interpersonal violence in the U.S. population.

Study Design

This is an open, single-armed pilot trial to study the feasibility, acceptability, and safety of a 12-week Integrated Yoga and Mindful Self-Compassion (I-YMSC) intervention in women survivors of interpersonal violence. We will also gather additional feedback from women to guide further refinement of the manual. Participants will attend I-YMSC study sessions twice per week for the 3-month intervention duration. Participants will also be invited to engage in personal practice of yoga or I-YMSC exercises up to four days per week.

Specific Procedures or Treatments

The planned I-YMSC intervention will change based on engagement with community survivor stakeholder partners as well as focus groups and qualitative interviews. The multicomponent *I-YMSC* intervention is proposed to run 12 weeks, twice per week. Across the 12 weeks, Component 1 (main *I-YMSC* sessions) will run once-weekly for 2-2.5 hours, integrating MSC training (experiential and relational exercises; meditations) with TIY (breathing exercises, meditation, mindful movement, and relaxation). Component 2 (weekly trauma-informed yoga [TIY] classes) will run once-weekly for 1-1.25 hours to regulate affect and reduce distress between study sessions. Component 3 (personal practice) will be offered up to four days per week for formal practices (approximately 10-25 minutes; TIY, meditation), and as-needed for informal in-the-moment practices (e.g., deep breathing, “self-compassion break” to cope with acute distress). Classes will take place in-person in the Providence, RI region at Butler Hospital or at our approved community partner sites. Potential risks include loss of privacy or breach of confidentiality, increased distress due to procedures, ineffective intervention (i.e., lack of improvement in distress), and mild physical injury.

Facilitator for Main Study I-YMSC Sessions. The PI or a qualified therapist with at minimum an MA degree or credential in teaching Mindful Self-Compassion and experience delivering related trauma-informed interventions will deliver I-YMSC main study sessions.

Yoga Instructors for TIY Classes. The Yoga Alliance is a professional organization which sets standards for yoga teacher training. One can be a Qualified Yoga Teacher at the 200- or 500-hour level. We will require that all study yoga teachers be trained at the 200-hour level and will have previous experience working with women. Teachers will also have study-specific training on research methods, working with interpersonal violence survivors, and the yoga manual. They will meet approximately monthly for supervision. There will be at least two trained yoga teachers.

Inclusion/Exclusion Criteria

Inclusion Criteria:

- a. Female
- b. Ages 18-65
- c. Report having experienced interpersonal violence (defined to include all forms throughout the lifespan, confirmed with the Trauma History Questionnaire (THQ))
- d. Report being distressed, defined by a score of ≥ 5 on the Kessler-6 screener
- e. Speak and understand English well enough to understand questionnaires when they are read aloud
- f. Have access to a telephone through owning one, a relative/friend, or an agency
- g. Have access to a device that will support use of the video platform we are using to conduct assessments and for home practice yoga video sessions

Exclusion Criteria:

- a) Inability to be physically active, determined by a score ≥ 1 on the Physical Activity Readiness Questionnaire (PAR-Q) and physician non-consent of participation
- b) Planned surgery in next 6 months, as this would interfere with study participation
- c) Pregnancy, as yoga should be modified for pregnancy
- d) Current mania or lifetime history of psychotic disorder as determined by the Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND)
- e) Current probable severe substance use disorder, as determined by the DIAMOND
- f) Current diagnosis of anorexia nervosa or history in past year, assessed via the DIAMOND
- g) Participants will be excluded if they are determined to be at moderate or high risk for suicide on the adapted Columbia Suicide Severity Rating Scale screen version-recent (C-SSRS) and/or they endorse suicidal plan/intent in the past 3 months. This means they will be excluded if: a) they say yes to item 3, 4, 5 (suicidal plan/intent, adapted to assess past 3 months instead of 1 month); b) they say yes to item 6 (suicidal attempt; past 3 months). Any participants who respond yes to items 2, 3, 4, 5 (past 3 months) or item 6 (past 3 months), or who report thoughts about suicide to a research staff member during or outside of the context of the baseline assessment - will have an immediate clinical risk assessment with a licensed mental health professional.
- h) Non-stable course of psychiatric treatments (medication, psychotherapy) for the last 8 weeks
- i) Plan to move from the area in the next 6 months, as this may preclude study participation given enrollment timeframes
- j) Self-report of experiencing intimate partner violence currently or within past six months (assessed by the adapted Revised Conflict Tactics Scale 2 [R-CTS2]), as this would require a different type of intervention
- k) Current weekly yoga practice or current participation in mindfulness-based programming, as these are the study interventions

Study Enrollment Procedures

Recruitment and Screening. Participants will be recruited through a broad outreach strategy. This includes flyers and referrals from (1) medical settings including Butler and community health centers, emergency departments, OBGYN offices, and federally qualified health centers; (2) flyers and referrals from relevant hotlines, support groups, family nurse partnerships; (3) flyers in churches, daycare centers, other places where women congregate (WIC offices, Medicaid offices, etc.), and (5) Craigslist/Facebook and other online/community venues/listservs, etc., including a Butler Hospital study website. In addition, staff will offer free workshops in settings with community partners that serve women, where information about the study will also be shared. Participants may also be recruited from Butler Hospital's inpatient, partial hospital, or outpatient services, including through medical record review.

Informed Consent Procedures. Potential participants will undergo phone screening to detail the study and assess preliminary eligibility for those interested. Following an eligible phone screen, written informed consent will be obtained from each participant with trained research staff. There will be two informed consent forms (ICF): one screening ICF administered prior to the baseline eligibility interview/questionnaires, and one primary ICF for those who screen eligible. During the informed consent process, research staff will carefully explain all aspects of the screening procedure and study, the potential risks and benefits, and the expected duration and time commitment of their participation. The participant will be given the opportunity to read through the consent form and ask questions. After screening informed consent is obtained, participants will be evaluated using the baseline assessment and diagnostic measures to confirm eligibility. Once eligibility is confirmed, the consent process will be repeated for the primary ICF.

At the end of all consent forms, research staff will sign and date to indicate that they conducted each consent process. Consent forms will be stored on secure servers or in a secure location at Butler Hospital in a locked filing cabinet (for hard copy consent forms). With their permission, participants will be sent (via mail or email) or given a copy of the consent form for their records, and this fact will be documented in their record.

Enrollment. Women who complete the main study ICF and proceed to score ≤ 1 on the Physical Activity Readiness Questionnaire are considered enrolled. Women who score ≥ 1 on the PAR-Q will be provided a form for their physician to document medical clearance for mild-moderate physical activity. They are not considered "enrolled," and cannot begin classes, until physician medical clearance is secured and they re-verify their interest at that time. Enrollment may occur at the Baseline 1 visit or at a separate Baseline 2 phone call (if there is a need to request and wait for medical clearance). Participants are invited to initiate the intervention within 40 days of enrollment. Additionally, if the participant has a mental health provider, we will ask for a release of information at the Baseline 1 visit to contact their provider in the event of significant clinical deterioration or the development of active suicidal ideation or behavior.

Documentation of Reasons for Ineligibility. All participants who express interest in the study (i.e., make contact with us regarding the study) will be tracked in a separate database along with the status of their participation. Any participant who is screened for any aspect of the

study (even if only one inclusion criterion is assessed before the participant is determined not eligible) will have a study record documenting which inclusion criteria were assessed and the outcome of that assessment (i.e., as part of a study log).

Study Evaluations

To maximize flexibility for the participant, informed consent and confirmation of remaining inclusion/exclusion may occur at the end of the initial screening or at the Baseline 1 visit. Following completion of the main study ICF, participants will complete remaining Baseline 1 assessments and a self-report survey. Assessments and a self-report survey will also be administered at 1.5- (mid-intervention) and 3-month (post-intervention) visits. A qualitative interview to aid intervention refinement will also be administered at the 3-month visit. See Table 1 for the Schedule of Evaluations.

Payment. Payment to participants for completion of the 6- and 12-week assessments is \$25 via a gift certificate to a local mall or supermarket. There is no compensation for the baseline assessment.

Table 1, Schedule of Evaluations and Participant Payments.

Assessment	Screening Evaluation	Baseline, Visit 1	Weekly M1, M2, M3	M1.5 Visit	M3 Visit
Inclusion/Exclusion	X	X			
Kessler-6 (K6) screener ⁶¹	X	X			
Informed Consent Forms	X	X			
Enrollment	X	X			
Columbia-Suicide Severity Rating Scale (C-SSRS) Screener version ^{62,63}	X	X		X	X
Revised Conflict Tactics Scale 2 (R-CTS2), rev. short form ⁶⁴	X	X		X*	X*
Trauma History Questionnaire (THQ) ⁶⁵	X	X		X*	X*
Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND) ⁶⁶	X	X			
Pregnancy	X	X		X	X
Physical Activity Readiness Questionnaire (PAR-Q) ⁶⁷		X			

Assessment	Screening Evaluation	Baseline, Visit 1	Weekly M1, M2, M3	M1.5 Visit	M3 Visit
Quick Inventory of Depression Symptoms (QIDS) ⁶⁸		X		X	X
Other Adverse Events		X	X	X	X
Demographics		X			
PTSD Checklist (PCL) ^{79,80}		X			
Depression, Anxiety, and Stress Scale-21 (DASS-21) ⁶⁸ †		X		X	X
Interpersonal Violence Stigma Scales (IVSS) ^{69–71} †		X		X	X
Self-Compassion Scale—Brief (SCS-B) ^{72,73} †		X		X	X
Difficulties in Affect Regulation Scale (DERS)-Short Form ^{74,75} †		X		X	X
Internalized Shame Scale (ISS) ⁷⁶ †		X		X	X
Injuries due to yoga			X	X	X
Validated acceptability, appropriateness, and feasibility intervention measure (AIM, IAM, FIM) ^{76,77}				X	X
Client Satisfaction Questionnaire (CSQ-8) ⁷⁸				X	X
COMBINE Systematic Assessment of Treatment-Emergent Events (SAFTEE) ^{79,80}				X	X
Qualitative interview					X
Payment (gift card)				\$25	\$25

Abbreviations: time points: M1, M2, M3 = months 1, 2, and 3, respectively.

*For adverse event assessment, only THQ items assessing interpersonal violence-related incidents are administered at 1.5M and 3M.

† These exploratory, secondary measures are administered in the open pilot trial to assess feasibility of the assessment battery.

SAFETY ASSESSMENTS

Potential Risks and Measures to Reduce Risks

Potential risks of study participation include:

1. Breach of confidentiality and loss of privacy
2. Increased distress due to intervention or assessment procedures, as well as ineffective intervention
3. Perception of coercion to participate in the study
4. Risk of further abuse, including if the partners of women who have experienced IPV find out about their participation in the research
5. Physical injury (mild) related to yoga. This includes mild aches or pain during or shortly after yoga classes

There are no alternative treatments and procedures provided in this study (e.g., to reduce distress in this population), though participants will be informed that alternative treatments to reduce distress are available by talking with their doctor.

Risks and measures to reduce those risks are detailed below.

Confidentiality and loss of privacy. Study personnel will be collecting considerable information about the study participants. This may create some distress and could cause social and psychological risk if released inappropriately. This risk is a serious one but we believe that it is highly unlikely. All information will be collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All information will be treated as confidential material and will be available only to research and clinical staff. All data collected will be entered into an electronic database which is stored on a secure server (REDCap) that is backed up on a daily basis. Patient identifying information may be stored in a separate database and will be password protected and stored on a secure server.

REDCap is a secure, web-based application developed by Vanderbilt University for building and managing surveys and databases. It is primarily designed to support online or offline data capture for research studies, quality improvement, and operations. Care New England's instance of REDCap is hosted within the Care New England data center in Warwick, RI. This REDCap instance is role-based and is fully integrated with CNE's Active Directory structure. It enjoys 24/7/365 enterprise-level support and security inherent to CNE's HIPAA-compliant data center. Network transmissions (data entry, survey submission, and web browsing) to and from REDCap are protected via TLS 1.2 encryption. REDCap's data is stored on encrypted servers within CNE's data center.

All paper files will be kept in a locked filing cabinet in a secured location at Butler Hospital. Audio recordings will be stored on a secure server or kept in a locked filing cabinet. No participant will be identified in any report of the project.

Due to the nature of text messaging technology, there is a small, but potential, privacy risk when communicating through text messages. Text message communications are not encrypted and therefore this information can be read if intercepted while in transit. Although we have a strict patient confidentiality policy there is a possibility for the text messaging communications to be intercepted or accessed without the participant's authorization. This will

be made clear in the informed consent process, and we will remind participants not to send sensitive information by text. We will only be conveying general information by text messaging. No confidential or sensitive information will be sent by text message at any time. Text messages will contain information about scheduling only. Text messages will be sent from a dedicated password-protected study cell phone. The loss of privacy is a serious risk but we believe that it is highly unlikely as we have extensive experience taking measures appropriate to safeguarding confidential information. Participants may be included in the study even if they decline to have text messages sent to them.

We will ask participants to sign a release of information so that we may communicate with their primary care provider and their specialty mental health providers (if any) about a) medical clearance for mild/ moderate physical activity; b) any serious mental health concerns that may arise. Although this could present a risk to confidentiality, we believe this is outweighed by concerns about the patient's safety.

Finally, being part of a group intervention carries with it a risk of loss of privacy. We will remind participants of this risk in the informed consent process, and also ask them to keep information learned about other group members, including the fact they were in the group, private.

Increased distress due to assessment or intervention procedures, as well as ineffective intervention. It is possible that some participants will experience increased distress as a result of participating in assessments or intervention. In the vast majority of cases, we believe that any increased distress experienced will be mild and transitory in nature. The risks of possible distress due to the assessment and treatment procedures will be minimized by: a) using assessments and procedures which have been widely used in previous research studies; b) allowing participants to refuse to answer any question or withdraw from the study at any time; c) training yoga instructors in how to minimize and manage distress that may occur in class; and d) having the PI and mentors (all licensed clinical psychologists with expertise in distress, suicidality, and/or interpersonal violence) or their designee (a licensed health professional) in their absence, on call to counsel participants should they report experiencing distress.

Risk of suicidal ideation or behavior. Given that all participants will have risk factors for suicidality (i.e., a history of interpersonal violence and elevated distress), some participants may experience suicide ideation or behavior in the course of study participation. Participants will be formally asked about suicide ideation or behavior at every assessment (i.e., baseline, 6, and 12 weeks); they may also report it during any contact with staff at any time.

Exclusion criteria. Participants will be excluded at the baseline assessment if they are determined to be at moderate or high risk for suicide on the adapted Columbia Suicide Severity Rating Scale screen version-recent (C-SSRS) and/or they endorse suicidal plan/intent in the past 3 months. (See exclusion criteria section for more detail). Any participants that appear at risk for suicide based on the detailed C-SSRS criteria, or who report thoughts about suicide to a research staff member during or outside of the context of the baseline assessment, will have an immediate clinical risk assessment with a licensed mental health professional. The elements of

the clinical risk assessment for suicidality include: Risk factors, protective factors, suicide inquiry, risk determination, clinical disposition, study disposition, documentation.

Monitoring for suicidality. The team will monitor for suicide risk at 6- and 12-weeks with the C-SSRS screener version (see exclusion criteria section), adapted to assess the 6-week timeframe since last assessment. Where warranted, this will be followed by a risk assessment with a licensed mental health clinician, an independent evaluator who is not part of the research study staff. When a clinician is asked to conduct an immediate evaluation, they will conduct a suicide risk assessment, involving a clinical interview that follows up on endorsed items of the C-SSRS and assesses risk and protective factors to guide next steps. The clinician will determine whether it is necessary to take immediate action to prevent the participant from causing harm to him/herself. If needed, the study clinician may ask to speak to a secondary contact or have someone or ambulance bring the person to Butler Hospital or another hospital.

If the participant is not in immediate danger of hurting themselves, we will take the following actions. First, we will work to develop a safety plan with the patient and encourage them to discuss this with a secondary contact and/or treatment providers. We will contact their primary care physician or other clinician to inform them of the suicidality. We will urge the patient to make an appointment with that provider to discuss treatment options. Regardless of outcome, suicide assessments are always documented in writing.

Clinical deterioration. Participants may also report significant clinical deterioration, as defined by an increase in QIDS score of 6 or greater from the previous QIDS assessment and a score of 16 or greater. The team will monitor for clinical deterioration at 6- and 12-weeks with the QIDS. This will also trigger a clinical evaluation with a licensed mental health clinician, an independent evaluator who is not part of the research study staff, within 24-48 hours. The clinical evaluation will involve gathering additional information about the participant's symptoms, contributing factors, and disposition, resulting in a determination of the best course of action for the participant based on clinical judgment. Typically, this will include notification of an outpatient mental health provider (if the participant has one) or offer of referrals to an outpatient provider. Actions could also include facilitation of higher levels of care (e.g., inpatient hospitalization).

The clinical evaluator will remind the participant that the study intervention is experimental, and therefore we do not know whether it will help the participant manage the symptoms. Therefore, they will strongly urge the participant to make an appointment with their community mental health clinician (if they have one), or to follow up with referrals for community treatment. Further, they will provide information about the Butler Hospital Outpatient Evaluation Center. This center that was designed to bridge people while they are waiting to be enrolled in mental health services in the community. If the participant does not have other treatment, they will be strongly urged to follow up with this center.

Determination of study continuation in the event of clinical deterioration or suicidality: A patient who has undergone a suicide risk assessment or who has had clinical deterioration may continue to participate in the study unless the study PI, patient, or the patient's community healthcare providers deem study participation to increase risk for this particular patient.

Per NCCIH guidance, participants will be removed from the study if any of the following conditions are met:

- a. Participants who are hospitalized due to concerns about clinical deterioration or suicidality
- b. If clinical deterioration is present and the participant meets the criteria for acute suicidal risk (exclusion criteria)
- c. If independent evaluator and/or the patient's community healthcare providers determine withdrawal to be the best option for the participant alongside their follow up care

Potential coercion. It is possible that individuals may feel coerced into participating. This risk is a serious one but we believe that it is highly unlikely given informed consent processes and the ease with which one may withdraw from the study. We will follow standard procedures for obtaining informed consent. Study staff will fully explain the study procedures, risks, benefits, and alternatives to all potential participants. Participants will be aware that they may refuse to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.

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 participants that endorse ≥ 1 items on the PAR-Q to have medical clearance for moderate physical activity; and b) requiring all instructors to be qualified, experienced 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, straps, 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.

Risk of further abuse. The risk of further interpersonal violence is low to moderate. Women with a history of interpersonal violence are more likely to be currently experiencing abuse than are women without a history of interpersonal violence. We will minimize the risk of study-related partner violence by enrolling women who have not experienced intimate partner violence in the past six months. All research personnel (i.e., research assistant) will be able to call the study team for advice on cases where there is a concern for the safety of the respondent. If child abuse is reported, then the interventionist, supervisor, or research staff person involved will provide notification of mandatory reporting guidelines and act accordingly. As an additional participant safety measure and for referral to appropriate care, the Trauma History Questionnaire (interpersonal violence items) and Revised Conflict Tactics Scale-2 will be assessed at 1.5 and 3-month follow-ups. Women who report experiences of interpersonal violence (since last study contact) will be referred for appropriate additional care but will remain in the research protocol.

Potential Benefits

The potential benefits of study participation are great, and include increased social support, reduction in distress, and enjoyment of yoga classes or better physical health (for those taking I-YMSC), although these benefits are not guaranteed. Moreover, participants are helping other women with interpersonal violence history through providing information that will improve distress reduction interventions for this population of women.

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. The potential risks associated with participation in this study appear to be mild to moderate. 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 for distress in this patient population.

Indeed, the procedures proposed for monitoring distress should ensure that participants who require a higher level of care receive it. Our assessment contacts present potential opportunities to identify and respond to at-risk thinking or behavior patterns which might remain undetected if women were not in this study. The potential benefits of study participation are great, and include increased social support, reduction in distress, and enjoyment of yoga classes or better physical health, although these benefits are not guaranteed. Moreover, participants are helping other women with interpersonal violence history through providing information that will improve distress reduction interventions for this population of women. Thus, the potential benefits seem to outweigh the potential risks of the study and the risk/benefits ratio seems favorable.

Specification of Safety Parameters

Please see Table 2 for a summary of safety issues, how they are assessed, when they are assessed, and relevant staff actions.

Table 2. Assessment and Management of Safety Issues, including methods and timing for assessing, recording, and analyzing safety parameters

Safety Issue	How assessed	When Assessed in Phase 1.2	Relevant Research Staff Actions
Suicide risk	QIDS and C-SSRS screener Participant report to research staff	B1, M1.5 (mid-point), M3 (endpoint)	Immediate clinical assessment as described in <i>Potential Risks and Measures to Reduce Risks</i>
Clinical Deterioration	QIDS Participant report to research staff	B1, M1.5 (mid-point), M3 (endpoint)	Immediate clinical assessment as described in <i>Potential Risks and Measures to Reduce Risks</i>

Injuries due to yoga	Structured self-report	Weekly during 3-month intervention	Follow until resolution; may result in changes to yoga instructor manual
Pregnancy	Single interview question	BL1 (exclusion) M1.5 (mid-point), M3 (endpoint)	Discontinuation from yoga participation
Other AEs	SAFTEE Participant report to research staff	M1.5 (mid-point), M3 (endpoint) Any point	If related to study participation, follow resolution; potential changes to procedures particularly if AE is also unexpected

Adverse Events and Serious Adverse Events

Adverse Event (AE) definition: An adverse event (AE) is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recording regardless of their relationship to the study intervention.

Serious Adverse Event (SAE) definition: 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.

Study staff will record all reportable events with start dates occurring any time after informed consent is obtained at least until the final day of study participation. Each time participants attend yoga classes, we will inquire about injuries due to yoga. At Months 1.5 (mid-treatment) and 3 (end of intervention), study staff will administer the SAFTEE in order to inquire about the occurrence of AE/SAEs during the previous 3 months. 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 contact 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.

With this information, the PI and Co-Mentor Dr. Lisa Uebelacker will code severity, causal relationship, and whether the event was expected. If necessary, they will seek further information from the participant or other source before coding. AEs will be coded on a weekly basis. Any potential SAE will be immediately reviewed by the PI and primary mentors (or a qualified designee in their absence) and coded.

Adverse Event Reporting Procedures

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the DSMB, IRB, and NCCIH in accordance with requirements. We will use the Butler Hospital IRB-approved AE report form.

- Unexpected fatal or life-threatening SAEs related to the intervention will be reported to the IRB and NCCIH Program Officer within 3 days of the investigator becoming aware of the event. Other serious and unexpected SAEs related to the intervention will be reported within 7 days. These timeframes follow guidance from NCCIH and are consistent to local IRB policies.

Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the IRB and other oversight organizations in accordance with their requirements, and will be reported to NCCIH on an annual basis.

- Unrelated SAEs that are fatal or life threatening must be reported to the Butler Hospital IRB within 7 days of the investigator becoming aware of the event.
- Unrelated SAEs that are not fatal or life-threatening must be reported to the Butler Hospital IRB annually.

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.

Follow-up for Adverse Events

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

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.

INTERVENTION DISCONTINUATION

In addition to the discontinuation reasons detailed above in the event of clinical deterioration or suicidality (see Section 7), participants will be discontinued from an intervention in the following circumstances:

- If the participant, their primary care provider, or their mental health provider does not believe it is in the best interest of the participant to continue. As soon as the PI is informed of this, she will speak with the participant about discontinuation. There may be circumstances (e.g., worsening distress, an injury in yoga class) when the PI reaches out to a primary care provider or MH provider to actively inquire if they have concerns about the participant continuing to participate.
- If a participant chooses to discontinue attendance.
- If the PI, in consultation with the relevant instructor, finds the participant to be so disruptive to the rest of the class that they have a repeated and substantive negative impact on the other participants.

Participants will continue with subsequent assessments with their permission. Assessment schedule and assessments used will not change.

STATISTICAL CONSIDERATIONS

Our primary overall objective for this open pilot trial, as part of a K23 Career Development Award, is to develop procedures and manuals and acquire data on feasibility and acceptability that will prepare for a pilot randomized controlled trial in the study population. Because this is the initial phase of a treatment development study, we have chosen our sample size (N=15) as being sufficient to assess feasibility and acceptability.

Table 3. Summary of objectives, endpoints, and data analytic strategy

Objective	Endpoint	Analyses
<i>Open Pilot Trial</i>		
Pilot the yoga intervention	15 participants enrolled & follow up assessments completed	N/A
Assess feasibility, acceptability, and safety of the I-YMSC intervention	See Table 4 for a complete list.	Descriptive statistics for all endpoints. See Table 4.
Revise manual and develop training materials and fidelity assessment scale	Revise instructor manual, instructor training materials, and fidelity assessment scale created	N/A

Data Analyses

Data analysis will occur at the end of the intervention. There is no single primary outcome, as this is a treatment development study. Primary data analyses will be focused on feasibility and acceptability (see Table 4) using an intent-to-treat population. Study measures and endpoints will continue to be collected for all enrolled participants, even in the event of premature discontinuation of the study intervention. To mitigate the problem of missing data, our research assistants will try to reach participants to encourage them to schedule/complete the assessment via multiple methods that a participant have said are acceptable. Descriptive statistics (mean, standard deviation) will be used to summarize quantitative variables. Qualitative data will be analyzed using a thematic analysis framework.⁸¹

Table 4. Primary Outcomes

Description (Assessment method)	Target
Feasibility, Acceptability, and Safety of Study Intervention and Procedure	
Participant Retention Rate (Feasibility of Procedure)	At least 80% complete post-intervention endpoint (M3) assessment
Feasibility of Intervention Measure, Intervention Appropriateness Measure, and Acceptability of Intervention Measure (M3)	With a mean score range of 1-5, higher scores indicate greater feasibility, intervention appropriateness, and intervention acceptability
Customer Satisfaction Questionnaire (Intervention Acceptability; M3)	Average > 24 (or a mean score of 3 on each of the 4 items)
Acceptability (qualitative interview)	Most feedback positive; few substantive negative comments. Negative comments used to enhance procedures
Adverse events (SAFTEE; injuries due to yoga)	No serious adverse events or injuries that are possibly, probably, or definitely related to study participation. Any AEs related to study participation might lead to changes in yoga manual or other relevant study procedures, particularly if AE is unexpected

DATA COLLECTION AND QUALITY ASSURANCE

Data Collection Forms

Most data will be collected and entered directly into REDCap. Data collected on paper CRF will be double-entered into REDCap. There will also be a database that we will use for tracking participants.

Any data, forms, reports, audiorecordings, and other records that leave the site will be identified only by a participant identification number (Study ID) to maintain confidentiality. All paper records will be kept in a locked file cabinet in a secured location at Butler Hospital. All data collected will be entered into an electronic database which is stored on a secure server (REDCap) that is backed up on a daily basis. Participant identifying information may be stored in a separate database and will be password protected and stored on a secure server. Care New England's instance of REDCap has been deemed HIPAA compliant by CNE Information Technology.

Data Management

All self-report data will be collected via REDCap, by telephone, via Zoom video, hard copy, and/or via REDCap survey (For self-report questionnaires).

Interviews (e.g., C-SSRS) have standardized forms that may be directly entered by the interviewer into REDCap or be double-entered into REDCap if collected via hard copy. Any discrepancies will be resolved by the Project Manager in consultation with the PI as needed.

Quality Assurance

All research personnel, including yoga instructors will have formal training in research with human subjects (e.g., CITI training, NIH Human Subjects training). The PI will provide training to and supervise research assistants. Research assistants will also have training in Good Clinical Practice.

REFERENCES

1. Houry DE, Smith SG, Chen J, et al. The National Intimate Partner and Sexual Violence Survey (NISVS) | 2010-2012 State Report The National Intimate Partner and Sexual Violence Survey (NISVS): 2010-2012 State Report. *National Center for Injury Prevention and Control*. Published online 2017:1-272.
2. Bacchus LJ, Ranganathan M, Watts C, Devries K. Recent intimate partner violence against women and health: A systematic review and meta-analysis of cohort studies. *BMJ Open*. 2018;8(7):1-20. doi:10.1136/bmjopen-2017-019995
3. Zlotnick C, Johnson J, Kohn R, Vicente B, Rioseco P, Saldivia S. Childhood trauma, trauma in adulthood, and psychiatric diagnoses. *Comprehensive Psychiatry*. 2009;49(2):163-169. doi:10.1016/j.comppsy.2007.08.007.Childhood
4. Scott KM, Smith DR, Ellis PM. Prospectively ascertained child maltreatment and its association with DSM-IV mental disorders in young adults. *Archives of General Psychiatry*. 2010;67(7):712-719. doi:10.1001/archgenpsychiatry.2010.71
5. Cerdá M, Digangi J, Galea S, Koenen K. Epidemiologic research on interpersonal violence and common psychiatric disorders: Where do we go from here? *Depression and Anxiety*. 2012;29(5):359-385. doi:10.1002/da.21947
6. Howard LM, Trevillion K, Agnew-Davies R. Domestic violence and mental health. *International Review of Psychiatry*. 2010;22(5):525-534. doi:10.3109/09540261.2010.512283
7. Campbell JC, Lewandowski LA. Mental and physical health effects of intimate partner violence on women and children. *Psychiatric Clinics of North America*. 1997;20(2):353-374. doi:10.1016/S0193-953X(05)70317-8
8. Hathaway JE, Mucci LA, Silverman JG, Brooks DR, Mathews R, Pavlos CA. Health status and health care use of Massachusetts women reporting partner abuse. *American Journal of Preventive Medicine*. 2000;19(4):302-307. doi:10.1016/s0749-3797(00)00236-1
9. Lown EA, Vega WA. Intimate partner violence and health: Self-assessed health, chronic health, and somatic symptoms among Mexican American women. *Psychosomatic Medicine*. 2001;63(3):352-360. doi:10.1097/00006842-200105000-00004
10. Dutton MA, Green BL, Kaltman SI, Roesch DM, Zeffiro TA, Krause ED. Intimate partner violence, PTSD, and adverse health outcomes: the immense health and mental health burden of IPV exposure. *Journal of Interpersonal Violence*. 2006;21(7):955-968. doi:10.1177/0886260506289178

11. El-Serag R, Thurston RC. Matters of the Heart and Mind: Interpersonal Violence and Cardiovascular Disease in Women. *Journal of the American Heart Association*. 2020;9(4):1-4. doi:10.1161/JAHA.120.015479
12. Peterson C, Kearns MC, McIntosh WLKW, et al. Lifetime economic burden of intimate partner violence among U.S. adults. *American Journal of Preventive Medicine*. 2018;55(4):433-444. doi:10.1016/j.amepre.2018.04.049
13. Overstreet NM, Quinn DM. The Intimate Partner Violence Stigmatization Model and Barriers to Help Seeking. *Basic and Applied Social Psychology*. 2013;35(1):109-122. doi:10.1080/01973533.2012.746599
14. Deitz MF, Williams SL, Rife SC, Cantrell P. Examining cultural, social, and self-related aspects of stigma in relation to sexual assault and trauma symptoms. *Violence Against Women*. 2015;21(5):598-615. doi:10.1177/1077801215573330
15. Kennedy AC, Prock KA. "I still feel like I am not normal": A review of the role of stigma and stigmatization among female sexual assault survivors of child sexual abuse, sexual assault, and intimate partner violence. *Trauma, Violence, and Abuse*. 2018;19(5):512-527. doi:10.1177/1524838016673601
16. Dale LP, Shaikh SK, Fasciano LC, Watorek VD, Heilman KJ, Porges SW. College females with maltreatment histories have atypical autonomic regulation and poor psychological wellbeing. *Psychological Trauma: Theory, Research, Practice, and Policy*. 2018;10(4):427-434. doi:10.1037/tra0000342
17. Cerulli C, Poleshuck E, Raimondi C, Veale S, Chin N. "What fresh hell is this?" Victims of intimate partner violence describe their experiences of abuse, pain, and depression. *Journal of Family Violence*. 2012;27(8):773-781. doi:10.1007/s10896-012-9469-6
18. Cordero MI, Moser DA, Manini A, et al. Effects of interpersonal violence-related post-traumatic stress disorder (PTSD) on mother and child diurnal cortisol rhythm and cortisol reactivity to a laboratory stressor involving separation. *Hormones and Behavior*. 2017;90:15-24. doi:10.1016/j.yhbeh.2017.02.007
19. Molnar BE, Buka SL, Kessler RC. Child sexual abuse and subsequent psychopathology: results from the National Comorbidity Survey. *American Journal of Public Health*. 2001;91(5):753-760.
20. Hatzenbuehler ML, Nolen-Hoeksema S, Dovidio J. How does stigma "get under the skin"? The mediating role of emotion regulation. *Psychological Science*. 2013;20(10):1282-1289. doi:10.1111/j.1467-9280.2009.02441.x.How
21. Thaggard S, Montayre J. "There was no-one I could turn to because I was ashamed": Shame in the narratives of women affected by IPV. *Women's Studies International Forum*. 2019;74(May):218-223. doi:10.1016/j.wsif.2019.05.005
22. Bhuptani PH, Messman TL. Role of blame and rape-related shame in distress among rape victims. *Psychological Trauma: Theory, Research, Practice, and Policy*. 2023;15(4):557-566. doi:10.1037/tra0001132

23. Sickel AE, Seacat JD, Nabors NA. Mental health stigma: Impact on mental health treatment attitudes and physical health. *J Health Psychol.* 2019;24(5):586-599. doi:10.1177/1359105316681430
24. Todorova ILG, Falcón LM, Lincoln AK, Price LL. Perceived discrimination, psychological distress and health. *Sociology of Health and Illness.* 2010;32(6):843-861. doi:10.1111/j.1467-9566.2010.01257.x
25. Meyer IH, Russell ST, Hammack PL, Frost DM, Wilson BDM. Minority stress, distress, and suicide attempts in three cohorts of sexual minority adults: A U.S. probability sample. Dunkle K, ed. *PLoS ONE.* 2021;16(3):e0246827. doi:10.1371/journal.pone.0246827
26. Quinn DM, Williams MK, Quintana F, et al. Examining effects of anticipated stigma, centrality, salience, internalization, and outness on psychological distress for people with concealable stigmatized identities. *PLoS ONE.* 2014;9(5). doi:10.1371/journal.pone.0096977
27. Hatzenbuehler ML, Phelan JC, Link BG. Stigma as a fundamental cause of population health inequalities. *American Journal of Public Health.* 2013;103(5):813-821. doi:10.2105/AJPH.2012.301069
28. Friedman EM, Williams DR, Singer BH, Ryff CD. Chronic discrimination predicts higher circulating levels of E-selectin in a national sample: The MIDUS study. *Brain, Behavior, and Immunity.* 2009;23(5):684-692. doi:10.1016/j.bbi.2009.01.002
29. Richman LS, Pek J, Pascoe E, Bauer DJ. The effects of perceived discrimination on ambulatory blood pressure and affective responses to interpersonal stress modeled over 24 hours. *Health Psychology.* 2010;29(4):403-411. doi:10.1037/a0019045
30. Sabri B, Gielen A. Integrated multicomponent interventions for safety and health risks among Black female survivors of violence: A systematic review. *Trauma, Violence, and Abuse.* 2019;20(5):720-731. doi:10.1177/1524838017730647
31. Messman-Moore TL, McConnell AA. Intervention for sexual revictimization among college women. *Sexual Assault Risk Reduction and Resistance.* 2018;(2018):309-330. doi:10.1016/b978-0-12-805389-8.00013-x
32. Iverson KM, Gradus JL, Resick PA, Suvak MK, Smith KF, Monson CM. Cognitive-behavioral therapy for PTSD and depression symptoms reduces risk for future intimate partner violence among interpersonal trauma survivors. *Journal of Consulting and Clinical Psychology.* 2011;79(2):193-202. doi:10.1037/a0022512
33. Trabold N, McMahon J, Alsobrooks S, Whitney S, Mittal M. A systematic review of intimate partner violence interventions: State of the field and implications for practitioners. *Trauma, Violence, and Abuse.* 2020;21(2):311-325. doi:10.1177/1524838018767934
34. Murray SM, Augustinavicius J, Kaysen D, et al. The impact of Cognitive Processing Therapy on stigma among survivors of sexual violence in eastern Democratic Republic of Congo: Results from a cluster randomized controlled trial. *Conflict and Health.* 2018;12(1):1-9. doi:10.1186/s13031-018-0142-4

35. Kulkarni S. Intersectional trauma-informed intimate partner violence (IPV) services: Narrowing the gap between IPV service delivery and survivor needs. *Journal of Family Violence*. 2019;34(1):55-64. doi:10.1007/s10896-018-0001-5
36. Novak ET. Trauma-Sensitive Mindfulness: Practices for Safe and Transformative Healing. *Transactional Analysis Journal*. 2018;48(3):288-290. doi:10.1080/03621537.2018.1471295
37. Treleaven DA. *Trauma-Sensitive Mindfulness*. WW Norton & Company; 2018.
38. Frewen P, Lanius R. *Healing the Traumatized Self: Consciousness, Neuroscience, Treatment*. W.W. Norton & Company; 2015.
39. Inwood E, Ferrari M. Mechanisms of change in the relationship between self-compassion, emotion regulation, and mental health: A systematic review. *Applied Psychology: Health and Well-Being*. 2018;10(2):215-235. doi:10.1111/aphw.12127
40. Diedrich A, Hofmann SG, Cuijpers P, Berking M. Self-compassion enhances the efficacy of explicit cognitive reappraisal as an emotion regulation strategy in individuals with major depressive disorder. *Behaviour Research and Therapy*. 2016;82:1-10. doi:10.1016/j.brat.2016.04.003
41. Wong CCY, Knee CR, Neighbors C, Zvolensky MJ. Hacking stigma by loving yourself: A mediated-moderation model of self-compassion and stigma. *Mindfulness*. 2019;10(3):415-433. doi:10.1007/s12671-018-0984-2
42. Chan KKS, Yung CSW, Nie GM. Self-compassion buffers the negative psychological impact of stigma stress on sexual minorities. *Mindfulness*. 2020;11(10):2338-2348. doi:10.1007/s12671-020-01451-1
43. Yang X, Mak WWS. The Differential Moderating Roles of Self-Compassion and Mindfulness in Self-Stigma and Well-Being Among People Living with Mental Illness or HIV. *Mindfulness*. 2017;8(3):595-602. doi:10.1007/s12671-016-0635-4
44. Johnson EA, O'Brien KA. Self-compassion soothes the savage ego-threat system: Effects on negative affect, shame, rumination, and depressive symptoms. *Journal of Social and Clinical Psychology*. 2013;32(9):939-963. doi:10.1521/jscp.2013.32.9.939
45. Ferrari M, Hunt C, Harrysunker A, Abbott MJ, Beath AP, Einstein DA. Self-Compassion Interventions and Psychosocial Outcomes: a Meta-Analysis of RCTs. *Mindfulness*. 2019;10(8):1455-1473. doi:10.1007/s12671-019-01134-6
46. Breines JG, Thoma M V., Gianferante D, Hanlin L, Chen X, Rohleder N. Self-compassion as a predictor of interleukin-6 response to acute psychosocial stress. *Brain, Behavior, and Immunity*. 2014;37:109-114. doi:10.1016/j.bbi.2013.11.006
47. Breines JG, McInnis CM, Kuras YI, et al. Self-compassionate young adults show lower salivary alpha-amylase responses to repeated psychosocial stress. *Self and Identity*. Published online February 2, 2015:1-13. doi:10.1080/15298868.2015.1005659
48. Arch JJ, Brown KW, Dean DJ, Landy LN, Brown KD, Laudenslager ML. Self-compassion training modulates alpha-amylase, heart rate variability, and subjective responses to social

- evaluative threat in women. *Psychoneuroendocrinology*. 2014;42:49-58.
doi:10.1016/j.psyneuen.2013.12.018
49. Germer C, Neff K. *Teaching the Mindful Self-Compassion Program: A Guide for Professionals*. Guilford Press; 2019.
 50. Cai RY. Backdraft in Self-Compassion: An Overlooked Yet Vital Research Focus. *Mindfulness*. 2024;15(3):716-720. doi:10.1007/s12671-024-02324-7
 51. Braun TD, Uebelacker LA, Ward M, Glanton C, McCallister K, Abrantes A. "We really need this": Trauma-informed yoga for Veteran women with a history of military sexual trauma. *Complementary Therapies in Medicine*. 2021;59(April):102729.
doi:10.1016/j.ctim.2021.102729
 52. Chad-Friedman S, Forgeard M, McHugh K, Beard C, Kopeski L, Björgvinsson T. Effectiveness of a brief adjunctive yoga intervention for short-term mood and psychiatric symptom change during partial hospitalization. *Psychiatric Rehabilitation Journal*. 2019;42(1):48-56. doi:10.1037/prj0000329
 53. Taylor J, McLean L, Korner A, Stratton E, Glozier N. Mindfulness and yoga for psychological trauma: systematic review and meta-analysis. *Journal of Trauma and Dissociation*. 2020;21(5):536-573. doi:10.1080/15299732.2020.1760167
 54. Gulden AW, Jennings L. How yoga helps heal interpersonal trauma: Perspectives and themes from 11 interpersonal trauma survivors. *International journal of yoga therapy*. 2016;26(1):21-31. doi:10.17761/1531-2054-26.1.21
 55. Rhodes AM. Claiming peaceful embodiment through yoga in the aftermath of trauma. *Complementary Therapies in Clinical Practice*. 2015;21(4):247-256.
doi:10.1016/j.ctcp.2015.09.004
 56. Clark CJ, Lewis-Dmello A, Anders D, et al. Trauma-sensitive yoga as an adjunct mental health treatment in group therapy for survivors of domestic violence: A feasibility study. *Complementary Therapies in Clinical Practice*. 2014;20(3):152-158.
doi:10.1016/j.ctcp.2014.04.003
 57. Ong I, Cashwell CS, Downs HA. Trauma-sensitive yoga: A collective case study of women's trauma recovery from intimate partner violence. *Counseling Outcome Research and Evaluation*. 2019;10(1):19-33. doi:10.1080/21501378.2018.1521698
 58. Capon H, O'Shea M, McIver S. Yoga and mental health: A synthesis of qualitative findings. *Complementary Therapies in Clinical Practice*. 2019;37(July):122-132.
doi:10.1016/j.ctcp.2019.101063
 59. West J, Liang B, Spinazzola J. Trauma sensitive yoga as a complementary treatment for posttraumatic stress disorder: A qualitative descriptive analysis. *International Journal of Stress Management*. 2017;24(2):173-195. doi:10.1037/str0000040
 60. Nicotera N, Connolly MM. The influence of trauma-informed yoga (TIY) on emotion regulation and skilled awareness in sexual assault survivors. *International Journal of Yoga Therapy*. 2020;30(1):19-31. doi:10.17761/2020-D-18-00031

61. Kessler RC, Andrews G, Colpe LJ, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological medicine*. 2002;32(6):959-976. doi:10.1017/s0033291702006074
62. Posner K, Brent D, Lucas C, et al. Columbia Suicide Severity Rating Scale (C-SSRS) - Screener Version. Published online 2008. Accessed September 12, 2023. <https://doc.sc.gov/sites/doc/files/Documents/policy/BH-19-11AttachmentC.pdf>
63. Oquendo M, Halberstam B, Mann J. Risk factors for suicidal behavior: Utility and limitations of research instruments. In: First MB, ed. *Standardized Evaluation in Clinical Practice*. 2003:103-130.
64. Straus MA, Douglas EM. *A Short Form of the Revised Conflict Tactics Scales, and Typologies for Severity and Mutuality*. Vol 19. 2004. <http://www.wpspublish.com>
65. Hooper LM, Stockton P, Krupnick JL, Green BL. Development, use, and psychometric properties of the trauma history questionnaire. *Journal of Loss and Trauma*. 2011;16(3):258-283. doi:10.1080/15325024.2011.572035
66. Tolin DF, Gilliam C, Wootton BM, et al. Psychometric Properties of a Structured Diagnostic Interview for *DSM-5* Anxiety, Mood, and Obsessive-Compulsive and Related Disorders. *Assessment*. 2018;25(1):3-13. doi:10.1177/1073191116638410
67. Thomas S, Reading J, Shephard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). *Can J Sport Sci*. 1992;17(4):338-345.
68. Rush AJ, Trivedi MH, Ibrahim HM, et al. The 16-Item quick inventory of depressive symptomatology (QIDS), clinician rating (QIDS-C), and self-report (QIDS-SR): a psychometric evaluation in patients with chronic major depression. *Biological Psychiatry*. 2003;54(5):573-583. doi:10.1016/S0006-3223(02)01866-8
69. Crowe BA, Overstreet NM, Murray CE. The Intimate Partner Violence Stigma Scale: Initial development and validation. *Journal of Interpersonal Violence*. Published online 2019. doi:10.1177/0886260519834095
70. Deitz MF, Williams SL, Rife SC, Cantrell P. Examining cultural, social, and self-related aspects of stigma in relation to sexual assault and trauma symptoms. *Violence Against Women*. 2015;21(5):598-615. doi:10.1177/1077801215573330
71. Smith LR, Earnshaw VA, Copenhaver MM, Cunningham CO. Substance use stigma: Reliability and validity of a theory-based scale for substance-using populations. *Drug and Alcohol Dependence*. 2016;162:34-43. doi:10.1016/j.drugalcdep.2016.02.019
72. Raes F, Pommier E, Neff K, Van Gucht D. Construction and factorial validation of a short form of the Self-Compassion Scale. *Clinical Psychology and Psychotherapy*. 2011;255(June 2010):10-11. doi:10.1002/cpp.702
73. Neff KD. The development and validation of a scale to measure self-compassion. *Self and Identity*. 2003;2:223-250. doi:10.1080/15298860309027

74. Gratz KL, Roemer L. Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. *Journal of Psychopathology and Behavioral Assessment*. 2004;26(1):41-54. doi:10.1023/B:JOBA.0000007455.08539.94
75. Kaufman EA, Xia M, Fosco G, Yaptangco M, Skidmore CR, Crowell SE. The Difficulties in Emotion Regulation Scale Short Form (DERS-SF): Validation and Replication in Adolescent and Adult Samples. *Journal of Psychopathology and Behavioral Assessment*. 2016;38(3):443-455. doi:10.1007/s10862-015-9529-3
76. Cook DR. Measuring shame: The Internalized Shame Scale. *Alcoholism Treatment Quarterly*. 1987;4(2):197-215. doi:10.4319/lo.2013.58.2.0489
77. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implementation Science*. 2017;12(1):1-12. doi:10.1186/s13012-017-0635-3
78. Attkisson CC, Zwick R. The client satisfaction questionnaire: Psychometric properties and correlation with service utilization and psychotherapy outcome. *Evaluation and Program Planning*. 1982;5(3):233-237. doi:10.1016/0149-7189(82)90074-X
79. Rabkin JG, Markowitz JS, Ocepek-Welikson K, Wager SS. General versus systematic inquiry about emergent clinical events with SAFTEE: Implications for clinical research. *Journal of Clinical Psychopharmacology*. 1992;12(1):3-10. doi:10.1097/00001573-199202000-00002
80. Uebelacker LA, Van Noppen D, Tremont G, Bailey G, Abrantes A, Stein M. A pilot study assessing acceptability and feasibility of hatha yoga for chronic pain in people receiving opioid agonist therapy for opioid use disorder. *Journal of Substance Abuse Treatment*. 2019;105:19-27. doi:10.1016/j.jsat.2019.07.015
81. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa